OPTN MPSC Functions & Operations Re-Engineering Report

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Table of Contents

Table of Exhibits

List of Acronyms

Acronym	Definition
AHRQ	Agency For Healthcare Research and Quality
API	Application Programming Interface
ASHI	American Society of Histocompatibility and Immunogenetics
BOD	Board of Directors
BPR	Business Process Re-Engineering
CAP	Corrective Action Plan
CLIA	Clinical Laboratory Improvement Amendments
CMS	Center for Medicare and Medicaid Services
COI	Conflict of Interest
DOT	Division of Transplantation
DSA	Donor Service Area
EFA	Exploratory Factor Analysis
FAA	Federal Aviation Administration
FDA	Food and Drug Administration
FMEA	Failure Modes and Effects Analysis
FTA	Fault Tree Analysis
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration
HCD	Human-Centered Design
HIPAA	Health Insurance Portability and Accountability Act
IHI	Institute for Healthcare Improvement
INVEST	Independent Network for Equitable and Safe Transplants
MPIC	Membership and Performance Improvement Committee
MPSC	Membership and Professional Standards Committee
NLP	Natural Language Process
NOTA	National Organ Transplant Act
NTSB	National Transportation Safety Board
OPO	Organ Procurement Organization
OPTN	Organ Procurement and Transplantation Network
oROC	Ordinal Receiver Operating Characteristic
OSHA	Occupational Safety and Health Administration
OTAG	Organ Transplantation Affinity Group
PMO	Project Management Office
PSO	Patient Safety Organizations
QAPI	Quality Assessment and Performance Improvement
SME	Subject Matter Expert
UNOS	United Network for Organ Sharing
US	United States
VA	Veterans Affairs

Executive Summary

The **Organ Procurement and Transplantation Network (OPTN) Membership and Professional Standards Committee (MPSC) Re-Engineering Report** provides a comprehensive overview of recommendations to improve the efficiency and effectiveness of the operations and functions of the MPSC within the OPTN. This report is part of a larger OPTN Modernization Initiative sponsored by the U.S. Department of Health and Human Services Division of Transplantation (HHS-DOT) to review and map the current state of the MPSC's structure, policies, workflows, and operations, and make recommendations to the HHS-DOT for best practices to improve patient safety, functionality, and accountability.

Methodology and Process Snapshot

This report is based on findings from three stages of a Business Process Re-Engineering approach (BPR) (i.e., Final Assessment, Design, and Change Management Preparation), synthesized with findings from:

- **A 372-source environmental scan** of OPTN policies, public records, federal guidance, and grey literature;
- **Thirty-nine key informant stakeholder interviews** with MPSC current and past leaders, professionals from transplant hospitals, organ procurement organizations (OPOs), histocompatibility labs, patients/patient advocates, federal partners, bioethicists, other adjacent experts, and other procurement and transplant community representatives;
- **Single-round, Delphi-style expert feedback** review of recommendations by five members of the broader OPTN community representing different perspectives.

Using these methods, our multidisciplinary team of researchers, clinicians, OPTN subject matter experts (SMEs), and process engineers conducted an in-depth assessment of the MPSC's structure, core functions, and relationship to the broader OPTN system. Beginning with the preliminary **assessment** recommendations provided in the Mapping Report, the team refined and advanced these concepts through a BPR whiteboarding session to identify critical operational and strategic objectives that each recommendation should achieve. In the **design** stage, we refined and formalized the re-engineering recommendations developed in the whiteboarding session, further defining the problem each recommendation addressed. We articulated the rationale for the recommendation, demonstrated alignment with the National Organ Transplant Act (NOTA) and the Final Rule, noting anticipated benefits and potential unintended consequences, and identified performance metrics to track implementation and impact. Finally, in the **change management preparation** stage, we developed implementation roadmaps for each re-designed process.

Key findings

We organized the findings into two main recommendations for re-engineering: 1) develop an HHS-DOT Office of Compliance and Safety responsible for reviewing OPTN member compliance and investigating patient safety events, and 2) rebrand and rescope the MPSC as the Membership and Performance Improvement Committee tasked with a) recommending OPTN member criteria, and b) leading an OPTN Performance Improvement Learning System. Within each recommendation, we have identified sub-recommendations and developed implementation roadmaps.

Recommendation1: Establish an HHS-DOT Office of Compliance and Safety

To strengthen oversight and foster a more proactive, system-oriented approach to accountability, we recommend establishing a dedicated OPTN Compliance and Safety Office within the HHS-DOT. This office would assume primary responsibility for the evaluation of OPTN member compliance with policies and the review of patient safety events.

Sub-recommendation 1: Centralize policy compliance within the HHS-DOT and modernize systems through risk-calibration and technology for greater accountability and transparency

We recommend that as part of the HHS-DOT's OPTN Compliance and Safety Office, a dedicated team focuses on a streamlined OPTN policy compliance review process. To modernize and scale robust compliance oversight across OPTN member types, we recommend a tiered, risk-calibrated framework that prioritizes high-impact OPTN policies linked to patient safety and systemic vulnerabilities. This includes automation of structured data monitoring, centralized policy repositories with NLP-enabled review, and checklist-based inspections to reduce administrative burden and improve consistency. Enhanced transparency, identity-based tracking, and expanded analytics should underpin a learning-oriented compliance system, that supports timely interventions, member accountability, and continuous policy improvement.

Sub-recommendation 2: Centralize patient safety reviews within the HHS-DOT, enhance oversight, and modernize infrastructure to advance patient safety and proactive risk detection

As part of the HHS-DOT OPTN Compliance and Safety Office, HHS-DOT staff will assume the regulatory responsibility of reviewing reported safety events within the OPTN. To enhance patient safety and strengthen oversight, we recommend expanding safety event definitions, more effectively integrating compliance and safety oversight, and shifting toward proactive, data-informed risk identification. A modernized infrastructure—with straightforward dashboards, tiered penalties, and streamlined reporting—will improve accountability, consistency, and systemic learning. These changes aim to align member practices with national safety standards, support strategic intervention, and ensure that oversight evolves from reactive case management to continuous system improvement.

Recommendation 2: Rebrand the MPSC to the Membership and Performance Improvement Committee (MPIC) and establish the OPTN Performance Improvement Learning System

To maximize and strengthen OPTN performance, we recommend changing the scope and title of the MPSC to the MPIC. The MPIC would be responsible for 1) proposing membership criteria, and 2) supporting a newly established OPTN Performance Improvement Learning System that is designed to share information and learnings across the OPTN.

Sub-recommendation 2: Rebrand and rescope the MPSC as the MPIC and specify the MPIC's responsibilities; engage the MPIC to review and recommend critical membership criteria

To better align the title with their focus, MPSC will be rebranded as the "Membership and Performance Improvement Committee" or MPIC to better align the title with their focus. The MPIC's scope will include several key activities: 1) review and recommend OPTN member criteria to the OPTN BOD, and 2) support the OPTN Performance Improvement Learning System (see the OPTN Performance Improvement Learning System section below). Rebranding the MPSC as the MPIC will aid in shifting the perception of the committee's scope to the new focus on maintaining membership criteria and supporting performance improvement. Retaining the work of setting and maintaining membership criteria within the OPTN is critical as the individuals within the organ procurement and transplantation community likely have the best wide-ranging view of the changing workforce landscape and necessary program and staffing components for OPTN members. The MPIC will engage in a comprehensive review of the OPTN member criteria to build in consistency and rigor while ensuring criteria are flexible for an evolving workforce (e.g., non-U.S.-trained physicians and surgeons) and the shifting medical landscape (e.g., new board accreditation requirements). Current member criteria for organ procurement organizations (OPOs) are less specified than for transplant hospitals and programs, which should be addressed. Member policies for other types of organizations that engage with the OPTN, such as transportation companies or perfusion companies, should be considered.

Sub-recommendation 2: Develop an OPTN Performance Improvement Learning System to Strengthen OPTN Member Performance

With the responsibility of policy compliance and patient safety event investigation moving to the new office within the HHS-DOT, we recommend the new MPIC support the OPTN Performance Improvement Learning System. The OPTN Performance Improvement Learning System includes three key components. First, we recommend expanding data collection and reporting activities to allow institutional OPTN members to submit additional data for process improvement and benchmarking. Second, we propose engaging the MPIC to continue to provide peer-to-peer performance improvement support to underperforming institutional OPTN members. Finally, we

suggest the development of a learning system to support the systematic incorporation of data and experience to make organizational and system-level improvements resulting in higher quality care.

Other suggestions to strengthen transparency, accountability, and operational consistency in the OPTN

As part of the comprehensive BPR processes, we identified areas to improve system-level OPTN processes and systems. Although these suggestions are broader than the scope of our project, we offer them to the HHS-DOT to support and further the recommendations specific to the MPSC's functions and workflows delineated in the recommendations. We believe these suggestions are critical for an improved OPTN by increasing transparency and clarity in workflows, improving data quality and interoperability, and managing the often-complex interconnections and potential conflicts of interest that can undermine trust in the system. The suggestions include to improve:

- OPTN process documentation, process metrics, and other mechanisms for transparency;
- Data quality and interoperability;
- Conflict of interest (COI) management.

Change Management Best Practices

Organizational and institutional change is difficult. Especially when making large changes like the ones recommended in this report, people with experience in the OPTN may experience common responses to change – fear of the unknown, comfort with how things have been done, a lack of trust in those who are implementing or leading the effort, and concerns about the potential negative impact on the U.S. procurement and transplantation system.[2,3] With change initiatives that are this large and transformative, it is critical that those implementing the recommendations suggested in this report carefully plan for it.

To support the implementation of the recommendations, we have identified best practices across four phases of implementation: Exploration and planning, Installation, Initial implementation, and Full implementation and sustainability. The best practices include: 1) to develop an implementation team to lead the change management effort, 2) develop an implementation plan, 3) engage stakeholders and partners, 4) develop a communications plan to provide information about the intended change, 5) build awareness and support, and 6) develop and apply metrics to measure change. We describe each best practice and provide tips and resources to support implementation.

Conclusions and Next Steps

The recommendations provided in this report are designed to support the efficiency and effectiveness of the critical functions of the current MPSC. By repositioning the activities related to policy compliance monitoring and safety event investigations within the HHS-DOT Office of OPTN Compliance and Safety, the U.S. organ procurement and transplantation system will be monitored

by a governmental body empowered to regulate it. The remaining MPSC can now focus on its ongoing mission– enhancing the quality improvement of OPTN members as the MPIC. Additionally, our discovery efforts led to OPTN-wide recommendations aimed at improving process transparency, data systems, and COI reporting and tracking.

The next steps of this effort include a challenging phase: implementation. We have included a section on change management best practices and implementation roadmap for every sub-recommendation provided to aid implementation. Large changes, like the ones recommended in this report, require thoughtful and intentional planning because of the high level of complexity, potential for major impact, and greater risk of unintended consequences. We recognize that the recommendations may be adopted in several stages; we have aimed to describe when we believe that changes need to be contingent on previous changes, sequential to other changes, or may occur in parallel. A systematic and measured approach is crucial to minimize disruptions, manage resistance and gain buy-in, and ensure successful adoption.

Introduction and Background

In 2023, the Securing the U.S. OPTN Act[4] was passed to address systemic issues with the U.S. national organ allocation system and to improve transparency and accountability across the transplant ecosystem.[5] The U.S. Department of Health and Human Services HHS-DOT, located as of June 15, 2025 in the Health Resources and Services Administration [HRSA]), is implementing the OPTN Modernization, previously referred to as the "OPTN Modernization Initiative" to strengthen accountability and performance of the US organ procurement and transplantation system. The OPTN Modernization aims to improve the OPTN's technology, data transparency, governance, operations, quality improvement, and innovation.[6] As part of this Initiative, Arbor Research Collaborative for Health was awarded the contract focusing on enhancing patient safety and policy compliance within the OPTN MPSC.

The MPSC, established by the OPTN BOD takes action under their oversight and makes recommendations for further action by the OPTN BOD. The HHS-DOT provides oversight of the OPTN as a system, including over the OPTN members and as the contracting entity for OPTN-related contracts. The MPSC has been tasked with:

- Reviewing events identified as presenting a risk to patient safety, public health, or the integrity of the OPTN;
- Assessing and providing recommendations to improve members' performance, compliance, and quality systems;
- Evaluating applications for membership in the OPTN, approval of transplant programs, and changes in OPTN member key personnel;
- Identifying opportunities for OPTN or system-wide community education;
- Developing membership criteria policies.

Arbor Research Collaborative for Health's contract includes two main tasks:

- Review and map the existing functions and operations of the MPSC;
- Assess the current state of the MPSC functions and operations to make a prioritized set of recommendations to improve the efficiency and effectiveness of the MPSC functions and operations and ultimately enhance patient safety protections.

The results from the second task – re-engineered recommendations – are reported here. Throughout this project, we used BPR to frame and organize the work. BPR is a framework designed to fundamentally rethink and redesign core processes to achieve significant improvements in performance and efficiency. It involves a complete overhaul of existing processes to optimize end-to-end workflows, eliminate redundancies, and achieve dramatic improvements in areas like productivity, quality, and other outcomes. The first three stages of BPR were discussed in the

MPSC Mapping Report. This Re-engineering Report discusses the following three BPR stages (**Exhibit 1**):

- Final Assessment
- Design
- Change Management Preparation

Exhibit 1. MPSC Re-Engineering Report in Relation to BPR Stages and Project Deliverables

BPR Stages	**Initiation**	**Mapping**	**Preliminary Assessment**	**Final Assessment**	**Design**	**Change Management Preparation**	**Implement-ation**
	Determine MPSC re-engineering goals in collabor-ation with technical experts	Analyze core MPSC components, decisions, and resources	Assess MPSC performance and areas for improvement through current and evolving state mapping	Refine MPSC performance assessment and prioritize areas for improvement based on HHS-DOT feedback	Develop and refine MPSC best practices	Plan MPSC best practice implement-ation with roadmaps	Implement best practices in the MPSC
Project Deliverables	Mapping Report			Re-engineering Report			

Mapping Report: draft due April 15, 2025; final due June 15, 2025. Re-Engineering Report (including Implementation Roadmaps): draft due May 15, 2025; final due June 15, 2025.

Throughout the project, we engaged a team of experts in BPR, implementation science, and transplantation, and we consulted with HHS-DOT to review our preliminary assessment findings and provide input on our recommendations. During the design stage, we developed detailed recommendations and revised process maps of tasks, workflows, and decision points that resulted from interviews with MPSC, OPTN member leaders, and other stakeholders. Acknowledging the key role of stakeholder engagement in providing feedback, we reviewed our recommendations with a Delphi panel comprised of a set of individuals from across the organ procurement and transplantation landscape. Finally, we developed implementation roadmaps to support change management drawing on findings from across the project and our internal experts.

In the sections below, we describe the methods the team used to conduct the study, a description of the process of completing the three BPR steps, the recommendations specific to re-engineering the MPSC's work, and suggestions for improving the OPTN based on our findings. In the final section, we describe the limitations of the work and outline a set of conclusions.

Methods: Data collection and analyses

The three stages of BPR reported here – Final Assessment, Design, and Change Management Preparation – were informed by our work using the following research methods:

- A **372-source environmental scan** of OPTN policies, public records, federal guidance, and grey literature;
- **Thirty-nine key informant stakeholder interviews** with MPSC current and past leaders, professionals from transplant hospitals, OPOs, and histocompatibility labs, patients/patient advocates, federal partners, bioethicists, other adjacent experts, and other transplant community representatives;
- **Single-round, Delphi-style expert feedback** review of recommendations by five members of the broader OPTN community representing different perspectives.

The environmental scan provided critical background using publicly available files, such as MSPC meeting notes, congressional reports and testimonies, best practice reports about patient safety reporting from other agencies (e.g., Federal Aviation Administration [FAA], National Transportation Safety Board [NTSB]). Stakeholder interviews with key informants informed both the mapping of the current state and identifying and refining recommendations for re-engineering. Finally, the Delphi panel provided key input by members of the OPTN community on preliminary recommendations to identify potential challenges and unintended consequences to overcome in planning for implementation. For detailed descriptions of each method, see **Appendix 1**.

Business process re-engineering stages

Final assessment stage

Our multi-disciplinary team of researchers, clinicians, OPTN SMEs, and process engineers conducted an in-depth assessment of the structure and function of the MPSC and its relationship with the OPTN. Beginning with the preliminary assessment recommendations provided in the draft Mapping Report (delivered April 15, 2025), the team continued to evolve the recommendations through a BPR whiteboarding session to identify critical objectives that need to be achieved. More information about this step is described in **Appendix 2.**

Design stage

In the Design stage, we refined and formalized the re-engineering recommendations developed in the whiteboarding session through identifying the rationale for the recommendation, describing how the recommendation aligns with NOTA and the Final Rule, noting key benefits and potential unintended consequences, and identifying potential process metrics to measure both member engagement and HHS-DOT/contractor operations and whether the recommendation is meeting its

aims. The team used a series of internal discussions and heuristics to test and refine the recommendations, which is further described in **Appendix 3.**

Change management preparation stage

In the Change Management Preparation stage, we developed implementation roadmaps for each re-designed process. With our experts in BPR, human-centered design (HCD), and implementation science, we reviewed each re-engineered process and identified key steps to implement, resources needed, personnel involved, timeline, intended outcomes, potential barriers to implementation, and approaches to overcome those potential barriers. The steps the team used to develop the implementation roadmaps are described in **Appendix 4.**

Re-engineering Recommendations

In this report section, we describe our recommendations, prioritizing those that sit at the intersection of high impact and low effort for all involved stakeholders, including HHS-DOT, the OPTN BOD and the larger transplant community membership. The two high-level recommendations are described in **Exhibit 2** While in the current state, the MPSC's scope includes reviewing membership applications, reviewing members for policy compliance and performance, and investigating potential safety events, we recommend moving that responsibility to a new dedicated office within HHS-DOT. With the significant change in scope, we recommend changing the name of the MPSC to its remaining responsibilities – recommending membership criteria and supporting performance improvement across the OPTN. In the section below, we describe the rationale for each recommendation and detail the redesigned process using updated maps and descriptions.

Exhibit 2. Recommendations for Re-Engineered MPSC Processes and Functions	
	**Recommendation 1:** Establish an HHS-DOT OPTN Compliance and Safety Office that is responsible for monitoring OPTN members for policy compliance (including member applications and other member policies) and safety event investigations. Develop a modernized risk-calibrated compliance system and modernized technology and infrastructure for patient safety investigations and proactive risk detection.
	**Recommendation 2**: Rebrand and re-scope the MPSC to the MPIC that is responsible for providing performance improvement support through improved data submission and dashboards, peer-to-peer support for underperforming members, and a learning system that supports OPTN-wide performance improvement.

Recommendation 1: Establish an HHS-DOT OPTN Compliance and Safety Office

Recommendation 1 Snapshot:

- Establish a dedicated OPTN Compliance and Safety Office within HHS-DOT
- Structure the office around two coordinated workstreams
  - HHS-DOT-led and contractor-supported compliance arm with modernized, risk-calibrated systems and improved technology for greater accountability and transparency
  - HHS-DOT-led patient safety arm to centralize patient safety reviews, enhance oversight, and modernize infrastructure to advance patient safety and proactive risk detection

To strengthen oversight and foster a more proactive, system-oriented approach to accountability, we recommend establishing a dedicated OPTN Compliance and Safety Office within HHS-DOT. This office would assume primary responsibility for two key OPTN functions:

1) the evaluation of OPTN member compliance with OPTN policies, and
2) the review or investigation of patient safety events at both the OPTN Member and OPTN system levels

A specialized independent contractor highly skilled in supporting government agencies in policy compliance and patient and system safety should support this critical function of the office. This contractor should also be distinct from the broader OPTN operations contractor, to ensure independence and promote transparency. Responsibility for patient safety event reviews should reside within HHS-DOT itself, reflecting the need for federal oversight in areas directly affecting patient safety and public health (as fully described in the Mapping Report). This tightly coordinated federal-contractor partnership would support real-time data analysis, HHS-DOT-led tiered enforcement strategies, and system-level failure assessment and learning structure. This approach represents a shift from reactive, one-off case reviews — limited to individual OPTN participants — toward a structure that prioritizes more independent compliance oversight and continuous, patient-centered improvement. This includes both improvements within transplant programs, OPOs, and histocompatibility labs, and system-level improvements in how these groups coordinate with each other. Specific recommendations that foster accountability, efficiency, and transparency within and across these two functions are described in detail below.

Fostering a Just Culture across the OPTN. To ensure oversight model functions effectively, the OPTN Compliance and Safety Office must support an approach to errors and near misses that reflects a commitment to the concept of just culture.[1] Just culture "balances the need for an honest and open reporting environment with the end of a quality learning environment and culture. . . that requires a change in focus from errors and outcomes to system design and management of behavioral choices."[7] In the context of OPTN, a commitment to just culture requires moving away from a punitive approach to errors that seeks to find, blame, and punish an institutional OPTN member or individual actor to one that acknowledges that punishing individuals for system-level failures is both unfair and counterproductive. While sometimes individuals or member institutions are at fault and should be held accountable, failing to identify system failures partially or primarily responsible for harms or near misses will discourage open reporting and perpetuate system failures that make future harms inevitable. If OPOs, transplant hospitals, or histocompatibility laboratories believe that OPTN system-level failures are being ignored and that they or their employees are being blamed for harms outside their control, a culture of fear and secrecy will guarantee continued harms to transplant donors, recipients, and people deprived of organs they need. A commitment to just culture acknowledges that errors and harms are inevitable and must be treated as learning opportunities. While persons and OPTN member organizations should be held accountable for harms caused by deliberate or willful failures to follow defined policies or procedures, harms resulting from system failures must also be acknowledged and addressed. Developing a set of just culture guiding principles,[8] and then using these principles to acknowledge harms or near misses, explore their underlying causes, and ensure that both systemic and individual causes are documented and used to foster continuous improvement will be essential to avoid perpetuating a punitive approach to harms within OPTN (see callout box).

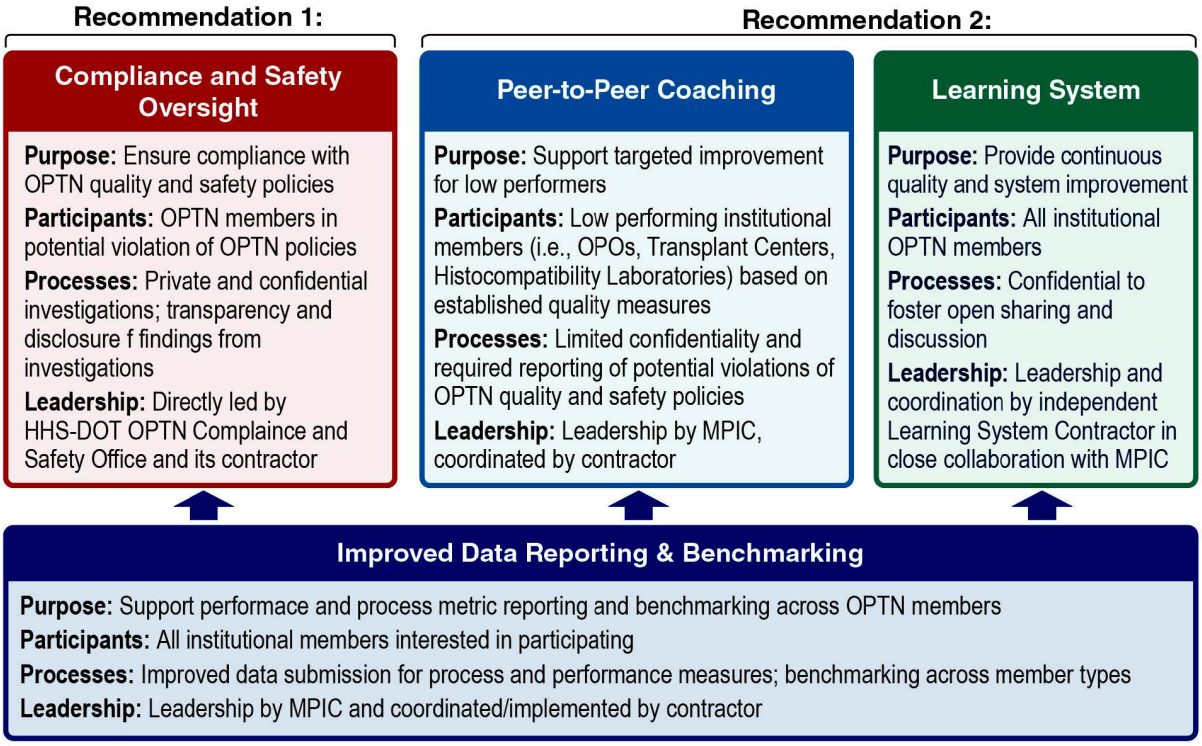
Inculcating a Just Culture: Conclusions of an Integrative Review[1]

- Leadership commitment
- Education and training
- Accountability
- Open communication

While a just culture is essential to the OPTN Compliance and Safety Office, at an operational level, it also must establish clearly defined, appropriate bidirectional pathways for case referral and information sharing between the HHS-DOT-led patient safety function and the contractor-led compliance function. These pathways should support frictionless handoffs of relevant case materials and analytic outputs, using shared dashboards, common data fields, and standardized referral protocols to support timely co-review and escalation. Routine coordination meetings and interoperable analytic platforms will help ensure that insights generated in one domain (e.g., recurrent low-impact compliance deviations) trigger risk analyses in the other (e.g., proactive patient safety reviews). Each oversight entity should retain domain-specific responsibilities while contributing to a broader learning system, enabling cross-cutting risk detection, joint investigation planning, and rapid alignment of compliance and safety interventions.

Fostering both the transparency and accountability expected by the U.S. government and the American public, while still enabling the transparency and openness needed to support continuous quality improvement, will require a balance that acknowledges the importance of both. **Exhibit 3** illustrates the structures recommended for supporting each of these aims.

Exhibit 3.Multi-Pronged Approach to Maximizing OPTN Accountability, Transparency, and Patient Safety



In this system, compliance and safety oversight for significant harms, near misses or other substantive policy violations that risk patient safety would be the responsibility of the newly created HHS-DOT OPTN Compliance and Safety Office discussed in recommendation 1. This system also supports broader system and individual member improvement through improved data reporting and benchmarking, peer-to-peer coaching, and the creation of a learning system. Institutional members, including OPOs, transplant hospitals, and histocompatibility laboratories, that perform poorly on defined quality and performance measures would receive mandatory peer-to-peer coaching and support through processes separate from the formal compliance investigations led by the Compliance and Safety Office. While major policy violations or harms would be reported to the Compliance and Oversight Office, the peer-to-peer coaching process would primarily support focused improvement efforts. All OPTN members would be encouraged to participate in the learning system, which would be completely voluntary and nonpunitive. This system would be sponsored by MPIC but led by a selected contractor with expertise in OPTN activities and quality improvement. Discussions would be private to support the open

communication needed to candidly discuss safety issues without fear of punitive consequences. Collectively, these four separate but related processes would support the OPTN members' need to learn and engage with peers in a risk-free environment, while still strengthening the transparency and accountability expected from the larger OPTN and its membership.

While full application of this recommendation would require attention to regulatory alignment, resource planning, and cultural change among OPTN members, these challenges are addressable through clear role delineation, modernized reporting infrastructure, expanded stakeholder engagement, and other specific recommendations described in this report.

Sub- recommendation 1.1: Centralize policy compliance within HHS-DOT and modernize systems through risk-calibration and technology for greater accountability and transparency

Problem Statement: The current system for monitoring member compliance with OPTN policies and other member obligations relies on multiple oversight mechanisms — including site surveys, automated digital monitoring, case-based audits, and peer review through the OPTN's committee structure. However, this system remains largely reactive, rather than predictive or risk targeted. This design limits the ability to proactively identify patterns of noncompliance, assess systemic vulnerabilities, or scale OPTN member interventions based on the severity or recurrence of noncompliance. Peer-based compliance monitoring within the OPTN raises concerns about COI, lack of enforcement independence, and inconsistent application of standards. Some peers may be reluctant to penalize colleagues, lack formal investigative training, and prioritize education over enforcement. As a result, the current model risks leniency, variability in oversight, and diminished public trust in the fairness of the compliance system.

Moreover, high-consequence violations (e.g., organ offer acceptance failures) and low-risk administrative errors (e.g., documentation lags) are often processed through similar workflows or degree of urgency, lacking a monitoring and enforcement framework calibrated to risk. This undermines efficiency and results in inconsistent prioritization across member types, exacerbating procedural ambiguity and diminishing trust in compliance oversight. While OPTN members follow the current MPSC-approved corrective action plans (CAPs) and monitoring plans, the current approach lacks a clear, tiered enforcement structure that distinguishes between low-, moderate-, and high-risk policy violations, making it difficult to drive sustained member engagement with proactive compliance strategies.

Operational inefficiencies are compounded by labor-intensive and manual processes, such as the review of member-specific policies, which often lack version control and uniform formats. These inconsistencies burden both reviewers and members and limit the scalability of site surveys. While some structured data enable automated monitoring, these capabilities remain underutilized and unevenly adopted across member types, especially OPOs. Without widespread use of centralized

tools or modern analytics (e.g., dashboards, application programming interface (API) integration, NLP-enhanced reviews), data transparency remains low, and important insights into recurrent issues or cross-member trends are frequently lost. In addition, longstanding data quality challenges, such as inconsistent data entry, missing fields, and lack of standardization across systems, further erode the reliability of compliance monitoring and limit the utility of automated tools.

As monitoring has expanded over time to include a broader array of organ procurement and pre- and post-transplant activities, the resource strain on the MPSC as an all-volunteer committee providing critical oversight in policy compliance has grown unsustainable, revealing clear gaps in operational capacity and enforcement infrastructure. For example, both underdeveloped and underutilized compliance metrics present barriers to evaluating whether occurrences of higher-risk events impact patient safety or system-wide integrity.

Another shortcoming of the current state of compliance monitoring is its failure to support a learning-oriented culture or agile response to emerging concerns. Stakeholder trust in the contractor's triage and escalation decisions has been weakened by limited transparency and unclear rationale in screening and referral pathways. The opacity of this process also falls short of fully aligning with recent federal priorities to modernize organ procurement and transplant oversight, particularly those emphasizing patient safety, appropriate allocation, transparency and accountability outlined in the OPTN Modernization Initiative and the HRSA-Center for Medicare and Medicaid Services (CMS) Organ Transplantation Affinity Group (OTAG) Action Plan.[9,10] The current approach to OPTN policy compliance is misaligned with evolving expectations for public-facing accountability, outcome-linked oversight, and data-informed improvement — threatening its ability to serve as a credible and effective regulatory framework.

Recommended changes – Optimizing OPTN Policy Compliance within HHS-DOT's Compliance and Safety Office

We recommend that as part of the HHS-DOT's OPTN Compliance and Safety Office, a dedicated team focuses on a streamlined OPTN policy compliance review process (see the updated process map In **Appendix 5**). In the future state, an external contractor under close HHS-DOT oversight, operating in accordance with standardized operational rules should implement the OPTN policy compliance process. The contractor should monitor member compliance with all OPTN policies, including membership-related requirements, using a tiered and multifaceted oversight model. This model should incorporate existing mechanisms with improvements for greater efficiency and quality, including structured site surveys to assess policy adherence on the ground; automated digital monitoring systems that flag potential deviations using real-time data; and targeted, case-based audits to investigate specific concerns or patterns of noncompliance. The HHS-DOT Compliance and Safety Office should provide clear governance and accountability, ensuring the contractor applies consistent criteria, escalates violations appropriately, aligns enforcement

intensity with risk levels, and ensures a frictionless referral pathway to the HHS-DOT's Patient Safety Team (see **Exhibit 4**).

Exhibit 4. The Future Contractor-led, HHS-supported Compliance Review Processes

- In the future state, compliance reviews should be housed within the HHS-DOT's OPTN Compliance and Safety Office and supported by a contractor. This should create an efficient, coordinated system ensuring members adhere to OPTN obligations.
- Site surveys, self-reporting, and automated reports should be redesigned to reflect the distinct roles and responsibilities of different institutional member types. New elements should also be added in order to verify that individual personnel meet applicable membership requirements.
- Automated reporting should include structured monitoring of individual personnel to confirm qualifications and adoption of recognized best practices.
- HHS-DOT should establish clear, publicly available, operational rules that define how compliance concerns relate to patient safety and guide the contractor's case escalation decisions.
- Violation of high-risk policies should trigger pre-defined, transparent disciplinary actions, encouraging members to proactively improve systems and behaviors that could pose patient safety risks.[11]
- Compliance monitoring data should be fully integrated with patient safety event reporting, with common platforms and operational rules to create a coordinated oversight structure that mutually reinforces accountability to support system-level learning.

This contractor, in close consultation with HHS-DOT, should review and evaluate the policy framework itself by identifying the need to rewrite or modernize OPTN policies beyond membership criteria, a process that will require coordination with the OPTN's formal policy development and review cycle. The contractor should also oversee compliance with performance-related policies, recognizing that NOTA mandates the use of performance indicators. While the future-state MPIC should focus on collaborative engagement and quality improvement to help members avoid disciplinary actions (see **Exhibit 4**), the OPTN Compliance and Safety Office should ensure that performance monitoring remains aligned with regulatory expectations and supports consistent enforcement across the network. Resources like transparent documentation, digital audit trails, and oversight dashboards—designed to enable proactive risk detection and continuous system improvement —are intended to reinforce these functions.

To modernize and scale robust compliance oversight across OPTN member types, we recommend a tiered, risk-calibrated framework that prioritizes high-risk OPTN policies linked to patient safety and systemic vulnerabilities. This includes greater automation of structured data monitoring, centralized policy repositories with NLP-enabled review, and a checklist-based structure for in-person OPTN surveys to reduce burden and improve consistency and rigor. Enhanced transparency, member identity-based tracking, and expanded analytics should underpin a learning-oriented compliance system that supports timely interventions, member accountability,

and continuous policy improvement. This recommended change includes several components specified below.

Prioritize Compliance with High-Risk Policies, Risk-Calibrated Monitoring, and Targeted Intervention.

To ensure robust and more balanced compliance oversight across OPTN member types, we recommend establishing a structured framework for identifying and continuously updating a subset of high-risk OPTN policies with the greatest potential to impact patient safety and/or signal broader systemic vulnerabilities. We recommend a risk-calibration model (see callout box) that is designed to invest proportional resources toward policies directly tied to critical failures (such as those conceptually aligned with HRSA's evolving "Wakefield Criteria"),[12] and upstream indicators of risk. Moreover, policies should be organized into operational categories aligned with national priorities included in the OPTN Strategic Plan and the HHS OTAG Action Plan.[9,10] This alignment would enable oversight bodies to better assess where progress is occurring and where gaps persist, especially in areas tied to access and patient safety. By grouping policies by strategic goal areas (e.g., increasing donation and improving patient safety outcomes), it would also be possible to evaluate whether compliance trends are advancing or falling short of national objectives and target data-driven interventions accordingly.

Examples from a Risk-Calibrated Monitoring Model

- **High Risk:** Prioritize oversight of policies tied to organ offer acceptance documentation or surgical personnel credentialing
- **Moderate Risk:** Require CAPs for recurrent errors that could evolve into safety threats
- **Low Risk:** Use expedited resolution for routine data submission delays with no patient impact

Compliance responses should be governed by a clear, tiered enforcement framework that calibrates the consequences of noncompliance to the risk posed. Repeated, high-risk violations would trigger stronger oversight actions, while minor or first-time deviations could be addressed through education and capacity building opportunities. This approach would reinforce the system's commitment to fairness, clarity, and continuous improvement across member types (see **Exhibit 5**).

Exhibit 5. Understanding OPTN compliance monitoring practices to inform appropriate risk-calibration by OPTN member type

- It is important to calibrate the intensity and type of enforcement based on member context, expectations, and the level of risk that noncompliance poses to patient safety, equity, or system integrity.
- To support this calibration, we recommend a mixed methods analysis of historical monitoring practices to identify oversight patterns by OPTN member type.
- This analysis would inform refinements to operational rules, identify underdeveloped policy areas by member type, and promote a more balanced enforcement framework—ensuring

that OPOs are not subject to overly permissive oversight, while transplant hospitals and histocompatibility laboratories are not disproportionately burdened.
- Compliance monitoring should also capture the causes and prevalence of undesirable outcomes associated with coordination failures between OPTN member types to ensure these system failures are also reduced over time.

We recommend using exploratory factor analysis (EFA) to identify clusters of OPTN compliance policies that tend to co-occur in member institutions (or sets of member institutions) with repeated safety events, other adverse outcomes, or elevated rates of noncompliance. By analyzing violation patterns across a broad policy set, EFA reveals latent groupings (e.g., donor data mismanagement, offer acceptance failures) that are statistically associated with OPTN member risk. These insights will support prioritization of oversight on high-risk policy clusters, enable targeted interventions where systemic breakdowns are most likely, and inform a risk-calibrated compliance model that accounts for multi-policy failure patterns rather than isolated violations. Following factor analysis, we recommend applying an ordinal receiver operating characteristic (oROC) analysis to assess how well each policy cluster predicts member noncompliance. An oROC analysis quantifies the predictive strength of each factor and enables oversight entities to validate high, moderate-and low-risk areas, direct monitoring resources accordingly, and refine a compliance and enforcement framework based on evidence-driven thresholds (see **Exhibit 6**).

Exhibit 6. Using EFA and oROC analysis to identify the relationship between OPTN compliance policies and problematic OPTN members

EFA Steps	

1. Define the dataset	• Units of analysis: OPTN member types or combinations of member types
	• Variables: Binary or ordinal indicators of noncompliance across a wide set of OPTN policies (e.g., policy violations = 1, no violation = 0)
	• Include additional variables to identify "problematic" members, such as:
	  ○ Number of safety events (e.g., 12 month rolling average, calendar year, 6 months)
	  ○ Escalated compliance cases
	  ○ Recurrence rates
	  ○ HRSA or MPSC interventions

2. Conduct EFA	• Use EFA to identify latent factors—policy clusters that tend to be violated together • Choose a suitable extraction method (e.g., principal axis factoring) • Use rotation (e.g., Varimax) to make factor loadings interpretable • Retain factors with eigenvalues >1 or use scree plot criteria
3. Interpret the factors	• Each factor represents a cluster of related policies (e.g., "donor data handling," "organ offer documentation," "credentialing") • Factor loadings show which policies are most associated with each cluster

EFA Steps	
4. Score each member	• Generate factor scores for each member based on how closely their violations align with each latent policy cluster
5. Compare problematic vs. non-problematic members	• Use statistical comparisons (e.g., t-tests, logistic regression) to test whether certain factor scores are significantly higher among problematic members • Use oROC analysis to evaluate whether certain clusters predict problematic status
oROC Steps	
1. Generate factor scores	• Each member receives a score for each factor (policy cluster), reflecting the degree to which their pattern of violations aligns with that cluster
2. Define the binary outcome	• Assign each member as either "high-risk" or “moderate-risk” or "low-risk " based on predefined criteria (e.g., ≥3 safety events per year, escalated cases, HHS-DOT referral)
3. Conduct oROC analysis	• For each factor score, assess how well it discriminates among all ordinal levels of risk status across member types (i.e., low, moderate, high) • Use Volume Under the Surface (VUS)[13] to evaluate the model’s ability to correctly rank-order members by risk across the three ordered categories
4. Interpret	• VUS = 1.0 indicates perfect ordinal discrimination — the model always ranks individuals correctly by risk • VUS = 1/6 (~0.167) for three classes reflects no predictive discrimination (random chance) • VUS ≥ 0.3 indicates moderate discrimination between ordinal categories • VUS ≥ 0.5 suggests strong ordinal predictive performance (similar to Area under the Curve ≥ 0.8 in binary settings)

Policy violations, regardless of their degree of impact, are subject to operational rules to ensure consistent triage and documentation. Policies that are low-risk but frequently violated (e.g., technical administrative missteps) should remain subject to streamlined resolution pathways, allowing reviewers to focus on higher-risk concerns and reduce regulatory burden. In contrast, violations deemed high priority, such as those tied to patient harm or systemic risk, should trigger differentiated workflows characterized by faster escalation, tighter timelines, and assignment to specialized review teams with domains expertise, and referral to the patient safety pathway at the HHS-DOT. The contractor should maintain a refined triage protocol as part of the larger set of operational rules, while the HHS-DOT OPTN Compliance and Safety Office oversees its implementation (**Exhibit 7**).

Exhibit 7. Operational Rules to Improve Consistency, Training, and Oversight in OPTN Compliance and Safety Functions
Operational rules are predefined, standardized procedures or decision-making criteria used to ensure consistency, efficiency, and fairness in carrying out routine tasks or handling recurring scenarios, especially valuable in a function that requires repeatable judgments, (e.g., compliance monitoring, safety reviews, or data processing). The HHS-DOT OPTN Compliance and Safety Office should develop and refine operational rules for all existing and forthcoming OPTN policies and determine appropriate training and quality assurance measures carried out by the contractor. Additionally, HHS-DOT should audit a representative sample of non-escalated safety cases on a recurring basis to ensure appropriate triage decisions and refine operational filtering rules.

Employ Transparent Triage Processes, Metric-Driven Dashboards, and Early Course Correction. To improve transparency, consistency, and shared oversight of policy compliance monitoring, HHS-DOT should collaborate with the contractor to formalize and document the triage protocols used to screen, escalate, or close potential violations. The contractor should retain the ability to apply these operational rules to filter high-volume, low-impact cases, but HHS-DOT must have full analytic visibility into how those filters operate and which cases are escalated for further review. This would allow HHS-DOT to evaluate the consistency of decision-making and identify potential areas for recalibration.

In support of this goal, the contractor should develop and maintain a real-time dashboard that displays the scope of compliance monitoring and evaluation criteria used to assess potential violations, and the outcomes of investigations. This dashboard should include both existing and newly developed compliance metrics, defined in partnership with HHS-DOT. Among others, metrics would continue to include race-neutral estimated glomerular filtration rate calculations, use of secure informational technology protocols, timeliness of required reporting, and frequency of documentation errors or self-reported events. Over time, these process metrics should evolve to include outcome-linked indicators that help assess whether compliance activity is contributing to improvements in patient safety, equity, and quality of care.

Using and learning from metrics related to HHS-DOT and future contractor operations and member participation in policy compliance and patient safety reviews is essential to strengthening the procurement and transplantation system. Process metrics are intended to improve oversight by identifying patterns of noncompliance and accountability gaps, while also enhancing patient safety through timely detection of systemic risks. These metrics should inform data-driven policy refinements, ensuring that oversight focuses on the most impactful areas. Moreover, operational metrics support efficient resource allocation and workflow improvements, and when shared transparently, they help build trust across the transplant community (for more detail, see **Exhibit 8** and corresponding **Appendix 6,** and **Exhibit 9** and corresponding **Appendix 7**).

Exhibit 8. Member process metrics to ensure active and responsible participation in the OPTN

Domains	Example Metrics
Structural Compliance	Policy documentation timeliness; credentialing and staffing compliance timeliness; bylaw acknowledgment compliance timeliness
Process Compliance	Policy compliance data reporting timeliness; waitlist management accuracy; organ offer response timeliness; match run integrity
Outcome-Based Compliance	Adverse event reporting compliance timeliness; confirmed violations; CAP resolution; repeat violations rate
Risk & Escalation	Flags per monitoring cycle; time from flag to review initiation; escalation to HHS-DOT
Member Engagement and Improvement	Policy education participation; self-reported issues; adoption of policy changes

Exhibit 9. HHS-DOT and contractor process metrics to support operational excellence

Domains	Example Metrics
Timeliness/Efficiency	Time to case closure; case backlog; timely case initiation; timely notification of affected parties
Quality	Error rate; rework rate; validated root analyses rate; CAP acceptance
Appeal	Appeal rate; reversal rate; appeal success rate
Stakeholder Engagement	Complainant satisfaction; internal staff satisfaction
Volume/Throughput	Cases reviewed; self-reports processed; investigations completed
Impact/Outcomes	Recidivism rate; sustained compliance; risk reduction

Improve Data Quality by Supporting Automated Compliance Monitoring and Expanded Data Fields. To strengthen the reliability and scalability of compliance oversight, HHS-DOT should expand the use of automated monitoring tools for policies supported by structured data, building on existing infrastructure, while ensuring compliance with Federal Information Security Management Act and Health Insurance Portability and Accountability Act (HIPAA) requirements. This includes refining alert logic, piloting new compliance flags, and evaluating system readiness across member types. While many transplant hospitals and histocompatibility laboratories already support rigorous electronic monitoring, targeted assistance may be needed for lower-resourced or under-performing OPOs to ensure consistent adoption. All triage logic and data quality assessments should be transparent to HHS-DOT to support consistent, risk-calibrated enforcement.

It is essential to develop a data submission system with required fields and standardized variable definitions to improve data accuracy and monitoring. HHS-DOT should also improve the quality of structured data used in compliance and patient safety reporting. Currently, many event reports lack detail or rely on vague categories like “other reason,” limiting their utility. For example, while confirmation of organ acceptance decisions is required, the lack of open text justification impedes system learning. HHS-DOT and its contractor should assess data completeness and integrity,

especially fields related to incident identification and intake, and gather qualitative input from users to identify and fix usability barriers. Information about coordination between different types of OPTN members should also be collected to ensure that systemic failures, especially those beyond the control of a single member, are also identified and addressed. These enhancements are intended to increase the accuracy of automated oversight and generate more actionable insights to drive compliance improvements systemwide.

Deploy In-Person Member Surveys using Checklist-Based Evaluations. To enhance transparency and efficiency during in-person member surveys, we recommend developing a standardized checklist that clearly defines the policies, procedures, and documentation to be reviewed during each visit, similar to CMS inspection surveys for transplant hospitals (see example of a CMS survey checklist in **Exhibit 10**).[14] Rather than relying on a limited or variable sample, this checklist would set consistent expectations for both the survey team and OPTN members.

Exhibit 10. CMS' Checklist to Ease Site Reviews

CMS, in collaboration with The Joint Commission, developed a checklist to assist hospitals in preparing for CMS surveys,[15] including:

- Assigning Conditions of Participation checklists to appropriate individuals
- Ensuring all hospital areas, including off-campus locations, are prepared for survey
- Preparing a Survey Readiness Binder
- Designating hospital representatives to accompany surveyors

The checklist helps identify areas needing attention prior to a survey and supports the development of action plans for improvement.

Additionally, site surveys should be strategically focused on areas that benefit from observational context or real-time interactions, such as facility-specific protocols that may appear compliant on paper but require more in-depth review to assess implementation fidelity, undocumented workflows, or staff interviews that allow for follow-up based on what is directly observed in the clinical environment. Though some components of the survey may be feasible to assess remotely, in-person engagement can yield deeper insights, for instance, probing for identification of discrepancies between documented procedures and actual practice or detecting the use of informal workarounds. In-person visits are also an opportunity to build rapport that can yield candid interactions and communication with the member. By reserving inspection for components that require this level of contextual understanding and direct engagement, this approach would clarify the interpretation of member-specific protocols and the application of OPTN policies in varied operational environments, while also optimizing resource dispersion.

Improve OPTN Member Policy Adherence and Member-Specific Policy Concordance by Leveraging NLP Processing Technology. Member compliance is currently assessed through a variety of methods, including site visits, desk or case reviews, self-reporting, and automated monitoring. Among these, the review of member-specific policies and procedures during site surveys is especially labor-

intensive. This process, which currently requires manual comparison between member-specific documentation and OPTN policies, at present performed by the OPTN contractor, places a substantial burden on both reviewers and member institutions. The time and resource demands of this approach limit its scalability, and the lack of standardized version control increases the risk of unintentional policy misalignment.

To reduce administrative burden, enhance the accuracy of policy comparisons, and more efficiently identify policy discordance, we recommend requiring all OPTN members to store their current policy and procedure documents in a secure, centralized digital repository. This repository would enable more efficient comparisons between local and national policies, support version tracking, and provide transparency into institutional alignment with evolving policy requirements. While care would need to be taken to define the scope of "relevant documents" and address potential legal considerations around document sharing, this system could focus on key documents required for OPTN compliance, while acknowledging the need for coordination with related regulatory frameworks (e.g., CMS Conditions for Coverage and Participation, Clinical Laboratory Improvement Amendments [CLIA]).

Over time, this repository could support the integration of NLP tools to identify policy discrepancies and generate alerts when OPTN policy updates are issued. These tools would not replace human review but would enhance its accuracy and efficiency. By reducing variation in document review practices and surfacing areas of discordance early, this system would support faster resolution, improved institutional awareness, and more reliable enforcement.

Additionally, as part of this shift toward a more learning-oriented compliance culture, we recommend that OPTN governance reassess member practices around self-reporting and disclosure, incorporating Just Culture principles[1] that emphasize safety, accountability, and non-punitive responses to good-faith reporting. A digital repository could help normalize transparency across member types, promote shared responsibility for policy adherence, and reinforce OPTN-wide learning and improvement.

Support a Learning System by Expanding Aggregate Compliance Data Analysis. The MPSC currently addresses noncompliance primarily on a case-by-case basis. Though the OPTN contractor does share aggregate counts of noncompliance by policy, these data are often not analyzed beyond basic summary statistics. More sophisticated analytic strategies (e.g., such as cross-tabulation, time-to-resolution tracking, or analysis of co-occurring violations) are not routinely used to identify root causes or inform system-wide learning. Additionally, although the MPSC collaborates with other OPTN committees such as the Operations and Safety Committee and the Data Advisory Committee to inform policy updates, their ability to generate and act on insights from compliance data remains constrained by siloed systems, limited transparency, and a perception that deeper analytic work may fall outside their purview. To strengthen the system's learning capacity, we recommend expanding the scope and capability of compliance data analytics, moving toward a

model that tracks members' process and outcome metrics (e.g., completeness of data submissions, annual and longitudinal member adherence over time, recurrence rates of specific violations, or impacts of targeted education on policy compliance) (see **Exhibit 8** and corresponding **Appendix 6**) and HHS-DOT and contractor process metrics that encourage and support operational excellence (e.g., timely review; number of cases reviewed per quarter) (see **Exhibit 9** and corresponding **Appendix 7**).

A robust compliance analytics platform should allow for identification of policy gaps (e.g., insufficient clarity around responsibilities for offer acceptance), process inefficiencies (e.g., cases stalled in review due to lack of needed documentation), and unintended consequences (e.g., a policy change increasing administrative burden without improving safety outcomes). Developing a dashboard for use by the contractor, OPTN BOD, and HHS-DOT could support real-time monitoring of compliance scope, case resolution timelines, and enforcement patterns—contributing to greater transparency and improved oversight strategies (see callout box).

OPTN System Learning and Performance Enhancement Using Aggregate Data

Expanded aggregate compliance data analysis designed to identify patterns, trends, and systemic performance challenges across OPTN member organizations:

- Inform a comprehensive OPTN performance improvement learning system that supports all members—particularly those underperforming—through targeted interventions, peer support, and shared learning resources.
- Promote improved data submission practices, the use of standardized process metrics, and benchmarking tools to foster continuous quality improvement across the entire network (see **Sub-recommendation 2.2: Develop an OPTN Performance Improvement Learning System to Strengthen OPTN Member Performance**).

To act on these insights efficiently, the HHS-DOT OPTN Compliance and Safety Office should be empowered to translate analytic findings into targeted policy refinements or operational adjustments without unnecessary procedural delays. For example, current OPTN processes may require extended committee cycles or BOD-level input before a policy clarification can be issued, whereas HHS-DOT could, in some cases, issue interim guidance or direct updates more quickly. Coordination between HHS-DOT and OPTN governance bodies will be essential to ensure these updates are appropriately scoped and communicated.

The implementation roadmap for this recommendation is in **Appendix 8**.

Sub-Recommendation 1.1 Overview: Centralize policy compliance within HHS-DOT and modernize systems through risk-calibration and technology for greater accountability and transparency

Rationale for Recommendation: Collectively, these specific recommendations under Sub-Recommendation 1 modernize the compliance oversight process by reducing non-value-added administrative burden and replacing fragmented, reactive procedures with a streamlined, risk-calibrated framework. By clearly delineating expectations for OPTN members and matching enforcement intensity to the severity of policy violations, the system becomes more equitable, efficient, and focused on patient safety and other outcomes that matter. Automating the monitoring of high-risk policies and expanding the use of standardized tools—such as checklists, dashboards, and NLP —enhances the system's ability to detect safety threats early and consistently. Additionally, tracking individual actors associated with repeat violations enables targeted interventions, reinforcing institutional and personal accountability. Taken together, these reforms align compliance oversight with core patient safety goals by prioritizing transparency, reducing systemic ambiguity, and enabling timely, data-informed responses to risks that threaten transplant quality and patient outcomes.

Connection between Recommendation and NOTA and the OPTN Final Rule: This recommendation aims to strengthen the federal oversight of OPTN policy compliance, acknowledging and addressing limitations in the current execution of responsibilities outlined in NOTA and the OPTN Final Rule.[16,17] As outlined in the Mapping Report, the MPSC, tasked by the OPTN BOD, is currently responsible for ensuring that member activities and OPTN policies remain aligned with federal law and regulations, including obligations related to equitable access, patient safety, and procedural fairness. Though NOTA broadly assigns the OPTN with responsibility for developing compliance plans and procedures, NOTA also specifies that the "Secretary or her/his designee may perform any reviews and evaluations of member OPOs and transplant programs which the Secretary deems necessary to carry out his/her responsibilities under the Public Health Services Act and the Social Security Act." Following that allowance, our recommendations reflect a shift in those functions to HHS-DOT in recognition of implementation gaps and the need for independent oversight based on HHS Secretary request. By modernizing compliance infrastructure, improving data accuracy, and enhancing the transparency of enforcement mechanisms, the recommended changes reinforce HHS-DOT's statutory mandate to uphold public trust, reduce risk, and ensure that member oversight is legally sound, operationally efficient, and accountable to federal priorities.

Potential Benefits to Adopting Recommendation: Establishing a well-integrated OPTN Compliance and Safety Office that is independent from the MPIC directed learning system would mark a significant shift toward proactive, data-informed oversight. Unlike the current structure, where peer-based committees like the MPSC are responsible for monitoring fellow members, this model introduces a more objective and independent approach to evaluating compliance and safety risks. By separating performance oversight from peer relationships, this system may reduce perceived COI and improve fairness and consistency in how incidents are reviewed and addressed.

This transformation would not only accelerate the delivery of timely, constructive feedback to OPTN members, but also enhance transparency and public trust in the system's ability to hold institutions accountable. Members would retain the opportunity to respond to noncompliance at the policy level, but in a framework that emphasizes longitudinal trends, continuous improvement, and shared learning,

Sub-Recommendation 1.1 Overview: Centralize policy compliance within HHS-DOT and modernize systems through risk-calibration and technology for greater accountability and transparency

rather than isolated punitive action. In doing so, the system becomes both more credible and more effective in promoting patient safety.

Potential Negative Consequences of Adopting Recommendation: The transition to a centralized OPTN Compliance and Safety Office, particularly one with expanded oversight authority, may generate concerns among OPTN members, especially if it is perceived as overly punitive or disconnected from clinical realities. Transplant professionals may worry that removing these functions from the MPSC, potentially limiting the input of SMEs, including practicing clinicians and procurement professionals, could compromise nuanced, peer-informed approaches to patient safety. Additionally, members might become more reluctant to self-report instances of noncompliance if the system lacks appropriate protection, transparency, or opportunities for collaborative remediation.

Implementing comprehensive, technology-driven compliance monitoring will also require substantial investment in infrastructure, staff capacity, and data standardization. Electronic measurement systems must be tailored to accommodate the diverse IT environments and data reporting practices of OPTN members. Without thoughtful coordination, variability in system readiness could limit the scalability and effectiveness of real-time tracking and analytics.

These challenges underscore the importance of a phased, collaborative approach to modernization that engages members early and often, while maintaining a clear focus on patient safety and accountability.

Potential Metrics for HHS-DOT and Contractor Operations and Members' Participation in Policy Compliance:

- Policy documentation timeliness *(member level)*
- Time to case closure *(contractor level)*
- Internal staff satisfaction *(DOT office level)*

For more metrics, see **Exhibit 8** and **Exhibit 9.** See their corresponding **Appendix 6** and **Appendix 7** for specific approaches to measuring all recommended metrics

Sub-recommendation 1.2: Centralize patient safety reviews within HHS-DOT, enhance oversight, and modernize infrastructure to advance patient safety and proactive risk detection

Problem Statement: The current system for reviewing patient safety events within the OPTN is hindered by fundamental inefficiencies that limit its ability to proactively safeguard transplant recipients and donors. Workflow efficiencies exist across intake, screening, triage, and escalation. Though the MPSC promptly reviews the highest risk cases requiring a 24-48 hour review where clear and present patient harm is detected (e.g., "Wakefield criteria"[12] of adverse events), the current contractor-led intake process for all other reported events or complaints lacks standardized, transparent criteria, resulting in delays, backlogs, and potential for inconsistent

escalation of safety events. Case review remains fragmented, with overly manual processes that are not designed to scale amid rising case volumes.

Some stakeholders have expressed limited confidence in the current model due to the contractor's autonomy in case triage, limiting visibility into cases that are ultimately screened out and never seen by the MPSC. There are unclear criteria for escalation, limited auditability of contractor decisions, and opacity around how safety events are prioritized. Key safety metrics are neither visible nor routinely shared across oversight entities, making it difficult to monitor trends or promote accountability. Furthermore, the infrastructure for reporting and tracking cases remains outdated, limiting completeness and usability.

This more reactive patient safety review structure emphasizes individual, one-off case reviews rather than strategic pattern recognition to identify system-level root causes. Without the integration of safety and compliance data, or the use of system-based methods like Failure Modes and Effects Analysis (FMEA)[18] and Fault Tree Analysis (FTA),[19] HHS-DOT cannot systematically identify and respond to recurring risks across members or policy areas. FMEA is a proactive method used to identify potential failures in a process or product, evaluate their impact, and prioritize areas that need improvement. FTA is a deductive approach that begins with a specific system failure and works backward to trace the chain of events, errors, or faults that could lead to it, helping to uncover root causes, evaluate risks, and inform corrective steps in complex fields including healthcare, engineering, and aviation.

In addition to the above structural deficiencies, resource strain is also evident across all phases of safety event reviews. The MPSC's capacity to impose timely and proportionate actions, including clear consequences when deemed appropriate, is constrained by the current set of bylaws, subjective penalty discretion, and limited enforcement mechanisms. This adds burden without necessarily improving safety outcomes or deterring future violations.

The current system exhibits misalignment with recent OPTN reforms, and the larger health care system's movement in the past two decades, to promote a more proactive, transparent, and accountable safety culture. Existing definitions of reportable events exclude many near misses and systemic failures, especially in donor-related processes. Without adopting national safety standards and modernized tools such as real-time dashboards, predictive analytics, and tiered penalties, the OPTN's oversight mechanisms fall short of ensuring the level of patient protection now expected under evolving federal directives.

These limitations, coupled with rising case volumes and a growing need for systemic risk identification, undermine the effectiveness and credibility of the current safety oversight model. Moreover, the national goal to increase the number of safe and effective transplants, spurred in part by rapid technological advancements in transplantation (e.g., xenotransplantation, perfusion) requires a system that is faster and more responsive.

A more transparent, efficient, and enforceable safety review structure is needed to ensure accountability and protect public trust. A modernized, data-driven framework—integrating compliance and safety functions, redefining reportable events, and expanding analytic capacity—is urgently needed to address these gaps, restore trust, and better protect patients throughout the organ procurement and transplantation system.

Recommended changes – Improving safety event reviews in the OPTN through HHS-DOT's OPTN Compliance and Safety Office

As part of the HHS-DOT OPTN Compliance and Safety Office, HHS-DOT staff will take on the regulatory responsibility of reviewing reported safety events within the OPTN (see **Exhibit 11** and the updated process map in **Appendix 9**).

Exhibit 11. The Future HHS-DOT OPTN Compliance and Safety Office

- In the future state, patient safety reviews should be led by HHS-DOT through its OPTN Compliance and Safety Office, enabling a streamlined, transparent, and accountable federal oversight function.
- Safety events should continue to enter the system through multiple pathways, including member self-reports, public or patient submissions, anonymous reporters, automated surveillance triggers, and referrals from the OPTN compliance contractor, OPTN BOD and internal committees, or HHS-DOT itself.
- Upon intake, each report should be triaged using standardized operational rules to assess severity, urgency, and potential for systemic harm.
- Low-risk events should be addressed through targeted education or monitoring, while high-risk or sentinel events should prompt immediate containment actions and formal escalation to appropriate regulatory authorities.
- For complex or high-impact cases, a dedicated Rapid Response Team should coordinate member communication and harm reduction efforts. HHS-DOT should also convene independent review panels—modeled after NTSB[11]—composed of external experts in procurement, transplantation, patient safety, systems engineering, and ethics. These panels will conduct root cause analyses and offer system-level recommendations.
    - In these cases, HHS-DOT may convene independent review panels—similar to the NTSB[11]—composed of external experts in transplantation, patient safety, systems engineering, or ethics. These panels will provide root cause analyses and system-level recommendations.
- Findings should inform policy refinements, disciplinary actions, follow up evaluations, and member education efforts. De-identified data should be incorporated into reporting dashboards and shared through routine safety bulletins to promote transparency and continuous improvement across the OPTN.

To enhance patient safety and strengthen oversight, we recommend expanding safety event definitions, more effectively integrating compliance and safety oversight, and shifting toward proactive, data-informed risk identification. A modernized infrastructure—with transparent dashboards, tiered penalties, and streamlined reporting—will improve accountability, consistency,

and systemic learning. These changes aim to align member practices with national safety standards, support strategic intervention, and ensure that oversight evolves from reactive case management to continuous system improvement. Moreover, like other industries, including the FAA and NTSB, we recommend developing a standardized process to engage external SMEs who bring deep technical knowledge, real-world experience, and contextual understanding that general investigators or administrators may lack.

Enhance Patient Safety Reporting by Refining and Expanding Safety Event Definitions. To strengthen patient safety oversight and lay the foundation for proactive system learning, we recommend that HHS-DOT establish a formal, expanded set of criteria for what constitutes a reportable safety event. This should include expansion of the "Wakefield Criteria"[12] to cover a comprehensive list of high-priority safety risks, including those related to donor processes and transitions of care, and building off the MPSC-sponsored Reporting of Patient Safety Events Policy[20] (see **Exhibit 12**). It should codify the expectation that "near misses," events that could have resulted in harm but did not, be systematically reported and analyzed alongside confirmed adverse events. In doing this, special attention should be placed on areas where narrowly defined thresholds currently prevent meaningful risk from being captured. These include donor patient related events (both deceased and living), incomplete organ transplant or labeling procedures, and clinical decision errors that do not meet current escalation criteria but may point to systemic weaknesses likely to cause events in the future if left unchecked.

To ensure clarity and consistency, safety event definitions should be aligned with the national safety patient frameworks such as those developed by the Agency for Healthcare Research and Quality (AHRQ) and the Institute for Healthcare Improvement (IHI). Standardizing and harmonizing definitions across the OPTN would allow for better integration with existing safety review processes including desk reviews, site surveys, and automated triage. Care should be taken to incorporate all newly determined definitions into operating protocols, training materials, and member-facing guidance to ensure shared understanding and a means for holding members accountable. Overall, this process is intended to enable earlier detection of risk and foster continuous quality improvement.

Exhibit 12. Evolution of Patient Safety Reporting

HHS-DOT should build on the current reporting expectations described in the Notice of OPTN Policy Changes on **Reporting of Patient Safety Events**[20] to underscore urgency, complete information, transparency, and analytic utility. As the system evolves, ongoing engagement with a future Member Performance and Improvement Committee (MPIC) and other stakeholders will be essential in refining definitions such as "near misses" and shaping expectations around reportable events.

Promote Fairness, Deterrence, and Accountability through a Tiered, Transparent Penalty Framework. To improve fairness and deter violations, HHS-DOT should apply a structured consequence framework that links specific violations to predefined sanctions. This could include a point-based

accountability system wherein infractions related to safety, compliance, or performance are tracked longitudinally. The system should weigh violations based on severity and recurrence, with buffers to reward improvements and innovations in safety practices. Intermediate penalties, such as escalating fines, increased membership fees, or temporary reimbursement reductions, should be defined and modeled against retrospective case data to ensure validity.

Systematically Identify Safety Risks and Patterns by Transitioning to Strategic, Data-Informed Safety Oversight. To shift from reactive to strategic oversight, HHS-DOT should use data-driven analyses to identify systemic safety risks and patterns by member type, streamline case escalation for faster, more efficient review, and improve prioritization based on severity and impact. Methods such as FMEA and FTA[18,19] should be applied to pinpoint weak points in current safety review processes, drawing as possible from the 2022-2024 HRSA-commissioned Historical Complaint Data Analysis.[21] These insights should inform redesigned escalation protocols, triage decisions, and case prioritization strategies. A subset of critical safety events should be predefined for direct escalation to formal HHS-DOT review—bypassing early-stage information gathering—based on severity, risk of recurrence, or public trust implications. Intermediate steps, such as HHS-DOT-led interviews or case hearings, should be built into the system to balance timeliness with due process.

Improve Usability, Transparency, and Analytic Power in Patient Safety Reporting by Strengthening the Reporting and Tracking Infrastructure. Streamlining intake, enhancing user experience, and enabling real-time surveillance is needed to drive system-wide improvement. We recommend updating the patient safety intake process to align with reporting best practices. This includes reducing administrative burden, improving data completeness, and providing a visible progress tracker that allows reporters and members to know where their case stands in the review pipeline. Customer service principles used in other industries (e.g., asynchronous communication tools, automated status updates) could help improve user experience, responsiveness, and trust in the process.

> "If there are opportunities for a modernized OPTN … to introduce when a document or when a process has happened, like for instance my husband and I just applied for global entry with TSA, and I can see exactly where we are in that process. That would be spectacular. One of the overarching observations by most OPTN members is that whatever the MPSC is doing, or whatever the member quality staff or member evaluation staff at [the legacy contractor] is doing is, we pretty much don't know anything about it." - OPO Leader

HHS-DOT should also expand its data analytics capacity to support real-time safety surveillance and predictive modeling. Aggregate data from patient safety reviews should be analyzed to inform policy development, rule refinement, and resource allocation. This should help to ensure that insights translate into measurable system improvements.

The implementation roadmap for this recommendation is in **Appendix 10**.

Sub-recommendation 1.2 Overview: Centralize patient safety reviews within HHS-DOT, enhance oversight, and modernize infrastructure to advance patient safety and proactive risk detection

Rationale for Recommendation: To restore public trust in the nation's organ procurement and transplantation system and alleviate mounting strain on the MPSC, this set of recommendations reconfigures patient safety oversight to promote greater transparency, accountability, and responsiveness. By transitioning key safety review responsibilities to a dedicated team within HHS-DOT, the system should move beyond its current reactive structure toward a more strategic, data-informed model. This structural shift enables faster triage, clearer escalation pathways, and centralized decision-making—critical improvements given the rising volume and complexity of reported events. Embedding safety oversight within HHS-DOT ensures alignment with federal authority, mitigates COI by shifting from peer oversight, and could enable the integration of cross-referenced safety data from independent sources, (e.g., MedWatch). Further, coordination between compliance contractor personnel and HHS-DOT safety staff should strengthen the identification of systemic risks, especially where noncompliance and safety failures intersect. Together, these changes modernize oversight infrastructure, reduce operational bottlenecks, and create a foundation for proactive, enforceable, and learning-focused patient safety governance.

Connection between Recommendation and NOTA and the OPTN Final Rule: Both NOTA[17] and the OPTN Final Rule[16] authorize HHS to oversee the OPTN and to issue contracts for its operation. The proposal to place the new office directly within HHS-DOT aligns with HHS's authority to ensure appropriate federal oversight of patient safety, compliance, and performance. Rather than delegating critical gatekeeping roles to the contractor (currently United Network for Organ Sharing [UNOS]), this shift would reassert the federal government's role in directly supervising and responding to safety risks.

The Final Rule[16] emphasizes the need for policies that are "equitable, effective, and in the best interest of patients." Creating a clearer distinction between the HHS-DOT-led patient safety review function and the MPSC's continued role in performance review supports this mandate by reducing perceived bias in peer oversight and strengthening the transparency, fairness, and credibility of safety-related investigations. In short, this separation reinforces the integrity of enforcement decisions and enhances public and member trust in how safety concerns are identified and addressed.

Potential Benefits to Adopting Recommendation: To restore public trust and alleviate operational strain on the MPSC, this recommendation centers on strengthening transparency, accountability, and the timeliness of patient safety oversight. Moving certain investigative and enforcement responsibilities from the MPSC's purview would allow the committee to focus its expertise and time on its refined core functions involving medical peer review for performance monitoring and membership criteria, areas wherein their professional judgment and collaborative deliberation remain essential.

Transferring the responsibility for safety event investigation to a dedicated team within the HHS-DOT OPTN Compliance and Safety Office would streamline the current two-step process, which involves triage by the contractor and subsequent review by the MPSC. A centralized team would be equipped to

Sub-recommendation 1.2 Overview: Centralize patient safety reviews within HHS-DOT, enhance oversight, and modernize infrastructure to advance patient safety and proactive risk detection

initiate investigations directly, ensure rapid escalation, and remove COIs by offering a reporting pathway that is independent of parties potentially involved in the event.

Importantly, transparency would not simply result from moving oversight to HHS-DOT, it must be operationalized through clear, publicly posted procedures, accessible summary reports or dashboards, and defined pathways for escalating high-risk issues. Housing this function within HHS-DOT also enables cross-referencing with independent data sources, increasing the integrity of investigations and the opportunity for system-level learning. As a federal entity, HHS-DOT is uniquely positioned to enforce consequences in alignment with statutory authority and to publicly demonstrate accountability, thereby reinforcing confidence among both professionals and the public.

Potential Negative Consequences of Adopting Recommendation: Adopting the proposed recommendation poses several risks that could hinder application and reduce its effectiveness. HHS-DOT would face increased staffing and coordination demands, including onboarding a new contractor and building new operational processes. The transition could be disrupted if the current contractor is uncooperative in transferring data or rules, creating early disarray. Resistance may also emerge: the contractor may withhold information, the MPSC could push back against reduced authority, and OPTN members may perceive the changes as burdensome or punitive. This could result in reduced voluntary reporting, especially of near misses, if members fear repercussions. Lastly, balancing transparency with confidentiality is critical; missteps could expose sensitive data and discourage open participation.

Potential Metrics for HHS-DOT and Contractor Operations and Members' Participation in Patient Safety Reviews:

- Adverse event reporting compliance *(member level)*
- Timely case initiation *(DOT office level)*
- Compliance method by which safety event was detected *(DOT office level)*

For more metrics, see **Exhibit 8** and **Exhibit 9.** See their corresponding **Appendix 6** and **Appendix 7** for specific approaches to measuring all recommended metrics.

Recommendation 2: Rebrand the MPSC to the MPIC and establish the OPTN Performance Improvement Learning System

Recommendation 2 Snapshot:

- Rebrand the MPSC to the "Membership and Performance Improvement Committee" (MPIC)
- Rescope the MPIC's work to focus on:
  - recommending critical membership criteria and
  - supporting a stronger performance review and quality improvement learning system
- Engage the MPIC to conduct a comprehensive OPTN membership criteria review

To maximize and strengthen OPTN performance, we recommend changing the scope and title of the MPSC to the Membership and Performance Improvement Committee (MPIC). The MPIC would be responsible for 1) proposing membership criteria and 2) supporting a newly established OPTN Performance Improvement Learning System that is designed to share information and learnings across the OPTN. The OPTN Performance Improvement Learning System includes both expansion of data collection activities to increase systematic data reporting, expand process measure reporting, increase data benchmarking and reporting, and the development of a learning system to engage transplant programs, OPOs, and others in making organizational and system-level improvements.

Sub-Recommendation 2.1: Rebrand and rescope the MPSC as the MPIC and specify the MPIC's responsibilities; engage the MPIC to review and recommend critical membership criteria

Problem Statement: In our discovery efforts, we heard of a long history of the MPSC being seen or perceived as the "OPTN police" enforcing policies with punitive actions. Interviews with current and recent MPSC committee members identified a shift in their approach toward performance improvement. However, many within the OPTN still perceive the MPSC as a punitive-action focused committee. Assuming the recommendation to change the scope of the MPSC (i.e., remove reviewing membership applications and conducting compliance reviews and patient safety investigations from the MPSC) is implemented, the role and scope of the MPSC within the OPTN will significantly change. As the compliance and safety event investigation responsibilities shift from the MPSC, it is likely that the OPTN community may maintain outdated perceptions of the role and scope of the MPSC.

The OPTN still has a need to set and establish membership criteria, as is specified in NOTA and the OPTN Final Rule. In addition, as the OPTN and existing MPSC have recognized,[22] the OPTN membership criteria are out of date and need a thorough review and overhaul. The criteria are also inconsistently defined, with criteria for some member types being highly specific and others being vague and left open to interpretation.

Recommended changes – Rebrand and rescope the MPSC to the MPIC and Engage the MPIC to review and recommend critical membership criteria

Rebrand and rescope the MPSC as the MPIC to better align the title with their focus. With the changes introduced in Recommendation 1, the policy compliance, membership review, and safety event investigation work of the MPSC will now be re-scoped to the HHS-DOT's Office of OPTN Compliance and Safety office. We recommend that the MPSC be rebranded as the "Membership and Performance Improvement Committee" (MPIC). Rebranding the committee will help to distinguish the new roles and responsibilities of the MPIC compared to the previous MPSC. MPIC's scope will include several key activities: 1) review and recommend OPTN member criteria to the OPTN BOD and 2) support the OPTN Performance Improvement Learning System (see the OPTN Performance Improvement Learning System section below).

Engage the MPIC to conduct a comprehensive review of current membership policies. Our discovery efforts have identified several concerns with the current membership criteria. For transplant hospitals and organ-specific programs, the current criteria are often overly specific and at times at odds with the evolving workforce (e.g., non-U.S.-trained physicians and surgeons) and the shifting medical landscape (e.g., new board accreditation requirements). In comparison to transplant hospitals and programs, the OPOs have fewer specified requirements, including no requirements for personnel qualifications or standards beyond key personnel. Future efforts should ensure that staff who interface with the public or clinicians in procuring organs from families of deceased donors, or living donors, have sufficient training and support to engage in patient-centered interactions (see callout box).

> "The bulk of the workforce is foreign trained graduates, and we need a way that we can map their experience in their native country to a U.S. experience, or else we're going to [...] be a club with no members." - Transplant Hospital Member

> "I think there should be minimum requirements for frontline practitioners. [...] The [Certified Procurement Transplant Coordinator certification] is the only objective way that I see currently that that can be done, and I'm certainly not opposed to it." - OPO Leader

As the organ transplantation landscape continues to evolve, the OPTN's policies must continue to evolve with them. A key area of concern is the responsibility of

organs in transition between donor hospitals and transplant hospitals, including managing timely organ delivery and addressing logistical challenges. In addition, the rise in organ perfusion has dramatically improved organ viability, however organ perfusion companies have little oversight. In the review of member policies, the OPTN should consider other types of organizations that interact with the OPTN and whether there should be established member criteria for them (see callout box).

To conduct a comprehensive review of OPTN membership criteria, the MPIC should first define the objectives the criteria are designed to achieve—ensuring that OPTN members have adequate facilities and qualified staff to support safe procurement and transplantation. Then, the MPIC should review the existing policies for relevance to the objective and accuracy to the current landscape. The MPIC should work with other OPTN committees to review and update organ-specific and member-specific recommendations. This review needs to consider the appropriate balance between flexible criteria that adapt to advancements in transplants and strict standards that ensure member organizations are staffed with qualified professionals and equipped with the necessary resources for safe procurement and transplantation. The membership criteria should be designed with built-in flexibility to adapt to the ever-evolving medical and workforce landscape, including documented processes for special reviews when applicants are clearly qualified but do not meet the written requirements.

The Implementation Roadmap for re-branding and rescoping the MPSC as the MPIC is in **Appendix 11.** The Implementation Roadmap for engaging the MPIC to review and recommend new OPTN member criteria is in **Appendix 12.**

Sub-recommendation 2.1 Overview: Recommended changes – rebrand and rescope the MPSC to the MPIC and engage the MPIC to review and recommend critical membership criteria

Rationale for Recommendation: Rebranding and rescoping the MPSC as the MPIC will aid in shifting the perception of the committee's scope to the new focus on maintaining membership criteria and supporting performance improvement (see the OPTN Performance Improvement Learning System section below). Retaining the work of setting and maintaining membership criteria within the OPTN is critical as the individuals within the organ procurement and transplantation community likely have the best comprehensive view of the changing workforce landscape and necessary program and staffing components for OPTN members. Oversight from HHS-DOT will ensure that criteria are consistently specific enough across member types and effectively address concerns about self-regulation.

Connection between Overall Recommendation and NOTA and the OPTN Final Rule: NOTA specifies that the OPTN shall establish membership criteria.[17] In this case, the OPTN BODs would cede creating recommendations to the MPIC, who would present recommendations to the OPTN BODs for review and approval. The OPTN Final Rule includes specifics about member criteria for transplant programs (§ 121.9)[16] which would be reviewed and incorporated as relevant into the comprehensive member criteria review.

Sub-recommendation 2.1 Overview: Recommended changes – rebrand and rescope the MPSC to the MPIC and engage the MPIC to review and recommend critical membership criteria

Potential Benefits to Adopting Recommendation: The main benefit of changing the committee's name and revamping its scope is to align with their new role in setting membership criteria and supporting the OPTN Performance Improvement Learning System, while also distancing OPTN membership from previous associations and perceptions tied to the former MPSC. Potential benefits to reviewing and recommending updated member criteria include the potential for more streamlined criteria with a similar level of specificity required for the different member types.

Potential Negative Consequences of Adopting Recommendation: There may be initial confusion about the changing scope and role of the MPSC/MPIC, but that will be addressed through a communication plan. The criteria may be changed to the degree that makes some member types 'out of compliance' with the membership criteria, and they may need to adjust their staffing, facility, or program accordingly. One potential concern about having the OPTN set its own membership criteria is that they may set the criteria in a way that is more loose or less regulated than an external entity. HHS-DOT, as the government regulator for the OPTN, will have the responsibility to review membership criteria to ensure criteria are appropriately detailed to uphold a safe procurement and transplantation system.

Potential Metrics for MPIC responsibilities and OPTN Members' Engagement with the Rebranded and Rescoped MPIC:

- Membership criteria policy acknowledgement and implementation timeliness *(member level)*
- Responsiveness to workforce trends *(MPIC level)*
- External validation and engagement *(MPIC level)*

For more metrics, see **Exhibit 8** and **Exhibit 9.** See their corresponding **Appendix 6** and **Appendix 7** for specific approaches to measuring all recommended metrics.

Sub-recommendation 2.2: Develop an OPTN Performance Improvement Learning System to Strengthen OPTN Member Performance

Problem Statement: The OPTN and its members continue to need data-driven and evidence-based quality improvement support. Comprehensive data submission and collection is one challenge. Currently, OPTN institutional members (i.e., OPOs, transplant hospitals, and histocompatibility labs) submit an extensive amount of outcomes-oriented data to UNOS, which is collected in both a manual and automated fashion, some of which is later provided to the Scientific Registry of Transplant Recipients for statistical processing and analysis. While UNOS has several data collection protocols (e.g., APIs) that allow for electronic submission of some of the data, much of the donor reporting is still manual (In March 2025 the rates were Living Donor Reporting Forms 30%, Deceased Donor Reporting Forms 72%, and Candidate & Recipient Reporting Forms 51%).[23] Additionally, the current process for triggering underperformance, and subsequently a

performance review, relies on outcomes-based data with long lags. This performance monitoring process could benefit from more upstream, interim-based or process-oriented measures.

Through our discovery efforts, we noted the desire and need for the OPTN to provide community-level learning and support. While the MPSC's approach to providing support to institutional OPTN members has shifted from punitive to focused on performance improvements in the last several years, there was still the perceived risk of OPTN members under review being punished by the MPSC when engaging in quality improvement efforts. In the potential future state where HHS-DOT leads the compliance and safety investigation responsibility, the MPIC's position can move to one of providing non-punitive, supportive quality improvement support. The OPTN continues to need quality improvement support, both for individual members that are underperforming and for system-wide improvements (see **Exhibit 3**).

Recommended changes – Develop an OPTN Performance Improvement Learning System to Strengthen OPTN Member Performance

With the shift of the responsibility of policy compliance and patient safety event reviews moving to the new office within HHS-DOT, we recommend the redesigned MPIC support a Performance Improvement Learning System that incorporates:

- More sophisticated data submission, including process measures, data dashboarding, and benchmarking
- Targeted MPIC-led peer-to-peer quality improvement support for underperforming members (see the updated process map in **Appendix 12 and Exhibit 3**)
- A structured learning system to enhance performance improvement within transplant programs and OPOs, and at critical transition points between system members

This comprehensive quality and safety improvement learning system provides targeted support to underperforming OPTN members, while providing improved data, benchmarking, and learning support to all OPTN members.

Support improved process- and outcome-oriented data submission and targeted data dashboards. To enhance data submission under recommendation 1, we propose implementing a modernized system where OPTN members submit all required data electronically. This approach would eliminate the need for lengthy forms or questionnaires, streamlining the process and improving efficiency.

To enable timely and more efficient tracking of indicators that may impact outcomes, we propose that OPTN collect and report a set of process measures specific to each member type (i.e., transplant programs, OPOs, and histocompatibility laboratories) as well as process measures capturing coordination between system types. See **Appendix 14** for suggestions of potential process measures. Key informant stakeholder interviews revealed that many transplant hospitals —and, in some cases, high-performing OPOs—already track similar process measures internally to

identify areas for improvement. By consolidating these process measures alongside outcome metrics, OPTN can develop more targeted dashboards with benchmarking, allowing for proactive interventions before longer-term poor outcomes result in significant patient safety concerns.

Histocompatibility laboratories have traditionally had fewer reporting requirements; we recommend expanding the data submitted to optimize OPTN performance improvements (see **Exhibit 13**).

Exhibit 13. Histocompatibility Laboratory Performance Monitoring – Present and Future

Currently, OPTN's performance monitoring process for histocompatibility laboratories is poorly defined.

It is unclear if communication occurs between accrediting bodies (i.e., CLIA accreditation organizations: including, ASHI or College of American Pathologists) and UNOS to share information regarding the results and interpretation of proficiency testing.

If issues with accreditation arise, the histocompatibility laboratory is required to self-report to the OPTN. However, it is unclear how warnings or penalties from the accrediting bodies affect laboratory operations.

Data submitted by histocompatibility laboratories to UNOS are analyzed and used to support patient safety during the transplantation process. Continuous monitoring of this data detects discrepant or inappropriate matches in a process designed to reduce the risk of rejection. The OPTN is currently not tracking the time at which samples are obtained prior to a donation event or organ is received, the amount of time required to process samples, and the time to report concerning results. Various deadlines exist within OPTN policies and between the laboratory and their OPO or transplant hospital partners.

Variations in practice—such as communication methods, digital reporting from Laboratory Information Systems, antibody testing preferences, and the timing of sample collection before procurement or transplant—likely exist. However, without performance measurement, OPTN is unable to determine which of these practices are the safest and most efficient.

We recommend the development of process measures that reflect laboratory performance in these areas to determine where best practices exist to avoid patient harm. To ensure laboratory quality, we recommend the simultaneous reporting of proficiency testing from CLIA accreditation organizations to OPTN data systems. This approach creates a performance record that is easily accessible to histocompatibility SMEs within the OPTN and tied to individual laboratories.

In collaboration with CLIA accreditation organizations, we recommend developing proficiency testing based on real-world scenarios that have contributed to OPTN safety events. Additionally, tracking the time required to report or communicate results should be incorporated as a key performance metric.

Submitted outcome and process measure data would be reported in an interactive dashboard allowing members (e.g., donor hospitals, OPOs, referring organizations, and transplant hospitals) to easily access their data, benchmark themselves over time to target areas of improvement, and

compare themselves to peers with similar characteristics (e.g., geographic area, size, or healthcare system). Additionally, benchmarking could help members analyze donor and recipient characteristics, (e.g., race, gender, age) more effectively. Standardized performance measures would provide deeper insights into both the geographical- and patient-level challenges within the organ procurement and transplantation system, enabling data-driven quality improvement initiatives that drive lasting change.

The implementation roadmap for this recommendation is in **Appendix 15**.

Engage the MPIC to provide targeted peer-to-peer quality improvement support for underperformers.

Throughout our discovery efforts, we noted that one of the MPSC's key strengths is its ability to provide individual member performance improvement support. Given the local expertise in organ procurement and transplantation, and experience supporting quality improvement efforts, a redesigned MPIC could provide targeted support to underperforming OPTN members. Here we propose using the specified performance improvement zones currently used by the OPTN for transplant hospitals[24,25] and the new performance tiers for OPOs to be introduced by CMS.[26] We recommend that MPIC provide mandatory educational and quality improvement activities tailored to members that currently fall into the lowest performance zone (**Exhibit 14**).

Transplant Hospitals: Members in the 'red' or current 'intervention' zone should be referred to the MPIC to design a Quality Assessment and Performance Improvement (QAPI) plan focused on achieving agreed-upon metrics, with on-going data review while in the low performing zone. Those in the 'yellow' zone may voluntarily engage but are not required.

- **OPOs**: If the CMS three-tiered performance system is implemented, all second-tier OPOs should work with the MPIC to design a QAPI plan ensuring continuous data review to improve performance. This assumes all third tier OPOs would have been de-certified.
- **Histocompatibility Laboratories**: Once performance data becomes available, the MPIC's scope could be expanded to support underperforming laboratories.

Exhibit 14. The Future MPIC-led Performance Review Processes

- In the future state, the MPIC will play an expanded role in member performance monitoring, leveraging the OPTN's quality improvement culture to support underperforming institutions and improve access to organ transplantation.
- Histocompatibility laboratories will be subject to enhanced performance reporting requirements focused on operational efficiency and alignment with standards set by CLIA-accredited organizations such as American Society for Histocompatibility and Immunogenetics (ASHI).
- Mandatory participation, for all institutional member types, in QAPI initiatives and peer-to-peer support will be required for members in low performing CMS tier or MPIC-designated underperforming zones. Optional engagement will be offered for at-risk transplant hospitals or histocompatibility laboratories.
- The MPIC will track performance trends over time and work collaboratively with members to promote improvement. Persistent underperformance may prompt join review with the HHS-

DOT OPTN Compliance and Safety Office to determine whether formal compliance or safety actions are warranted.

OPTN members receiving MPIC quality improvement support should meet with committee members to discuss their metrics, develop a quality improvement plan in collaboration with their local QAPI, and engage with the MPIC as needed. The MPIC and HHS-DOT should coordinate every six months to review quality improvement cases and determine if any cases need to be escalated to a compliance or safety review. HHS-DOT can collaborate with the MPIC to offer expert consultation to underperforming OPTN members, while still maintaining regulatory oversight and ensuring a clear structured approach to performance improvement. See **Exhibit 15** for an example of how ombuds supports long term care improvement prior to CMS escalation. The implementation roadmap for this MPIC-supported peer-to-peer quality improvement recommendation is in **Appendix 16**.

Exhibit 15. Lessons from the Long-Term Care Ombudsman Model

During key informant stakeholder interviews, a former Michigan State Long-Term Care Ombudsman described how the ombuds model provides a valuable example for supporting facilities through early-stage concerns before formal regulatory action is required. Local, Long-Term Care ombudsmen serve as neutral, trusted intermediaries who help surface issues, facilitate resolution, and guide facilities toward improvement, often preventing escalation to CMS sanctions. In the context of OPTN oversight, a similar function could be envisioned through the MPIC peer-to-peer quality improvement support offered to underperforming OPTN members. These members can identify emerging risks, provide technical guidance, and promote system learning without immediately triggering punitive consequences. They can provide a key avenue to escalate critical issues to HHS-DOT and help bridge the gap between reactive enforcement and proactive quality improvement.

Engage the MPIC to support a learning system to support continuous improvement across all organ procurement and transplantation activities. The AHRQ defines a learning system as a system that systematically incorporates internal data and experience with external evidence and then puts that knowledge into practice.[27] Instituting learning systems can result in patients receiving higher quality, safer, more efficient care, and health care delivery organizations becoming better places to work.[27]

An effective OPTN learning system should be guided by three core principles. First, **it must be all encompassing and designed to evolve over time.** An all-encompassing learning system recognizes the unique improvement needs of OPOs, transplant hospitals, and histocompatibility labs, while also viewing their improvement efforts as interconnected and interdependent. The OPTN learning system will have an infrastructure that can support the needs of all these groups and actively foster sharing and collective improvement efforts that may involve multiple stakeholders. An effective OPTN will require better collaboration and coordination between the transplant hospitals and OPOs; the learning system must model and promote these aims and

address both improvement needs within each of the stakeholders' unique operations and better collaborate to improve organ assignment and rates of successful transplantation. Because these needs will evolve in response to improvements and potential changes in the organizations functioning as OPOs or transplant hospitals, an OPTN learning system should be designed to evolve in response to emerging needs and priorities.

Second, **the learning system must be grounded in a commitment to Just Culture**. As noted above, a just culture promotes transparency, shared accountability, and system-level improvements to safety and quality. Importantly, it also supports open communication about less severe medical errors and near-misses in a non-punitive context. While HHS-DOT and the public are both committed to improving transparency and accountability for the OPTN, a learning system in which participants fear that the experiences or data they share may be used to punish them will not be successful. To address this dilemma, AHRQ used federal legislation to create recognized patient safety organizations whose data sharing and discussions were legislatively protected.[28] Establishing a transplant-focused patient-safety organization to lead the OPTN learning system may maximize its effectiveness and encourage greater participation. [i]

Finally, **an effective learning system should be led by the MPIC and supported by a qualified contractor team with no perceived COIs or other regulatory functions.** The MPIC, with extensive experience and deep knowledge of OPOs, transplant hospitals, and histocompatibility labs, will support the effort, with direct leadership provided by a contractor with extensive healthcare improvement and learning system experience. The MPIC and contractor should collaboratively set learning system priorities in consultation with learning system members and other key stakeholders (e.g., HRSA and CMS staff, OPTN members, and patients and family caregivers). They should be accountable for progress using defined process and outcome measures. **Process measures** may include levels of participation, qualitative and quantitative feedback from learning system participants, and evaluations of learning system materials and events by external expert reviewers. **Monitoring measures** may include rates of data submission, changes in required OPTN data and feedback from families.

Use a learning system to create and regularly update improvement resources and support learning activities offering value to low, medium, and high performing OPOs and transplant hospitals. Support for a learning system should demonstrate a long-term commitment to continuous improvement by both transplant hospitals and OPOs. It is essential to avoid framing a learning system as a short-term fix for a problem. Instead, a permanent learning system is needed that periodically sets data-driven improvement priorities, supports progress in those areas, and then refocuses on additional improvement opportunities. This system, comprising both improvement activities and resources,

[i] There are over 100 PSOs officially acknowledged by AHRQ but none of these are focused on organ procurement or transplantation.

will reinforce the importance of continuous improvement for both lower and higher performing OPOs and transplant hospitals.

Support both learning collaboratives and shorter-term improvement sprints. We recommend that the learning system offer both learning collaboratives and shorter-term improvement sprints. IHI-style learning collaboratives are proven methods for improving targeted outcomes that have been used successfully within the OPTN community. In general, such collaboratives work best when they are focused on a problem that lacks a single, unidimensional solution that is perceived as important, is supported by the leaderships of the participating organizations, and takes place in a context where participants are not competing against each other. If transplant hospitals need to meet benchmarks to retain certification, then helping other collaborative participants meet those benchmarks will pose no risks to others in the collaborative. However, if OPOs are evaluated against each other, openly sharing information could inadvertently help competitors improve, potentially pushing those sharing their success strategies into the yellow or red tier. To use collaboratives effectively, it is crucial to understand the conditions that make them successful.

At the outset, the learning system contractor with support from the MPIC may explore levels of interest in three collaboratives:

- **A collaborative for transplant programs** focused on an issue (or set of related issues) that are recognized, internal problems. Some high performing programs might function as faculty, but this collaborative would primarily support transplant programs with a measurable need to improve in the selected area. Since transplant hospital certification is based on defined performance levels, there should be few reasons not to share strategies or help each other.
- **A collaborative for OPOs** targeting an issue (or set of related issues) that are recognized, internal problems. Such a collaborative is unlikely to succeed if OPOs believe they are competing to avoid the loss of their contract. Strategies that lessen this concern are needed for the success of this collaborative.
- **A collaborative involving a mix of higher performing OPOs and transplant hospitals** that work to improve coordination issues that commonly lead to suboptimal outcomes. Such a collaborative would a) reinforce the value of continuous improvement even for high performers, b) foster better working relationships between OPOs and transplant hospitals, c) help develop coordination process measures that may support measurable improvement, and d) surface collaboration improvement strategies for sharing with the rest of the community.

In addition to organizing and supporting learning collaboratives, we recommend the learning system contractor, with support from the MPIC, develop a limited number of improvement events or short-term sprints that focus on specific areas for improvement. Such activities are well suited for issues with defined potential solutions that are comparatively easy to explain and enact. They also can feature both experts and peers describing solutions to problems that activity participants

can incorporate. Making these activities as interactive and participative as possible will maximize their value to the OPTN community.

Develop learning resources and a learning infrastructure to support continuous improvement across the OPTN over time. An effective learning system should strengthen the resilience of the communities it supports. Transplant hospitals and OPOs inevitably face staff turnover, resulting in a loss of organizational memory. Additionally, as new transplant hospitals and OPS emerge within OPTN, preserving improvement strategies and lessons learned is essential to sustaining progress.

To ensure long-term support, the learning system must document and curate improvement resources in an accessible, online format. Many valuable resources can be gathered from learning collaboratives and other improvement initiatives, including:

- Collaborative change packages, tips and strategies shared during learning sessions and learning collaboratives
- A dedicated online platform containing improvement resources, dashboard results, information on measures, and upcoming learning activities
- Best practices for promoting organ transplantation
- Patient/family perspectives on ways to encourage organ transplantation, including outreach to prospective living donors

The implementation roadmap for the OPTN Learning System recommendation is in **Appendix 17**.

Sub-recommendation 2.2 Overview: Develop the OPTN Performance Improvement Learning System

Rationale for Recommendation: These recommendations aim to enhance member accountability and drive quality improvement by collecting process measures, creating dashboards that are easy to use and interpret for members and the public — all supported by the implementation of a learning system to move members forward in patient safety. Together, these efforts will help increase the number of organs safely procured and transplanted while improving the quality of care provided for both pre- and post-transplant services.

In terms of performance monitoring, the new MPIC could be well positioned to provide a more comprehensive performance improvement system that includes use of modernized data submission systems, data dashboarding and benchmarking for OPTN members to better gauge their performance, and the development of a learning system as described in more detail below.

Connection between Recommendation and NOTA and the OPTN Final Rule: NOTA specifies the need for the OPTN to carry out projects to improve procedures for organ procurement and allocation (§274 b.2.A.J),[17] which is the aim of the learning system. By expanding the collection, reporting and benchmarking of process measures in addition to the outcomes required in SRTR reporting, this recommendation also supports the aim of

Sub-recommendation 2.2 Overview: Develop the OPTN Performance Improvement Learning System
NOTA to collect, analyze, and publish data concerning organ donation and transplants (§274 b.2.A.I).[17]
Potential Benefits to Adopting Recommendation: The MPIC volunteers include clinicians and other procurement and transplant professionals with extensive expertise in organ transplantation. By changing the mission of the MPIC to focus on member performance and quality improvement, the OPTN can create an environment that leverages this expertise to improve patient safety and the quality of care. This streamlined approach will lighten the workload of the all-volunteer MPIC, enabling its members to leverage their expertise to focus on quality improvement for all members. A qualified contractor to support the learning system can access MPIC member expertise and maintain the sustained focus that a successful long-term learning system requires.
Potential Negative Consequences of Adopting Recommendation: Currently the MPSC has a broad range of responsibilities. By restructuring those responsibilities to focus on member performance and quality improvement, there will be a significant change in both focus and function. This realignment of the MPSC (into the MPIC) could potentially affect the relationship between HHS-DOT, the existing OPTN, and the members. Additionally, since participation in the peer-to-peer learning activities is mandatory, transplant hospital members in the red and yellow zones, as well as lower-tier OPOs, may be less willing to engage if they perceive it as punitive. If learning system data or discussions are discoverable, this may discourage the open sharing of mistakes and near misses needed to foster continuous improvement. Leveraging an independent contractor to lead the learning system and using the protections available to patient safety organizations to ensure confidentiality within the learning system, can help mitigate this risk.
Potential Metrics for OPTN Members' Engagement with the MPIC and the OPTN Performance Improvement Learning System: • Waitlist management accuracy *(member level)* • Policy education participation *(member level)* • Aligned metric with The Alliance Guidance (Strategy 6.6) that drive QAPI efforts *(member level)* For more metrics, see **Exhibit 8** and **Exhibit 9.** See their corresponding **Appendix 6** and **Appendix 7** for specific approaches to measuring all recommended metrics.

Other suggestions to strengthen transparency, accountability, and operational consistency in the OPTN

As part of the comprehensive BPR processes, we identified areas to improve system-level OPTN processes and systems. These suggestions aim to support HHS-DOT and expand on the recommendations for MPSC's functions and workflows. While they extend beyond the scope of our project, we believe they are essential for strengthening OPTN. By enhancing transparency, clarifying workflows, and improving data quality and interoperability, these efforts help manage complex interconnections and potential COIs that can undermine trust in the system. These efforts support operational continuity and institutional memory, enable performance improvement through process evaluation, and promote equitable, standardized application of policies across all member types. Together, these suggestions help ensure a consistent, efficient, and trustworthy national procurement and transplantation system.

Suggestions for improvement: Process documentation, process metrics, and other mechanisms for transparency

The future OPTN should prioritize transparency by clearly reporting its operational processes and regularly sharing key metrics.

Document and disseminate critical processes, workflows, and functions of the OPTN. To ensure clarity in a multi-vendor environment, especially with the new BODs beginning their term on July 1, 2025, OPTN must document and disseminate its critical processes, workflows, and functions. Doing so will enhance transparency, facilitate informed decision-making, and support necessary course corrections.

Without a clear understanding of roles, responsibilities and timelines, there may be ambiguity that results in delays and missteps. Value stream maps outline workflows at a high level detailing all the steps of a process. We suggest developing value stream maps for critical process of the OPTN, including information about the process steps, information flows, and timelines for each step. **Appendix 8**, **Appendix 10**, **Appendix 11, Appendix 12**, **Appendix 15, Appendix 16,** and **Appendix 17** illustrate the value stream maps for the critical functions re-engineered in this report, including compliance reviews, patient safety investigations, performance monitoring, and managing COIs. By creating and sharing value stream maps of its critical processes, OPTN enhances transparency, fostering trust, accountability, and informed decision-making. Clearly outlining how processes function, who is responsible, and what to expect allows OPTN to improve efficiency and strengthen collaboration among stakeholders.

Develop and learn from process metrics. Process metrics tracking HHS-DOT operations, its future contractor, and members' active, responsible participation in OPTN are critical to strengthening the U.S. procurement and transplantation system. The proposed metrics improve oversight by

identifying patterns of member noncompliance and accountability gaps, while also enhancing patient safety through timely detection of systemic risks (see **Exhibit 8** for member level metrics and corresponding **Appendix 6** for specific measurement approaches and **Exhibit 9** for contractor and HHS-DOT office metrics and corresponding **Appendix 7** for specific measurement approaches). These metrics will inform data-driven policy refinements, ensuring that oversight focuses on the most impactful areas. Additionally, process metrics support efficient resource allocation and workflow improvements within the new OPTN Compliance and Safety Office and its contracted support. Regularly sharing metrics through public reporting, including user-friendly dashboards (as described below), will support greater trust across the transplant community and the broader public.

Enhance oversight transparency by creating real-time operational dashboards and feedback loops. Data-informed oversight through real-time tracking of key metrics and routine audits of triage decisions enable early detection of risks and continuous improvement. Sharing dashboards with leadership and oversight bodies enhances transparency and strengthens accountability across the system. HHS-DOT should adopt metrics that track and publicly communicate members' active and responsible participation in the OPTN and support operational performance (see **Exhibit 9)**. Policy compliance dashboards should be maintained by the contractor and shared with HHS-DOT leadership for oversight and course corrections. Additionally, they should be provided to the MPSC and OPTN BOD as needed to enhance situational awareness and support their specific initiatives. Similarly, the HHS-DOT Office of Compliance and Safety should maintain comparable dashboards for all patient safety review efforts (see **Exhibit 8)**.

Suggestions for improvement: Improved data quality, data interoperability and data systems

The current OPTN data systems are outdated, lack necessary interoperability, and contribute to incomplete and poor-quality data—undermining efficiency, effectiveness, and the protection of patient safety.

Bolster Individual and OPTN Member Accountability through Improved Data Systems. To strengthen the integrity of compliance monitoring, we recommend enhancing the identity and access management (IAM) system used by the OPTN contractor to more effectively track key personnel and other designated users (e.g., those submitting data, clinical leads) across OPTN member institutions. An IAM system strengthens policy compliance monitoring across member organizations by enforcing role-based access aligned with defined OPTN policies, tracking user activity through audit trails, and flagging access anomalies or segregation-of-duties violations. When integrated with compliance dashboards and tools that govern access, IAM enables oversight bodies to detect unauthorized actions, ensure timely deactivation of user accounts, and connect access patterns to potential policy breaches or safety risks. Currently, personnel data are housed within membership records, but limitations in cross-institutional tracking can make it difficult to

understand whether patterns of noncompliance are associated with specific individuals, roles, institutions, or transitions between them.

By establishing a centralized, longitudinal tracking system that links individuals with their roles and authorizations, the OPTN could support more accurate attribution of data management concerns and ensure greater transparency. For example, if an OPO staff member edits donor records or a transplant program bypasses organ offers, an IAM system can verify that the actor was authorized for that action, log the event for real-time review, trigger an alert if access exceeded role-based permissions, and link the access pattern to broader compliance audits or safety investigations. This system would be designed to promote both individual and institution-level accountability, safeguard against repeat patterns of risk, and improve data quality and responsiveness across the transplant network.

> "As far as the member hospital itself, if we have issues with, let's say, the lead surgeon coming on or the lead cardiologist that you guys [MPSC] are reviewing to approve for a program. Can we have a system in place where they have to provide, let's say, enough background information on these individuals. And that would be, you know, insurance screening, whether or not... they're leaving one program that you know is going through disciplinary actions and trying to move to start another program."
>
> - HHS-DOT Leader

Improve member and personnel tracking and monitoring through integrated and interoperable systems.
The current system for managing member applications and program updates does not optimize system- or individual-level tracking and data analytics. Membership records include limited information about some personnel (i.e., key personnel), but that individual-level information cannot be tracked across members when individuals change positions. The current limitations in cross-institutional tracking can make it difficult to understand whether patterns of noncompliance are associated with specific individuals, roles, institutions, or transitions between them. We suggest establishing a longitudinal tracking system that expands the current tracking of OPTN members by linking and tracking individuals and their role within individual OPTN member institutions. This OPTN member system should be interoperable with compliance and performance data to allow the OPTN to better support more accurate attribution of performance concerns and facilitate timely feedback. This system could also be optimized for improved utility by allowing an individual's 'file' to be easily re-assigned to a new OPTN member, reducing the time and effort to resubmit previously submitted documentation and only update new relevant details. This system would not be designed for punitive individual surveillance, but rather to promote both individual and institution-level accountability and safeguard against repeat patterns of risk. It could also help identify individuals who may pose elevated risk, such as surgeons or staff in other roles that are repeatedly associated with adverse events at their member organizations, while at the same time

maintaining appropriate protection and due process (see callout box). HHS-DOT could also consider expanding required information submitted for each member, including all personnel that engage with patients in critical roles.

Engage end users to assess features needed across data systems or databases to inform strategic reorganization. In our discovery efforts, we identified the need for data system improvement that is informed by user experience testing and needed use cases. For example, the membership application system should be interoperable with compliance and performance data systems so member and individual (e.g., key personnel, individual clinicians) data can be linked to critical outcomes and observed over time. Future OPTN data systems need to maximize interoperability to ensure information flows across systems seamlessly. In the membership application system, everyone should have their own 'file' that can be transferred to a new OPTN member organization, allowing the individual to only update new information, thus reducing burden. The system should have built in notifications of next steps or missing information, for example flags for members of incomplete application materials, or flags for investigators on required next steps. Clearly mark what fields are required and do not allow submission when information is missing.

Suggestions for improvement: COI management

The current Conflicts of Interest policy for the OPTN BOD and permanent standing committees, including the MPSC, lacks sufficient detail and operational clarity to ensure consistent interpretation and application. Although the OPTN Code of Conduct[29] requires disclosures and mitigation steps, there is limited transparency around how disclosures are reviewed, how mitigation plans are developed, and what enforcement mechanisms exist when conflicts are not disclosed or properly managed. Federal agencies such as the Food and Drug Administration (FDA) (see **Exhibit 16**) offer illustrative models for structured COI processes, including centralized disclosures, external review, and public transparency, can reinforce ethical decision-making and institutional credibility (see **Exhibit 17**).

Exhibit 16. Federal Model for Transparent COI Process

FDA provides a useful reference for managing COI through structured processes and transparency. This agency reviews financial interests of employees, investigators, and their families to ensure that individuals involved in regulatory processes are not influenced by personal gain. Though focused primarily on financial COIs, its structured approach demonstrates how centralized oversight can strengthen impartiality and promote public trust.

- FDA employees must report prohibited financial interests within 30 days of hire, and again if a new interest is acquired
- Special government employee disclosure forms before participating in meetings
- Clinical investigators disclose financial interests prior to the start of a study

Once disclosed, financial interests are reviewed by the FDA, which may require recusal, instituting bias mitigation strategies, or granting of a waiver in certain defined circumstances. To demonstrate transparency, all advisory committee financial interests are made public.

Exhibit 17. The Future OPTN COI Management Processes

- In the future state, COI management will be strengthened through enhanced intake tools that enable automated cross checks, flag changes over time, and prompt timely follow-up evaluations.
- Individual members will have access to a dynamic COI record and may submit updates or request reviews as their disclosures evolve.
- Key evaluation checkpoints will remain in place, including COI review at onboarding, annually, prior to committee participation, and upon identification of a previously undisclosed conflict. These structured intervals will ensure COI data remains current and actionable.
- To reduce the burden on the OPTN BOD and Executive Committee, a dedicated COI Officer within the HHS-DOT OPTN Compliance and Safety Office will be responsible for reviewing and contextualizing reported conflicts, developing mitigation strategies, and flagging severe conflicts that may disqualify members from participation in specific committee or board activities.[11]

Modernize and centralize the COI disclosure process by updating the secure digital portal used by members. Refinements to this portal should allow users to review, update, and track disclosures in real time, while incorporating automated cross-checking functions to flag inconsistencies, omissions, or potentially outdated information. These changes will improve accuracy of the applicant information on file and simultaneously reduce administrative burden by minimizing the need for manual extraction of data.

Engage a dedicated COI Officer who is external to the OPTN to review and adjudicate COI. The person in this role would be responsible for advising on potential risks, design and coordinate mitigation strategies, and work in close partnership with the MPSC, President of the OPTN BOD, and other OPTN committee chairs to ensure impartial and timely resolution of conflicts. Re-examine the role of the Executive Committee and committee chair in COI mitigation decisions, particularly in sensitive or high-stakes contexts, to ensure impartiality and reduce the risk of perceived internal bias. Consider mechanisms such as recusal, external consultation, or shared review panels for complex cases.

Incorporate detailed COI definitions and contextual examples into OPTN code of conduct[29] and Management and Membership policies[30] to support a shared understanding of what constitutes a conflict. These should include personal, financial, academic, institutional, and geographic affiliations, along with illustrative "presumptive conflict" scenarios that guide members in proactively identifying and disclosing risks. Codify commonly presumed COIs, such as shared institutional affiliations, geographic proximity, supervisory relationships, or recent employment or training history, in the written policy to reduce ambiguity in interpretation and promote consistent interpretation and enforcement across committees and leadership structures.

Establish mandatory COI orientation and ongoing training for all MPSC members, with updates provided when policy language, definitions, or procedures change. Training should focus on real-world

scenarios and emphasize the importance of consistent, transparent practice to maintain public trust.

Implement routine COI audits and policy effectiveness reviews, with findings used to refine definitions, improve mitigation protocols, identify trends, and strengthen the system's ability to prevent, detect, and address conflicts over time. This learning-focused approach would align COI policy with broader efforts to modernize OPTN governance and support ethical, unbiased decision-making.

The implementation roadmap for the suggested changes to the OPTN COI processes is in **Appendix 18**.

Change Management Best Practices

Organizational and institutional change is incredibly difficult. Especially when making large changes like the ones recommended in this report, people with experience in the OPTN may experience common responses to change – fear of the unknown, comfort with how things have been done, a lack of trust in those who are leading the effort, and concerns about the potential negative impact on the US procurement and transplantation system.[2,3] With change initiatives that are large and transformative, it is critical that those enacting the recommendations, suggested in this report, plan the process.

We developed specific implementation roadmaps for each recommendation (see **Appendix 8**, **Appendix 10**, **Appendix 11**, **Appendix 12**, **Appendix 15, Appendix 16,** and **Appendix 17**). In drafting these roadmaps, we identified common themes, recurring methods, and a need for shared language to describe implementation activities consistently. To support this, we framed each roadmap around four standard phases:

Exploration & Planning – the resources and needs are explored for the fit and feasibility of the intervention within the organizational and system context. Much of this work was started in the current contract.

Installation – a planning and preparatory period dedicated to developing infrastructure that will support the program or practice, including building individual, organizational, and system capacity.

Initial Implementation – a time of intentional data and information gathering for continuous improvement beginning when the intervention was initially implemented.

Full Implementation & Sustainability – when the intervention has been adopted by most or all, and indicators of implementation show improvement.

In the section below, we describe several high-level change management and implementation best practices to align knowledge and expectations around change management. In the implementation roadmaps specific to each recommendation(see **Appendix 8**, **Appendix 10**, **Appendix 11**, **Appendix 12**, **Appendix 15, Appendix 16,** and **Appendix 17**)**,** we provide specifics related to these best practices, as well as the resources needed, personnel involved, barriers and approaches to overcome barriers, and timeline for each step in each phase.

Exploration & planning phase

Develop an Implementation Team to Lead the Change Management Effort. An implementation team of five to seven members should be formed to champion and lead the change. Team members should have experience in organizational change and, ideally, direct experience in the specific area being addressed. The implementation team is tasked with partnering with HHS-DOT, the OPTN BOD, and others as identified to ensure the team has the competencies necessary to support and sustain the changes. They are also responsible for engaging stakeholders in key decisions, determining what should be implemented, identifying challenges or needed adaptations, establishing support for the OPTN members during implementation, defining and measuring relevant implementation metrics, and ensuring that the change achieves its intended outcomes.

Useful references:

- Dynamic Implementation Teams: Figuring Out What Works When Working Together, The Center for Implementation
- The development of an implementation team is a key step for successful implementation, The Centre for Effective Services
- Implementation Teams: Best Practices and Tools to Establish Implementation Teams, Collaborative for Implementation Practice at UNC School of Social Work

Develop an Implementation Plan. An implementation plan typically includes several key components to ensure successful execution. These include defining clear objectives and scope, creating a detailed timeline with milestones, outlining roles and responsibilities, allocating necessary resources, assessing potential risks, establishing a communication plan, and setting clear success criteria. Key components of the implementation plan have been identified in the Implementation Roadmaps (**Appendix 8**, **Appendix 10**, **Appendix 11**, **Appendix 12, Appendix 15, Appendix 16,** and **Appendix 17**); however, as the implementation team, timeline, or other project components continues to evolve it is important to keep the implementation plan updated. Key components of an implementation plan include:

Objectives and Scope: Define the project's goals and scope.

1. **Objectives and Scope:** Define the project's goals and scope.

2. **Timeline and Milestones:** Create a schedule with timelines and key tasks and activities; identify milestones along the way to mark progress
3. **Roles and Responsibilities:** Assign tasks to individuals or teams and clearly define who is responsible for what.
4. **Resources and Budget:** Identify and allocate necessary resources to support implementation.
5. **Risk Assessment and Mitigation:** Identify potential risks or barriers to implementation and develop mitigation strategies to mitigate their impact.
6. **Communication Plan (see section below for more detail):** Identify and establish communication challenges, audiences, key messages, and metrics to measure communication success.
7. **Success Criteria and Metrics:** Set specific goals and establish clear metrics to track progress and assess the overall success of the implementation. Key components of the implementation plan have been identified in each of the Implementation Roadmaps (see **Appendix 8**, **Appendix 10**, **Appendix 11**, **Appendix 12**, **Appendix 15, Appendix 16,** and **Appendix 17**); however, as the implementation team, timeline, or other project components continues to evolve, it is important to keep the implementation plan updated.

Develop a Communications Plan to Provide Information about the Intended Change. A communications plan is a strategic document that outlines how the implementation team will communicate with its internal and external stakeholders. Communications plans help to ensure consistency and effectiveness in all communication efforts. The plan should include objectives, key messages, channels, and communication activities, as well as a timeline for execution. Critically, the communications plan must outline a clear rationale for the change. Persuasive messaging often includes both data and examples of stories of why the change is needed. HHS-DOT will need to engage with the implementation team to support the development of key messages about current challenges related to allocations out of sequence and other compliance issues, as well as critical investigations about patient safety issues, leading to a higher need for regulatory oversight.

As part of the communications plan, identify all the audiences who need to understand and support the recommended change. These include OPTN members (including individuals who work in transplant hospitals, OPOs, and histocompatibility laboratories), OPTN volunteers, adjacent professional societies, patient advocacy groups, and previous or potential donors, recipients, or their caregivers. Use both quantitative metrics and qualitative examples to describe the need for the change. Tailor the messages for each audience type describing the key features of the recommendation. In the tailored messages, describe the changes from both a macro and micro level so that each audience type understands how the recommendations will impact the broader organ procurement and transplantation system, and what these changes will look like in practice for that specific audience. Plan for feedback loops to engage those affected by the recommended

change. To the degree possible, measure whether the communication plan has had its intended effect.

Failing to effectively manage resistance to change is a common reason for why change management strategies fail.[31] Key reasons individuals resist change within organizations are: 1) a lack of awareness of the need for change, 2) the impact the change will have on the individual's role, 3) the organization's past experience with change, and 4) lack of visible support from leaders, and 5) job loss.[32] Adapting those lessons to the OPTN, it is critical that OPTN members are made aware of the reason for the change and the impact the change will have on the OPTN, its members, and individuals (including recipients, donors, and those on the wait list). Moreover, a clear and transparent plan for implementation should be shared, with dedication to supporting change by HHS-DOT leaders and ideally key OPTN opinion leaders. The implementation team should work with HHS-DOT to provide tailored messaging and provide a rationale for why these changes are necessary. For each specific change recommended, develop messaging to answer the following questions:

- How does this change impact me (from a variety of perspectives)?
- How does this impact the OPTN?
- How does it impact my organization (e.g., transplant hospital or program, OPO, histocompatibility lab, other)?
- How will this change affect our day-to-day responsibilities?
- How does this change align with the OPTN's aim to improve the US procurement and transplantation system so that more life-saving organs are available for transplant?
- What are the risks if the OPTN does not change?

Barriers to implementation may draw from people's varying levels of engagement and experience with the MPSC in its current form and recognition of the need for change and how to change. Consider developing messaging based on the ADKAR model, which is a model that describes the five stages individuals experience when making a change:[3,33]

- **A**wareness of the need for change
- **D**esire to participate in and support the change
- **K**nowledge about how to change
- **A**bility to implement new skills and behaviors
- **R**einforcement to keep the change in place

Depending on where an individual is in the ADKAR model, different messaging may be tailored to manage change. Listening to people who are early adopters may identify reasons for enthusiasm and the perceptions of benefits. Hearing from those in opposition may allow for nuanced communication to respond to concerns.

Useful references:

- Communication Planning Tool, Centers for Disease Control and Prevention
- Communications Planning Template and Samples, State of Oregon
- Step 6: Implementation Plan, Health Communication Capacity Collaborative

Engage Stakeholders and Partners. To successfully engage stakeholders and partners in a change effort, it is important to focus on clear communication, transparency, and building relationships. When identifying potential stakeholders and partners, consider characterizing stakeholder groups in relation to the topics of organ procurement and transplantation. For example, individuals can be categorized as primary stakeholders (those who may be directly impacted by the proposed changes), secondary stakeholders (those who may not be the directly impacted by the changes but may experience secondary impacts because of them) and key stakeholders (who might be primary or secondary but who are influential and can have a key impact). Engaging stakeholders from all three categories early on offers several benefits, such as fostering buy-in for proposed changes and providing the implementation team with an opportunity to address concerns proactively before implementation. Once the implementation team has identified all relevant stakeholders, they should tailor communication to the specific needs of each group and actively solicit their input and feedback. The implementation team should establish a clear communication plan and regularly update stakeholders on progress and any challenges. Emerging implementation science literature also suggests that cultivating trusting relationships among partners can increase motivation and capability for evidence use, especially in the face of resistance. Relationship building strategies, including empathy-driven exchanges, bi-directional communication, and demonstrating early wins, can enhance psychological safety, build buy-in, and foster collective commitment to implementation goals.[34] See additional information about communication strategies in the communication plan section above.

- Section 8. Identifying and Analyzing Stakeholders and Their Interests, Community Toolbox at the University of Kansas

Installation phase

Build Awareness and Support. Critical to successful implementation is building community awareness and support for the need for change and the proposed solution. In this phase, the implementation team uses the recommendations in the communications plan (discussed above) to build awareness and support among the OPTN community. In the installation phase, it is critical that members of the OPTN understand the need for change and why the change is being implemented as designed. The team should be aware of resistance and tailor responses to concerns or complaints. By intentionally engaging stakeholders to understand the areas of resistance among the OPTN community, the implementation team can craft a communication

strategy that responds to those concerns. As implementation advances, ongoing stakeholder engagement helps the team stay responsive to shifting attitudes and adapt effectively to evolving communication needs. Champions, or individuals who are trusted among members of the OPTN community and are aligned with the recommendations and vocal in supporting change, can be a useful tool for building awareness and support for the change.[35] To build awareness and minimize resistance, the change needs to be communicated early and often. Given the focus on fostering transparency across the OPTN, it is critical that HHS-DOT and the implementation team provide regular and frequent updates about the status of the implementation process.

Useful references:

- Tool: Champion Identification and Reflection, SISEP Active Implementation Hub
- Section 8. Identifying and Analyzing Stakeholders and Their Interests, Community Toolbox at the University of Kansas

Develop and Implement Metrics to Measure Change. Metrics for measuring change are developed and deployed to quantitatively and qualitatively assess the outcomes of organizational changes, track progress, identify areas for improvement, and ensure that changes are effectively aligned with strategic goals. Without these metrics, the OPTN cannot accurately gauge the success of change initiatives or make necessary adjustments. Several factors can hinder the development of effective metrics to measure change. These include unclear objectives, a lack of buy-in by leaders, poor communication, resistance to change, insufficient resources, and difficulties in identifying appropriate metrics or key performance indicators. Additionally, challenges with data quality, availability, and the timeliness of data collection can also impede the process.

To overcome these challenges, as part of the OPTN modernization effort, we have recommended a robust set of process metrics that directly measure both the performance of HHS-DOT and its contractor, and the level of member engagement and compliance. As illustrated in **Exhibit 8** and **Exhibit 9** these metrics are designed to detect operational inefficiencies, noncompliance patterns, and system-level risks—creating feedback loops that inform data-driven adjustments (also see corresponding **Appendix 6** and **Appendix 7**). By embedding these metrics into oversight workflows and making results transparent through publicly available dashboards, the OPTN ensures that change initiatives remain measurable, accountable, and targeted toward sustained improvement in U.S. procurement and transplantation system performance and patient safety.

Initial implementation phase

Gather and Analyze Data. Implementation and outcome measures can be critical in supporting a change initiative. As part of the implementation plan, the implementation team should identify metrics and goalposts. During the initial implementation phase, the implementation team should capture the available data, conduct analyses, and produce results. If quantitative metrics are used, the baseline measures should be collected prior to implementation to monitor change over

time. The team should regularly track progress by collecting data and comparing to the baseline measures. In examining progress, the implementation team should analyze any expected or unexpected results, identify potential reasons for unexpected results, and suggest mid-course corrections.

Iterate and Evolve Process(es) that Are Not Working. Instituting improvement cycles, like Plan-Do-Study-Act, offers a structured approach to refining organizational and administrative frameworks within OPTN members, committees, or HHS-DOT, ensuring effective change. Quality improvement cycles should:

- Identify barriers and facilitators to implementation, along with strategies for process improvement.
- Engage the implementation team to quickly address obstacles, test adaptations, and determine necessary changes or additional support.
- Assess whether OPTN bylaws or policies need revision based on process changes.
- Update the communication plan to reflect policy iterations and implemented changes.
- Document challenges, solutions, adaptations, and lessons learned to guide future improvement efforts.

Maintain Communication. Use the communication plan to disseminate early lessons learned and to engage partners in problem solving. Identify meaningful messages to share about implementation processes, timelines, accomplishments, and outcomes to monitor and report their impact on underserved communities. Using established communication strategies, collaborate with innovation challengers and note perceptions of challenges, what could be going better, and what needs to change to sustain capacity.

Full implementation & sustainability

Review Successes and Challenges. Reviewing successes and challenges helps acknowledge achievements, build momentum for future efforts, and identify the root causes of obstacles—allowing for the development of effective strategies to overcome them. The implementation team, along with other engaged or interested parties, should review the successes and challenges throughout the project, especially in the full implementation and sustainability phase. Broader community-level conversations about implementation success and challenges can also inform future work.

Evaluate Outcomes. By continuing to collect data that began as part of the initial implementation phase, the implementation team should continue to collect process and outcome data throughout the full implementation phase. The team should review the outcomes, evaluate the success of the

intervention, learn from the process of implementation, and document ways to improve future initiatives.

Limitations

The report and its findings are limited by several factors. We received limited information about UNOS' existing processes and procedures, which impacted our ability to provide specific instructions in the implementation roadmap about how to 'de-implement' the existing processes while 'implementing' the new recommendations.[36] Our interview participant and Delphi panel lists were reviewed and informed by HHS-DOT's input. We were able to speak to individuals and OPTN member representatives across the organ procurement and transplantation spectrum, including donors and organizations supporting donor or procurement services, transplant providers, and patients and their caregivers. However, we recognize there may be a high degree of variability in context and experience that we may not have fully captured. Some government employees outside of HHS-DOT, including from the FAA, FDA, Veterans Affairs (VA), Occupational Safety and Health Administration (OSHA) and some groups within CMS, were unable to participate. Many of these potential interview participants never responded to multiple outreach attempts.

Conclusion and Next Steps

The recommendations in this report aim to enhance the efficiency and effectiveness of the MPSC's critical functions. By shifting policy compliance monitoring and safety event investigations to the HHS-DOT OPTN Compliance and Safety Office, oversight of the U.S. organ procurement and transplantation system will be placed under a governmental body with the authority to regulate it. We recommend using data-driven strategies to identify the most critical OPTN policies and OPTN Management and Membership policies to monitor and streamline the compliance monitoring to lighten workloads while increasing effectiveness. We suggest expanding and specifying the "Wakefield criteria"[12] and "near misses" to match current knowledge. The remaining MPSC can now be re-branded and focus on the work it has been pursuing – quality improvement of OPTN members. We recommend that the MPSC is rebranded as MPIC, tasked with setting membership criteria and supporting performance improvement efforts. We recommend the MPIC provide underperforming OPOs and transplant programs (which could potentially be expanded to histocompatibility laboratories) peer-to-peer individualized performance improvement support. We also suggest supporting a voluntary learning health system that supports learning collaboratives or other education efforts to learn within and across member types. Finally, our discovery efforts led to suggestions that apply across OPTN, including enhancing process transparency, strengthening data systems, and improving COI reporting and tracking.

The next phase of this effort—implementation—will be challenging. To support this process, we have included a section outlining change management best practices and an implementation

roadmap for each sub-recommendation. Large changes, like the ones recommended in this report, require thoughtful and intentional planning because of the high level of complexity, potential for major impact, and greater risk of unintended consequences. We recognize that the recommendations may be adopted in several stages; we have aimed to describe when we believe that changes need to be contingent on previous changes, sequential to other changes, or may occur in parallel. A systematic and measured approach is crucial to minimize disruptions, manage resistance, gain buy-in, and ensure successful adoption.

Appendices

Appendix 1: Methods

Environmental scan

We conducted the initial environmental scan using HHS-DOT-aligned search terms, focusing on materials from the OPTN website, MPSC-specific pages, and other federal sources between September 28, 2024, and March 31, 2025. This effort aimed to capture all relevant documentation associated with the NOTA and OPTN Final Rule, including bylaws, policies, guidance documents, notifications, meeting minutes, presentations, and public comments. Identical search strategies were applied to peer-reviewed and grey literature via PubMed and Google Scholar, supplemented by materials shared by HRSA SMEs. In this initial environmental scan, we began gleaning various practices that appeared to address identified inefficiencies of the current MPSC functions. Building on this foundation, we expanded our review, completed though May 2, 2025, to include regulatory practices from other safety-critical federal systems—namely, the FDA, FAA, and NTSB—to identify cross-sector best practices relevant to procurement and transplantation oversight. For example, we examined how these agencies operationalize COI safeguards, engage independent SMEs in safety evaluations, and ensure impartiality in decision-making. This comparative analysis informed a series of recommendations to enhance transparency, independence, and subject matter integration in the OPTN's future-state safety review process. These insights also guide our proposed COI recommendation and structured approaches for SME consultation during investigation.

Key informant stakeholder interviews

In tandem with our HRSA SME team, Arbor Research developed a list of potential key informants representing a variety of stakeholder types (see **Exhibit 1-1** for the proposed list of stakeholder categories). Beginning in January 2025 and continuing into May 2025, a total of 35 individuals participated in one-on-one or group interviews, with four respondents taking part in a second interview, for a total of 39 interviews. This recruitment effort yielded first-hand accounts of personal and professional experience from a breadth of perspectives, including: MPSC past and present leadership; representatives from the BOD; transplant directors/surgeons; OPO leaders, histocompatibility lab directors and staff; professional societies and foundations; patients (i.e., living donors and recipients) and patient advocates; federal agencies CMS and HRSA; bioethicist/lawyer; and former state ombudsmen for long-term care. Notably, though we invited representatives from UNOS and several federal agencies (i.e., FAA, OSHA, VA), no one from these groups was available to be interviewed. Semi-structured interview guides were prepared in anticipation of interviews. Each guide-type was built around a HRSA-approved core set of questions with additional questions specifically tailored to the individual's stakeholder experience and expertise. All participants allowed their interviews to be recorded and transcribed for analysis. The analysis of the interview transcripts was accomplished using the approach described earlier in the Environmental Scan section. Two trained and experienced analysts coded all interviews, and we reviewed code application for consistency in each transcript. We found it necessary to create

two separate code books reflecting the distinction between patient-stakeholders and systems-level stakeholders (see **Exhibit 1-2** for the final key informant stakeholder interview codebook and **Exhibit 1-3** for the final donor/recipient/caregiver interview codebook).

Exhibit 1-1. Key Informant Stakeholder Interview Outreach Categories

PMO Stakeholder Segment	PMO Stakeholder Segment Sub-Group	PMO Stakeholder Segment Category	Arbor Research Internal Category
OPTN	Policymaking & Compliance	OPTN BOD and committees	BOD
			MPSC Member
Regulatory*	Regulatory & Oversight	Health Resources and Services Administration	HRSA Health System Bureau Vendor Lab
		Centers for Medicare and Medicaid Services	CMS
		Food and Drug Administration	Food and Drug Administration
		Congressional committees of jurisdiction (Finance, Oversight, Ways and means, HELP)	
		U.S. Government Accountability Office	
		Health and Human Services Office of the Inspector General	
Providers	Facilities	Acute care hospitals	
		Trauma centers	
		Organ procurement organizations	OPO leaders
		Transplant centers	Transplant center leaders†
		Histocompatibility labs	Histocompatibility labs
		Military treatment facilities/TRICARE facilities	
		Veterans Administration medical centers	Veterans Administration
		Dialysis centers	
	Clinical Care Providers	Emergency services (paramedics, EMTs)	
		Emergency room providers (including physicians, nurses, and advanced practice providers)	
		ICU providers (including physicians, nurses, advanced practice providers, and respiratory therapists)	
		Procurement surgeons	
		OPO coordinators	
		Family services coordinators	
		Perioperative professionals	
		Anesthesiologists	

PMO Stakeholder Segment	PMO Stakeholder Segment Sub-Group	PMO Stakeholder Segment Category	Arbor Research Internal Category
		Allocation coordinators	
		Aftercare coordinators	
		Hospital development coordinators	
		Transplant surgeons	Transplant surgeons
		Specialty referral providers for end stage organ failure patients (nephrology, hepatology, cardiology, etc.)	Specialty providers
		Psychologists and psychiatrists	
		Transplant care specialists, including pre- and post-transplant coordinators	
		Transplant coordinators	
		Transplant social workers	
		Transplant infectious disease providers	
	Allied Professionals	Transplant administrators	Transplant program leaders†
		Quality assurance and performance improvement (QAPI) staff	
		Independent living donor advocates (ILDAs)	
Patients, Families, and Caregivers	Transplant Patients	End stage organ disease patients	Patient advocacy organizations and professional associations with a patient arm or group‡
		Pre-waitlist patients	
		Waitlisted adult patients	
		Pediatric waitlisted patients	
		Post-transplant patients, or transplant recipients	
		De-listed patients	
	Donor Patients	Deceased donor families	
		Patients referred to an OPO for potential organ donation	
		Deceased donor patients	
		Patients who experienced a failed organ recovery	
	Living Donors	Prospective living donors	

PMO Stakeholder Segment	PMO Stakeholder Segment Sub-Group	PMO Stakeholder Segment Category	Arbor Research Internal Category
		Living donors	
		Living donor families/support persons	
	Patient Caretaking	Pediatric patient parents/guardians	
		Caregivers	
		Chaplaincy and related hospital patient support services	
		Patient advocates	
Community	Registered Organ Donors	Approximately 170 million Americans across all states and territories in 2024	
	Peer Support	Transplant patient and family peer support	
		Pediatric patient and family peer support	
	Financial Assistance Programs	Transplant patient financial assistance	
	Patient Advocacy	Donor patient and family advocacy	Patient advocacy organizations‡
		Transplant patient and family advocacy	
		Grief support and family advocacy	
		Pediatric patient and family advocacy	
Industry	Healthcare Products & Services	Third party procurement services, including normothermic regional perfusion contractors	
		Organ transportation and logistics vendors	
		Pharmaceutical companies	
		Device manufacturers	
		Biotechnology companies	
	Professional Societies	Surgical and specialty provider guilds and associations	Professional societies and foundations
	Vendors	Existing HRSA vendors	UNOS
		Prospective HRSA vendors	
Research^	Research	National Institutes of Health	
		Veterans Administration	

* Arbor Research outreach expanded beyond the categories within the **Regulatory** segment to include CLIA Accreditors, the FAA, and the Occupational Safety and Health Administration.

† Interview participants in the **Provider** segment, under the **Transplant Administrators** category, often had many roles, including as a practicing physician, surgeon, as well as administrative leader.

‡ Arbor Research outreach to **Patients, Families, and Caregivers** segment entailed contacting patient advocacy organizations and professional associations with a patient arm or group for recommended individuals with firsthand experience in organ donation or transplantation (i.e., transplant recipients and/or caregivers of transplant recipients; transplant waitlist candidates; living donors; family members of deceased donor patients) who were then individually contacted to assess interest in interview participation.

^ Arbor Research outreach expanded beyond the PMO categories within the **Research** segment to include bioethicists.

Exhibit 1-2. Key Informant Stakeholder Interview Codebook

Topic	Parent Code	Child Code	Grandchild Code
A. Waitlist Acceptance Criteria and Processes			
B. OPTN Membership, Compliance, & Performance Monitoring	B.1 Reviewing New/Revised Membership Applications	B.1.a. Setting and Adapting Membership Criteria	
		B.1.b. OPTN Members in Legal Compliance	
		B.1.c. Challenges with Membership	
		B.1.c. Opportunities to Re-Engineer Membership	
	B.2.Compliance Review	B.2.a. Allocation Reviews	
		B.2.b. Challenges with Compliance Reviews	
		B.2.c. Opportunities to Re-Engineer Compliance	
	B.3. Performance Review	B.3.a. Performance Monitoring Metrics	B.3.a.i. SRTR Metrics
			B.3.a.ii. CMS Metrics
		B.3.b. Functional Inactivity	
		B.3.c. Challenges with Performance Reviews	
		B.3.d. Opportunities to Re-Engineer Performance	
	B.4 Patient Safety and Non-Routine Compliance Reviews	B.4.a. How the OPTN/MPSC Hears of Potential Adverse Events	
		B.4.b. Initial Event Triage Process	
		B.4.c. Challenges with Safety Reviews	
		B.4.d. Opportunities to Re-Engineer Safety	
		B.4.e. Confidentiality and/or Privacy in the Safety Review Process	

Topic	Parent Code	Child Code	Grandchild Code
	B.5. HRSA-Directed Special Reviews		
	B.6. MPSC Actions	B.6.a. Informal Discussions	
		B.6.b. Interviews with the MPSC	
		B.6.c. Hearings with the OPTN MPSC	
		B.6.d. Appearances before the OPTN BOD	
	B.7. Other Re-Engineering Ideas	B.7.a. Technology improvements	
	B.8. Overlapping Scope	B.8.a. Role of State Law	
		B.8.b. Overlap with CMS	
		B.8.c. Overlap with Joint Commission/Accreditors	
		B.8.d. Overlap with Others	
	B.9. Sanctions	B.9.a. Member Not in Good Standing	
		B.9.b. Probation	
		B.9.c. Other HHS-Level Sanctions	
	B.10. OPTN Member Community - Quality Improvement		
C. OPTN Member Type and Roles	C.1. OPO		
	C.2. Transplant Hospital		
	C.3. Histocompatibility Laboratory		
	C.4. Other		
	C.5. Other OPTN Roles	C.5.a. Past Experience as MPSC Member	
		C.5.b. Past Experience as Other OPTN Committee/Board Member	
D. MPSC Management, Overall Functions, and Composition	D.1. Administrative and Logistical Support		
	D.2. Communication With...	D.2.a. BOD	
		D.2.b. BOD Executive Committee	
		D.2.c. OPTN Members	
		D.2.d. HRSA	
		D.2.e. UNOS	

Topic	Parent Code	Child Code	Grandchild Code
		D.2.f. Other OPTN Committees	
		D.2.g. Public	
	D.3. Legal Compliance in the MPSC		
	D.4. MPSC Composition, Membership & Roles	D.4.a. MPSC Conflicts of Interest	
	D.5. Records Management		
	D.6. Updates to OPTN Policies and Bylaws		

Exhibit 1-3. Donor/Recipient/Caregiver Interview Codebook

Topic	Parent Code	Child Code	Grandchild Code
A. Waitlist Acceptance Criteria and Processes	A.1. Marginal Organs		
	A.2. Finding a Transplant Center		
	A.3. Waitlist Process Communication		
B. OPTN Performance and Safety	B.1. Patient Perspective/Understanding of…	B.1.a. OPTN	
		B.1.b. UNOS	
		B.1.c. HRSA	
		B.1.d. Other	
		B.1.e. How Patients Learn Information About Organ Donation/Transplantation	B.1.e.i. OPTN Website
	B.2. Performance Review	B.2.a. Performance Monitoring Metrics	
	B.3. Patient Safety	B.3.a. How Patients Report Potential Adverse Events	
		B.3.b. Patient Safety Challenges	
		B.3.c. Opportunities to Re-Engineer Safety	
	B.4. Other Re-Engineering Ideas	B.4.a. Technology Improvements	

Topic	Parent Code	Child Code	Grandchild Code
		B.4.b. OPTN Communication Improvements	
		B.4.c. Opportunities to Re-Engineer Communication Surrounding Marginal Organs	
C. Organ Donation and Transplantation Actors	C.1. OPO		
	C.2. Transplant Center		
	C.3. Dialysis Center		
	C.4. Advocacy Organization		
D. OPTN Management and Communication	D.1. Communication	D.1.a. About the Organ Donation and Transplantation System	
		D.1.b. With Medical Staff	
		D.1.c. With Public	
	D.2. Policy Compliance in the OPTN	D.2.a. Patient Information Letter	
E. Good Quotes			

As part of the interview request process, we asked interview participants to complete a conflict of interest form that asked four questions:

- Are you involved in any volunteer work, including committee or board memberships, related to the Organ Procurement and Transplantation Network (OPTN)? If yes, please describe.
- Do you, or any family members, have any other business interests or investments in groups, technologies, or agencies that support or are supported by the OPTN? If yes, please describe.
- Do you have any personal relationships, such as close friendships or family connections, with OPTN vendors or contractors? If yes, please describe.
- Do you have any other relevant conflicts of interest or appearances of a conflict that you have not disclosed? If yes, please describe.

Of the 23 participants who completed the form, 10 reported conflicts of interest. These included disclosing their particular roles within the OPTN (in response to the first question), their engagement in other professional organizations that interact with the OPTN, and two mentions of financial support received or stock owned related to organ procurement and transplantation. In addition, three respondents included specific references to their employers as potential conflicts of interest, but most participants did not. One respondent also reported individual lived experience as an organ recipient. No one reported any conflicts of interest related to the third question asking about personal friendships with OPTN vendors or contractors.

Delphi Panel

We used a modified Delphi approach to engage experts in a feedback and consensus-building process to deal with a complex problem.[37,38] We chose the Delphi process as a basis for this exercise, as it serves as a structured, asynchronous method for gathering both qualitative and quantitative feedback on our team's draft recommendations for re-engineering the MPSC. A panel of nine individuals with direct experience engaging with the OPTN, as members, SMEs in organ transplantation and procurement, or through other forms of lived experience, was identified. Each prospective participant received an email invitation to join the Delphi process. Those who agreed to participate were subsequently presented with five distinct scenarios the Arbor Research team developed as part of the Assessment Stage discussing the MPSC functional areas targeted for re-engineering including, Patient Safety Event Investigations, OPTN Policy Compliance Reviews, Setting OPTN Membership Criteria, OPTN Membership Applications and Program Updates, and OPTN Membership Performance Monitoring. Descriptions included a brief summary of identified weaknesses and inefficiencies alongside draft recommendations aimed at addressing these issues. Using a feedback form designed to capture both open-ended written input and closed-ended responses on a 7-point Likert-scale, participants reacted to questions assessing key dimensions of the proposed changes, including (1) the urgency or importance of re-engineering

each functional area, (2) the likely acceptability of the proposed changes to the broader OPTN community, and (3) any additional suggestions for improving implementation or strengthening the recommendations. At the conclusion of the response period, we received five completed forms.

Summary of Responses

Quantitative responses indicated strong agreement across all functional areas regarding the need for reform, with criticality scores averaging between 5.8 and 6.0 on a 7-point scale. Perceived acceptability was somewhat lower, ranging from 4.8 to 5.8, suggesting moderate support within the OPTN community and potential concerns about the changes.

Patient Safety Event Investigations

Respondents generally supported increasing transparency in the handling of safety events and expressed dissatisfaction with the current peer review model, which some viewed as insufficiently rigorous for high-stakes scenarios. While there was support for federal oversight, concerns were raised about delegating responsibilities to entities perceived as lacking procurement- or transplant-specific expertise. Participants emphasized the need to clarify which events warrant reporting and to communicate clearly how new processes will differ from the status quo to ease resistance within the community.

OPTN Policy Compliance Reviews

There was strong consensus around the need to streamline compliance processes and reduce burdens on transplant hospitals. Several participants opposed expanding compliance reviews for OPOs and histocompatibility labs, advocating instead for clearer, role-specific standards. Feedback emphasized the importance of using automation to reduce administrative workload and aligning OPTN compliance activities with existing accreditation systems to minimize duplication.

Setting OPTN Membership Criteria

Participants agreed that membership criteria should reflect current workforce realities and accommodate shifts in training and certification. Suggestions included reviewing licensure requirements, creating opportunities for junior professionals, and developing mentorship programs to support new entrants. Members agreed that policies must balance rigor with flexibility to ensure safety and adapt to change.

OPTN Membership Applications and Program Updates

Feedback was broadly supportive of efforts to consolidate and simplify application workflows and improve data interoperability. Participants appreciated proposals to allow individual profiles to transfer between institutions, reducing redundancy. However, there was concern about linking performance metrics to individuals, with some noting that individual performance is shaped by systemic factors. To improve uptake, participants suggested clarifying expectations around key personnel changes to reduce administrative strain during transitions.

OPTN Membership Performance Monitoring

Respondents supported enhancing performance monitoring to include short-term process measures in addition to outcome metrics. Some questioned the transparency of current performance review processes and advocated for distinguishing compliance from performance monitoring to reduce confusion and resistance. Concerns were raised about the administrative burden on transplant hospitals and the relevance of current metrics, with calls for more meaningful indicators tied to quality improvement.

Appendix 2: Final assessment stage

Our multidisciplinary team of researchers, clinicians, OPTN SMEs, and process engineers conducted an in-depth assessment of the structure and function of the MPSC and its relationship with the OPTN. Our team conducted a review of the critical functions and operations of the MPSC to identify process redundancies and inefficiencies, with specific attention to the quality and safety of patient and donor care. Through reviewing findings identified in the environmental scan and in combination with findings from the key informant stakeholder interviews, we identified and assessed strategies to re-engineer the MPSC's essential functions and operations. Initial 'preliminary assessment' ideas were reported as part of the draft Mapping Report submitted April 15, 2025.

During a whiteboarding session, the team, composed of researchers, clinicians, implementation scientists, and change management experts, began with the end in mind: What are the key objectives of the MPSC's work? Each team member was asked to individually draft their ideas about the key objectives on an interactive whiteboard where each member could see others' suggestions. The whiteboard also included excerpts and links to NOTA and the Final Rule for reference. Through a brainstorming conversation, the team identified several key objectives that the re-engineering ideas needed to address. The team then walked through a series of thought prompts including: "What is hindering meeting the objectives?" "Where are there natural overlaps in work or functions?" "Where should key distinctions in processes exist?" and "What is the most different way we could meet these objectives?" In the end, the team identified two key re-engineered recommendations, highlighted in the recommendations section.

Appendix 3: Design stage

In the Design stage, we refined and formalized the re-engineering recommendations developed in the whiteboarding session. In this stage, the team split into smaller subgroups, each focusing on a recommendation. They worked to further specify the recommendation through identifying the problem the recommendation is designed to solve, identifying the rationale for the recommendation, describing how it aligns with NOTA and the Final Rule, noting key benefits and potential unintended consequences, and identifying potential metrics to measure performance and assess whether the recommendation is meeting its aims. Through a series of internal reviews, the team discussed the recommendations and provided feedback and critique. Teams focused on each recommendation reviewed using several heuristics. The first used a series of prompts from business-process re-engineering, including:

- Eliminate non-value-added steps
- Simplify processes and reduce handoffs
- Ensure adequate resources
- Clear responsibilities – who handles each step?
- Are all tasks assigned to an individual able to be completed within their allotted time commitment? If no, backlog, delays, burnout, errors
- Is all of the information needed to complete a task readily and easily accessible? Goal: Streamline, automate, routine processes
- Improve transparency and accountability
- Which steps/metrics need to be transparent and to whom?
- How will this be communicated?
- Identify barriers to new processes
- Ensure metrics are readily calculable now and on implementation
- Ensure ease in continual monitoring of process performance

As these prompts revealed new ideas or areas of concern, the team discussed and incorporated edits. The second heuristic was a ‘lens review’ – with different people taking on different perspectives to review the recommendation. The lenses included:

- Legal lens – the perspective of identifying the degree to which the process aligns with NOTA as the paramount guiding principle, followed by OPTN bylaws, and OPTN final rule.
- Frustration lens – the perspective of the people who work in it or are affected by it; to identify the frustrations, hurdles, challenges faced by the participants in the process. Different team members reviewed recommendations from different perspectives, including those of the OPTN members, MPSC members, members of the broader transplantation community, HHS-DOT, and donors/recipients.

- Time lens – the perspective of the non-value-added steps in a process, with a focus on determining how to reduce/eliminate waste. In this lens, we will estimate time for each step in the process and identify places where it can be reduced.
- Quality lens – the perspective of identifying problems that affect the overall quality of the resulting work and overall aim of improving patient safety.

The recommendations continued to evolve as challenges and critiques were identified.

To get feedback from the OPTN community on the recommendations, we drafted simplified, high-level versions of each recommendation for the Delphi Panel (see **Appendix 1**). Feedback from the Delphi Panel was incorporated into the recommendations. The findings were particularly helpful for identifying strategies to facilitate execution of the implementation roadmaps, described further in the Change Management Preparation section below.

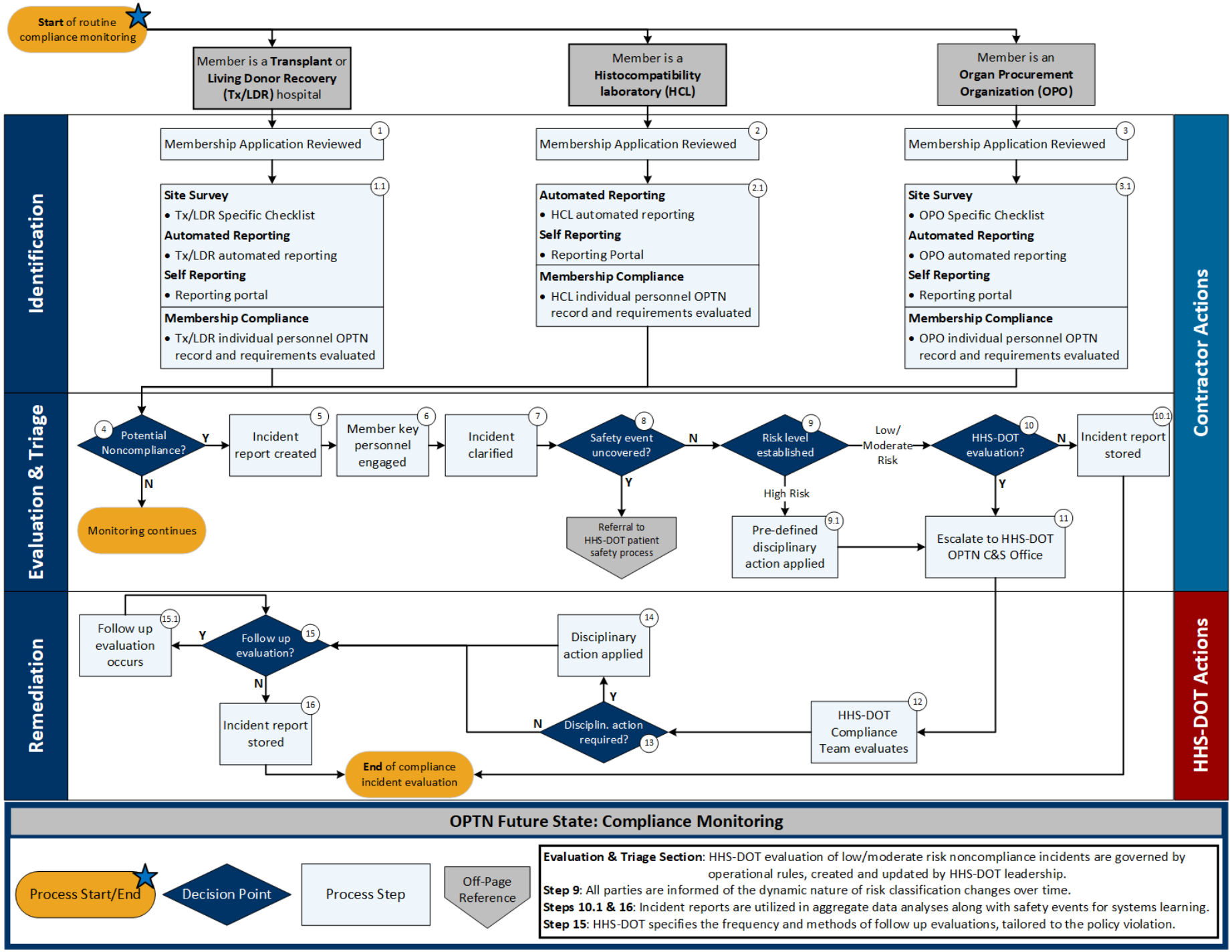
As the team was designing and refining the recommendations, they also developed future state process maps focused on each recommendation. For each recommendation, we developed value stream maps, a tool that outlines activities with a high-level of detail at every step of the process.[39] Developing and iterating on the value stream maps helped to identify process improvements that decreased waste and increased efficiencies. The value stream maps include information about the process steps, information flows, and timelines for each step.

Appendix 4: Change management preparation stage

In the Change Management Preparation stage, we developed implementation roadmaps for each re-designed process. These re-designed processes affect different audiences, require different resources, call for different timelines, and result in different challenges. With our experts in BPR, HCD, and implementation science, we reviewed each re-engineered process and identified key steps to implement, resources needed, personnel involved, timeline, intended outcomes, potential barriers to implementation, and approaches to overcome those potential barriers. Critically, we identified evaluation criteria to assess whether the process is implemented with fidelity and is having the desired effect at recommended points.

While drafting the implementation roadmaps, the team identified several common steps across the roadmaps, including creating an implementation team, developing an implementation plan, and writing a communications plan. To avoid redundancies across the implementation roadmaps, we developed a new section of the report entitled "**Change Management Best Practices**" that highlights these common techniques. The roadmaps refer to the section and specify recommendation-specific adaptations or areas of focus for each best practice.

Appendix 5: OPTN policy compliance process map



Appendix 6: Member process metrics to support active and responsible OPTN membership

1. Structural Compliance

Assessing whether members maintain foundational systems and personnel required for compliance

- **Policy documentation timeliness**: Percentage of required submissions (e.g., QAPI plans, CAPs) received by deadlines
- **Credentialing and staffing compliance**: Percentage of transplant hospitals, OPOs, and histocompatibility laboratories meeting staffing requirements (e.g., qualified transplant surgeons, histocompatibility directors)
- **Bylaw acknowledgment compliance**: Percentage of members who attest to reviewing and implementing OPTN policies annually, including membership criteria policies

2. Process Compliance

Assessing member adherence to operational processes embedded within updated OPTN policies

- **Policy-adherent data reporting**: Percentage of mandatory data elements submitted accurately and on time to reporting platform (note: currently, UNet)
- **Waitlist management accuracy**: Percentage of listings consistent with policy (e.g., proper use of status codes, eligibility criteria met)
- **Organ offer response timeliness**: Percentage of responses within required timeframes per policy
- **Match run integrity**: Percentage of match runs with no policy violations (e.g., skipping candidates without documentation)

3. Outcome-Based Compliance

Assessing member actions to sustain policy adherence and favorable patient safety outcomes

- **Adverse event reporting compliance**: Percentage of potential safety events reported within mandated timeframes by OPTN members
- **Rate of confirmed violations**: Number and severity of confirmed OPTN policy violations per member per year
- **Resolution of CAPs**: Percentage of CAPs closed within designated timeframes and verified as effective
- **Repeat violations rate**: Percentage of OPTN member organizations with recurring policy violations over a specified rolling period

4. Risk and Escalation

Assessing frequency and severity of issues detected through routine or triggered monitoring

- **Flags per monitoring cycle**: Number of compliance flags raised in routine monitoring or triggered review
- **Time from flag to review initiation**: Median days between detection of potential noncompliance and initiation of review
- **Escalation to HHS-DOT**: Percentage of cases referred for formal HHS-DOT consideration versus resolved administratively

5. Member Engagement and Improvement

Assessing proactive participation and responsiveness to oversight activities

- **Policy education participation**: Percentage of designated staff attending mandatory compliance training or policy webinars
- **Self-reported issues**: Percentage of transplant hospitals, OPOs, and histocompatibility laboratories self-reporting issues before HHS-DOT (or HHS-DOT vendor) discovery (indicator of proactive compliance culture)
- **Adoption of policy changes**: Percentage compliance with newly enacted policies within specified transition periods

6. New Metrics

Align the HHS-DOT Patient Safety Review Needs with the Suggested Metrics Articulated by The Alliance under Strategy 6: Quality Assessment Performance Improvement

- **Aligned metric with The Alliance Guidance re:** 6.5 Establish and enact written policies to identify report, analyze, and address transplant-related adverse events*
- **Aligned metric with The Alliance Guidance re:** 6.6 Routinely utilize regulatory and professional resources to strengthen and drive QAPI efforts

**While The Alliance's guidance specifies transplant-related adverse events, we recommend considering both procurement- and transplant-related adverse events*.

Source: https://www.organdonationalliance.org/wp-content/uploads/2020/10/The-Transplant-Resource-Guide.pdf

Appendix 7: Process metrics to support OPTN operational performance

Note: Metrics intended to support operational performance of the DOT OPTN Office Compliance and Safety, or the future contractor supporting this Office, unless otherwise noted.

1. Timeliness / Efficiency

- **Time to case closure:** Mean number of business days to complete a compliance review, patient safety event review, or compliance audit from opening to final action
- **Distribution of time to completion by case type**: Histogram of days to closure grouped by case type (e.g., compliance, membership, program change)
- **Cycle time:** Mean duration in business days for each phase (e.g., intake, investigation, review, resolution)
- **Case backlog rate:** Number or percentage of overdue or outstanding cases past expected closure dates (e.g., 45 days)
- **Count of open cases over time:** Monthly count of active cases by type, with thresholds for percentage exceeding 1.5x or 2x expected duration
- **Timely case initiation:** Percentage of cases initiated within three business days of trigger (e.g., incident report, audit flag, or policy deadline)
- **Response time to OPTN members:** Mean number of business days for compliance staff to respond to OPTN member inquiries, complaints, or regulatory reporting obligations
- **Timely response to HHS-DOT:** Mean number of business days for compliance staff to respond to data and other informational requests made by HHS-DOT
- **Timely notification to affected parties:** Percentage of cases where impacted parties were notified within three business days of final determination
- **Responsiveness to workforce trends:** Number and type of membership criteria updates initiated based on documented shifts in the transplant workforce (e.g., new board certifications, evolving clinical roles like APPs or telehealth-based consults) *(MPIC)*
- **Time from workforce signal to policy proposal:** Median number of months from identification of a workforce-related issue (e.g., workforce shortage or training pathway change) to proposal of a criteria update *(MPIC)*

2. Quality

- **Error rate:** Percentage of reviews needing correction or additional revision due to mistakes
- **Re-review / rework rate:** Percentage of initial compliance determinations requiring escalation, appeals, or re-analysis
- **Rate of validated root cause analyses:** Proportion of events that include a root cause analysis reviewed and accepted by HHS-DOT/contractor

- **CAP acceptance:** Percentage of CAPs accepted on first submission without required revision
- **Number of new CAPs initiated:** Count of new CAPs initiated per quarter, tracked over time
- **Substantive findings rate:** Percentage of investigations that yield at least one confirmed noncompliance or risk factor
- **Audit/review accuracy:** Concordance between internal compliance findings and external audit outcomes
- **Documentation completeness:** Percentage of case files meeting 100% of documentation requirements on internal checklist
- **Compliance method by which safety event was detected:** Categorization and count of safety event detection method (e.g., audit, self-report, data flag)
- **Rate of safety alerts issued with follow-up:** Percentage of safety alerts issued that include a documented follow-up within 30 days
- **Interdisciplinary role integration:** Frequency and scope of criteria revisions that recognize non-physician roles (e.g., nurse coordinators, data analysts, behavioral health specialists) as critical to transplant program functioning *(MPIC)*
- **Representation in criteria development:** Percentage of updated criteria that explicitly account for: Geographic workforce disparities (e.g., rural access to transplant professionals), underrepresented groups in transplant leadership roles, international medical graduates or alternative credentialing pathways *(MPIC)*

3. Appeal (Dispute/Challenge)

- **Appeal rate:** Number and percentage of compliance actions that are appealed, and proportion overturned or modified
- **Appeal success rate:** Number and percentage of compliance actions that overturn the original compliance decision (can indicate poor initial review quality if too high)
- **Reversal rate after appeal:** Number and percentage of compliance actions where an external body (e.g., court, regulator) overturns a compliance decision
- **Time to resolve appeals impacting patient care:** Mean number of business days to resolve appeals classified as patient-impacting

4. Stakeholder Engagement

- **Complainant satisfaction:** Mean rating on a 1–5 scale from surveys issued to complainants after case closure, measuring perceptions of fairness, timeliness, and respect
- **Respondent satisfaction:** (For members under review) Mean rating (1–5 scale) from surveys issued to respondents after case closure measuring perceptions of fairness, timeliness, and respect

- **Patient/family and clinician engagement in safety reporting:** Number of reports submitted by patients/families or clinicians per 1,000 transplants
- **Internal and contractor staff satisfaction:** Survey-based scores on workload, process usability and team morale, conducted semiannually
- **Staff safety culture perception scores:** Aggregate score from safety culture surveys aligned with AHRQ or comparable frameworks
- **External validation and engagement:** Number of external professional societies (e.g., AST, ASTS) or credentialing bodies engaged for input as part of updated criteria *(MPIC)*
- **Transparency of rationale for membership criteria update:** Proportion of membership policy updates with publicly posted justifications citing data (e.g., workforce studies, certification trends, or clinical practice changes) *(MPIC)*
- **Relevance and impact of membership criteria update:** Percentage of members reporting that updated criteria more accurately reflect their program structure or staff composition (via surveys or other feedback *(MPIC)*
- **Implementation and education timeliness:** Number of days from membership criteria update approval to publication of updated guidance, training materials, and application forms *(MPIC)*

5. Volume / Throughput

- **Types and count of cases:** Monthly and annual count of cases by type, including compliance reviews, membership applications, and program changes
- **Distribution of case type:** Percentage breakdown of total cases by type in a given time period
- **Case volume by type over time:** Trendline of monthly case volumes by category to assess fluctuation and resourcing needs
- **Compliance cases reviewed:** Count of cases completed per quarter, by type
- **Patient safety events reviewed:** Count of cases completed per quarter, by type
- **Number of events reported in specified time period:** Count of reported safety events per quarter
- **Policy noncompliance self-disclosures/reports processed:** Total voluntary reports reviewed and closed, grouped by type (policy vs. safety)
- **Investigations opened vs. closed:** Ratio of investigations opened to those closed within the same reporting period
- **Proactive vs. reactive case openings:** Ratio or proportion of cases initiated from proactive surveillance versus member-triggered reporting

6. Impact and Outcomes (in relation to metrics described in Appendix 6)

- **Recidivism rate:** Percentage of members repeating the same or similar violation within a 24-month period post-correction

- **Sustained compliance:** Percentage of members remaining in full compliance for 12 months post-correction
- **Sustained implementation of safety-related CAPs:** Percentage of CAPs still active and adhered to six months after initiation
- **Risk Reduction:** Qualitative or quantitative reduction in incident rates or flagged risks post-intervention and corrective action
- **Reduction in donor-derived disease transmissions:** Change in the number of confirmed donor-derived transmissions per 1,000 transplants year-over-year
- **Rate of safety recommendations adopted system-wide:** Percentage of issued recommendations that are enacted by 80%+ of OPTN members within one year
- **Unresolved safety cases:** Percentage of safety cases still unresolved after 90 or 180 calendar days
- **Number of members found out of compliance with updated membership policies:** Count of members determined to be out of compliance following adoption of new policy criteria

Appendix 8: Implementation Roadmap—Centralize Policy Compliance within HHS-DOT (Sub-recommendation 1.1)

This implementation roadmap supports the creation of a dedicated HHS-DOT OPTN Compliance and Safety Office, with emphasis on the policy compliance arm. It includes steps to shift compliance review processes from a peer-review model to an independent, federally coordinated model with contract support, focusing on risk-calibrated enforcement, infrastructure modernization, and systematic data use. The implementation roadmap is organized across four phases, each grounded in change management and implementation science best practices (see the **Change Management Best Practices** section): Exploring & Planning; Installation; Initial Implementation; and Full Implementation & Sustainability.

Roadmap Objectives

1. **Establish a centralized federal oversight structure** for OPTN compliance that ensures independence, transparency, and uniform application of standards and accountability across all OPTN institutional member types.
2. **Implement a risk-calibrated compliance framework** that aligns oversight intensity with the potential impact and recurrence of policy violations.
3. **Modernize compliance infrastructure** through interoperable systems that support real-time monitoring, automated flagging, and centralized document storage.
4. **Promote fair and consistent enforcement** by integrating just culture principles to distinguish human error or complex, system-wide challenges with compliance from at-risk or reckless behavior on the part of individuals or organizations lacking institutional controls.
5. **Foster trust and sustained engagement** through transparent, inclusive communication with OPTN members and other stakeholders.
6. **Enable continuous learning and system improvement** by leveraging compliance data to identify vulnerabilities and inform responsive policy or operational changes.

Overview of Roadmap Steps by Implementation Phase

Phase	Steps
Exploration & Planning	1. Build Foundational Data Architecture 2. Convene the Implementation Team 3. Identify Internal and External Experts
Installation	1. Build and Validate Risk-Calibrated Compliance Monitoring Framework 2. Develop and Test Automated Tools, Dashboards, and Data Infrastructure 3. Define and Pilot an Updated Site Survey Model 4. Develop Operational Rules, Triage Protocols, and Decision Pathways

	5. Develop Member-Facing Guidance, Training, and Communication Needs 6. Pilot Test and Refine Core Components
Initial Implementation	1. Transition to Live Compliance System 2. Support Members Through System Adoption 3. Monitor System Use and Member Adoption 4. Define Dashboard Requirements and Assign Build Task
Full Implementation & Sustainability	1. Integrate Compliance System into OPTN Operations 2. Monitor System Performance and Impact 3. Update Risk Framework, Monitoring Tools, and Operational Rules 4. Establish and Maintain Governance for Stability

Exploration & Planning Phase

This phase establishes the foundational conditions for transitioning compliance oversight responsibilities to the HHS-DOT OPTN Compliance and Safety Office and is predicated on the adoption of the overall restructuring of the current MPSC tasks. Key activities include convening the Implementation Team, assessing current-state processes, and identifying high-risk policies and systemic vulnerabilities to prioritize in the new oversight model. Though some exploratory work has been initiated under the current contract (e.g., mapping workflows, defining broad risk categories), this phase completes the groundwork by aligning stakeholders on operational goals, scope, and readiness.

Personnel Involved

- HHS-DOT Compliance and Safety Office leadership and staff
- HHS-DOT data analytics staff
- HHS-DOT legal and regulatory staff
- HHS-DOT human-centered design staff (as applicable)
- OPTN contractor leadership and technical staff
- OPTN contractor data architecture and analytics staff
- Project management support
- External consultants/SMEs (compliance systems, risk-based oversight, data architecture, automated monitoring, NLP)
- MPIC members or OPTN member representatives with operational expertise

Resources Needed

- Staff time for HHS-DOT and OPTN contractor team members
- Project management tools to support planning and tracking
- Tools and resources for data architecture mapping and definition
- Tools and resources for expertise mapping and engagement planning
- Budget for external consultant/SME engagement (if needed)

- Meeting facilitation resources
- Platforms for internal and external collaboration (e.g., virtual workshops, document sharing)
- Resources to support data governance and security review during architecture planning

Step 1: Build Foundational Data Architecture

Developing a modernized, risk-calibrated compliance system requires a strong data foundation to support automated monitoring, risk analytics, and transparency. Early in the planning phase, the HHS-DOT Compliance and Safety Office and the OPTN contractor should assess existing data assets, identify gaps, and define requirements for a foundational data architecture that enables scalable and consistent monitoring across all OPTN member types. This includes specifying required data fields and standard variable definitions; identifying opportunities to improve data quality and interoperability; and planning for infrastructure to support automated monitoring tools such as natural language processing (NLP), dashboards, and risk-based alerts. Priority should be given to aligning data architecture with key risk domains and compliance metrics identified in the body of this report (e.g., **Exhibit 7**). The resulting data architecture plan will inform system design and ensure readiness for implementation of enhanced monitoring processes.

Timeline: Three months

- System review and design planning: Two months
- Specification development: One month
- Handoff to IT contractor (start of Installation Phase)

Step 2: Convene the Implementation Team

The HHS-DOT Compliance and Safety Office should convene a dedicated implementation team to lead the planning and execution of the modernized, risk-calibrated compliance system. This team should include representatives from HHS-DOT (e.g., compliance, patient safety, data analytics, regulatory affairs), OPTN contractor leadership and technical staff, and project management support. They should establish clear roles and responsibilities, develop an internal project charter to guide their work, and define processes for coordinating with other key stakeholders (such as the MPIC and the OPTN BOD). Once formed, this team will lead key planning activities, including identifying additional internal and external experts to advise on specific elements of the system design described in detail in the following step.

Timeline: Three months (can be concurrent with previous step)

- Team identification and invitations: Two to three weeks
- Initial planning meetings: Three meetings over six weeks
- Summary report on early priorities and implementation scope: Two weeks following final session

Step 3: Identify Internal and External Experts

To ensure the compliance system is grounded in best practices and practical for implementation, the HHS-DOT Compliance and Safety Office, in collaboration with the OPTN contractor, should identify both internal and external subject matter experts to advise on design and planning. This should include HHS-DOT staff with expertise in compliance, data analytics, patient safety, legal and regulatory affairs, and human-centered design; external experts from fields such as healthcare compliance, advanced analytics (e.g., NLP, machine learning), survey design, enforcement policy, and risk-based oversight; and OPTN member representatives or MPIC members with operational insight. A mapping exercise should be conducted to identify priority areas of expertise needed, drawing on HHS-DOT expert networks and potential external consultants. Early engagement of this expert group will inform critical planning decisions related to tiered risk calibration, automated monitoring, operational rules, and system usability.

Timeline: Three to four months (can be concurrent with previous step)

- Should be completed near the beginning of the planning period, to ensure expert input prospectively informs all subsequent design aspects.

Challenges & Solutions: Exploration & Planning Phase

Challenge	Solution
Unclear roles, responsibilities, or ownership across implementation team members	Establish clear roles and responsibilities through an internal project charter during team formation; revisit and refine as needed throughout planning.
Difficulty aligning data architecture requirements across existing systems and member types	Conduct a structured data architecture mapping early in the phase, using internal and external SMEs, and prioritize alignment of core data fields and definitions to guide design.
Identifying and securing the right external expertise to inform system design	Use a structured mapping exercise and expert consultations to prioritize needed areas of expertise; initiate outreach and engagement early in the planning period.
Insufficient coordination between data architecture planning and risk calibration design	Ensure that foundational data architecture planning explicitly aligns with priority risk domains and compliance metrics, and that outputs from this work directly inform subsequent design steps in the Installation phase.

Target Outcomes: Exploration & Planning Phase

- ☐ Foundational data architecture requirements defined, including required fields, standard definitions, and initial data quality priorities
- ☐ Implementation team formally convened with clear roles, responsibilities, and project charter established

- ☐ Priority internal and external experts identified and initial engagement planned or underway
- ☐ Initial alignment established between data architecture and priority risk domains and compliance metrics
- ☐ Internal project plan for Installation phase developed and endorsed by HHS-DOT Compliance and Safety Office leadership

Installation Phase

During the Installation Phase, planning activities are translated into concrete tools, infrastructure, and procedures that support operational compliance monitoring. This includes developing a risk-calibrated enforcement framework, establishing monitoring infrastructure, and launching internal and external communication strategies. The HHS-DOT OPTN Compliance and Safety Office will lead this work in coordination with a selected compliance contractor, ensuring operational readiness across both federal and contractor-led components.

Personnel Involved

- HHS-DOT Compliance and Safety Office leadership and staff
- HHS-DOT data analytics staff
- HHS-DOT legal and regulatory staff
- OPTN contractor leadership and technical staff
- OPTN contractor data architecture and analytics staff
- Project management support
- External consultants/SMEs (risk-based compliance, automated monitoring tools, site survey design, data governance, health system compliance)
- OPTN member representatives and MPIC members (as pilot participants and advisors)
- Communications and training specialists
- Human-centered design specialists (as applicable)

Resources Needed

- Staff time for HHS-DOT and OPTN contractor team members
- Project management tools to support planning, coordination, and tracking
- Tools and resources for developing automated monitoring tools, dashboards, and data infrastructure
- Platforms for secure data exchange and pilot testing
- Resources for site survey model development, testing, and evaluation
- Legal and regulatory review support to ensure alignment with NOTA and the Final Rule
- Budget for external consultant/SME engagement
- Tools and platforms for developing and delivering member-facing guidance, training, and communication materials

- Data governance and security review resources
- Resources for quantitative and qualitative evaluation of pilot testing results

Step 1: Build and Validate Risk-Calibrated Compliance Monitoring Framework

An initial priority in the Installation phase is to build and validate the risk-calibrated compliance monitoring framework that will serve as the foundation for the modernized system. The HHS-DOT Compliance and Safety Office, in partnership with the OPTN contractor, should translate the policy risk classification work conducted during Exploration & Planning into a structured framework that defines tiered levels of risk and associated monitoring strategies. This framework should align with relevant elements of NOTA and the OPTN Final Rule and include mechanisms for continuous updating as policies or risk patterns evolve. It should specify how automated tools (dashboards, NLP, monitoring flags) will be layered onto the framework to support risk-calibrated oversight. Initial validation activities should test the framework against historical OPTN data to assess face validity, calibration, and transparency to members. The validated framework will guide all subsequent system elements, including operational rules, triage pathways, and member-facing tools, and should be approved by HHS-DOT leadership before advancing to broader piloting.

Timeline: Three to four months

- Should conclude as early as possible during the Installation Phase so that subsequent system elements are in alignment with the validated risk framework.

Step 2: Develop and Test Automated Tools, Dashboards, and Data Infrastructure

With the risk-calibrated compliance monitoring framework in place, the next step is to develop and test the technical infrastructure needed to realize it's operationalization. The HHS-DOT Compliance and Safety Office and the OPTN contractor should collaborate to design and build automated monitoring tools, dashboards, and the underlying data infrastructure to support continuous, risk-based oversight. This includes expanding the OPTN's capacity for structured data submission, enhancing data quality and interoperability, and integrating advanced analytic techniques such as natural language processing (NLP) where appropriate. Dashboards should be designed to ensure transparency for members, with clear presentation of risk status and compliance expectations. Prototype tools and dashboards should be tested internally using historical data and simulated cases to verify functionality, accuracy, and usability. Early testing is meant to identify refinements needed before external pilot testing and broader system rollout.

Timeline: Six to eight weeks

- Should be done be done sequentially to Step 1, or with flexibility to integrate final decisions made in Step 1.

Step 3: Define and Pilot an Updated Site Survey Model

The modernized compliance system will include an updated, risk-informed site survey model designed to promote consistency, efficiency, and transparency. The HHS-DOT Compliance and

Safety Office, in collaboration with the OPTN contractor and drawing on effective models from CMS and other national oversight bodies, should develop a standardized site survey checklist and updated site survey protocols aligned with the validated risk-calibrated compliance framework. The updated model should clearly define which elements of member compliance will be verified through site surveys, how survey focus areas will be selected based on risk, and how survey findings will integrate with automated monitoring results. The draft site survey model should be piloted with a subset of OPTN members, using structured evaluation criteria to assess consistency, operational feasibility, and stakeholder perceptions of fairness and value. Feedback from the pilot should inform final adjustments to the site survey model before full implementation.

Timeline: Five to six months total

- Six to eight weeks: define standardized checklist and draft protocols
- Four weeks: prep for pilot
- Eight to ten weeks: conduct pilot site surveys with subset of OPTN members
- Four to six weeks: analyze pilot results

Step 4: Develop Operational Rules, Triage Protocols, and Decision Pathways

A critical component of the modernized compliance system is the development of clear and consistent operational rules, triage protocols, and decision pathways to guide how compliance concerns are identified, escalated, and addressed. The HHS-DOT Compliance and Safety Office, in collaboration with the OPTN contractor, should translate the validated risk-calibrated framework into operational filtering rules that define which events or patterns will trigger further review and what pathways those cases will follow. These rules must be aligned with the requirements of NOTA and the OPTN Final Rule, and designed to promote consistency, fairness, and transparency across all member types. The team should also define clear triage protocols to prioritize cases based on severity and risk and establish decision pathways that specify how cases move through the compliance process, including escalation points and potential corrective actions. Draft rules and protocols should be tested using historical data and simulated case scenarios to ensure they are practical, predictable, and support fair and consistent decision making. Final rules and pathways should be reviewed and approved by HHS-DOT leadership prior to Initial Implementation.

Timeline: Five months

- Can commence when risk framework is ready; other timing considerations should be aligned to support pilot testing.

Step 5: Develop Member-Facing Guidance, Training, and Communication Needs

Transparent communication and effective training are essential to support member adoption of the modernized compliance system. During the Installation phase, the HHS-DOT Compliance and Safety Office and the OPTN contractor should develop clear, accessible guidance documents, training materials, and communication products to explain the structure, expectations, and processes of the new system. Materials should cover key elements such as the risk-calibrated

monitoring framework, automated tools and dashboards, updated site survey model, and operational rules and decision pathways. Development of these materials should be informed by the Change Management Best Practices outlined in this report, including alignment with the overall implementation plan and communications plan, and engagement with OPTN members to ensure clarity and usability. Draft materials should be tested with a sample of members and refined based on feedback. Finalized materials should be prepared and approved in advance of Initial Implementation.

Timeline: Six weeks

- Must be completed in advance of the Initial Implementation

Step 6: Pilot Test and Refine Core Components

The final activity in the Installation phase is to conduct integrated pilot testing of the modernized compliance system components and refine them based on pilot results and stakeholder feedback. The HHS-DOT Compliance and Safety Office and the OPTN contractor should design and execute a structured pilot involving a subset of OPTN members. The pilot should test the risk-calibrated monitoring framework, automated tools and dashboards, updated site survey model, and operational rules and decision pathways as an integrated system. Pilot participants should submit data through the enhanced data submission processes, interact with the dashboards, and participate in pilot site surveys as applicable. Throughout the pilot, the team should collect both quantitative and qualitative feedback from members and internal reviewers to assess functionality, usability, fairness, and alignment with system goals. Pilot results should be systematically analyzed and used to refine system elements before transition to Initial Implementation. This step is critical to ensure that the modernized system is ready for broader rollout and that members are supported through a transparent and predictable transition.

Timeline: Four to five months

Challenges & Solutions: Installation Phase

Challenge	Solution
Aligning risk framework, automated monitoring tools, and operational rules to function as an integrated system	Use an iterative, collaborative development process across workstreams; establish regular cross-functional reviews to ensure alignment and identify gaps early.
Ensuring data quality and interoperability are sufficient to support automated monitoring and risk-based oversight	Prioritize data quality and interoperability improvements in the early Installation steps; engage data governance SMEs and conduct structured testing before pilot launch.

Managing member understanding and expectations during system piloting and refinement	Develop clear, transparent communication and training materials; engage pilot participants early and provide channels for feedback to build trust and support successful adoption.

Target Outcomes: Installation Phase

- ☐ Risk-calibrated compliance monitoring framework validated and approved to guide system operations
- ☐ Automated monitoring tools, dashboards, and data infrastructure developed, tested, and ready for Initial Implementation
- ☐ Updated site survey model piloted and refined based on pilot results
- ☐ Operational rules, triage protocols, and decision pathways finalized and approved by HHS-DOT leadership
- ☐ Member-facing guidance, training materials, and communications developed, tested with members, and approved for rollout
- ☐ Integrated pilot testing of core system components completed, with refinements implemented to support readiness for Initial Implementation

Initial Implementation Phase

This phase marks the transition from system design to early execution. Foundational components, including centralized policy storage, identity tracking, and compliance dashboards, are deployed, tested, and refined. Emphasis is placed on ensuring that the infrastructure functions as intended, supports actionable insights, and reflects stakeholder needs. Early results will guide future enhancements and inform broader system rollout.

Personnel Involved

- HHS-DOT Compliance and Safety Office leadership and staff
- OPTN contractor leadership and technical staff
- Project management support
- OPTN contractor member training and support staff
- OPTN contractor system monitoring and analytics staff
- Communications specialists
- Helpdesk or user support team members
- Human-centered design specialists (as applicable)
- MPIC members or OPTN member representatives (for feedback during system refinement)

Resources Needed

- Staff time for HHS-DOT and OPTN contractor teams

- Project management tools and collaboration platforms
- Platforms for system monitoring and reporting
- Resources for member training delivery
- Resources for member communication
- Helpdesk or user support systems
- Tools for collecting and analyzing member feedback and system performance data
- Resources for iterative system refinement and documentation

Step 1: Transition to Live Compliance System

The Initial Implementation phase begins with the formal transition to live operation of the modernized compliance system. The HHS-DOT Compliance and Safety Office, in collaboration with the OPTN contractor, should move all validated system components, including the risk-calibrated monitoring framework, automated monitoring tools and dashboards, updated site survey model, and operational rules and decision pathways, into active use across the OPTN membership. There should also be plans should also include clear procedures for tracking and addressing any technical or operational issues that arise during early live operation. Successfully completing this step establishes the foundation for full system adoption and enables the team to shift focus to member support, performance monitoring, and continuous refinement.

Timeline: Four to six weeks

- Priority at the beginning of this phase, other steps cannot proceed until this is completed

Step 2: Support Members Through System Adoption

The Initial Implementation phase begins with the formal transition to live operation of the modernized compliance system. The HHS-DOT Compliance and Safety Office, in collaboration with the OPTN contractor, should move all validated system components, including the risk-calibrated monitoring framework, automated monitoring tools and dashboards, updated site survey model, and operational rules and decision pathways, into active use across the OPTN membership. There should also be plans should also include clear procedures for tracking and addressing any technical or operational issues that arise during early live operation. Successfully completing this step establishes the foundation for full system adoption and enables the team to shift focus to member support, performance monitoring, and continuous refinement.

Timeline: Implement once system is live and continue throughout the duration of this phase

Step 3: Monitor System Use and Member Adoption

Throughout Initial Implementation, the HHS-DOT Compliance and Safety Office and the OPTN contractor should actively monitor how members are engaging with the modernized compliance system and how the system is performing in live operation. Key areas of monitoring should include member data submissions (timeliness, completeness, and quality), member interactions with dashboards and automated tools, and the consistency of risk flags and triage decisions generated

by the system. The team should also track member participation in training and support activities and collect qualitative feedback on member experiences with the new processes. This early monitoring provides critical insights into system functionality, adoption trends, and potential areas for refinement. Findings should be reviewed regularly to inform responsive adjustments and to ensure that the system is operating as intended and supporting equitable and transparent oversight.

Timeline: Implement once system is live and continue throughout the duration of this phase

Step 4: Define Dashboard Requirements and Assign Build Task

As the modernized compliance system moves through its initial period of live operation, the HHS-DOT Compliance and Safety Office and the OPTN contractor should maintain a structured process for identifying and addressing early implementation issues. This should include systematically collecting and reviewing member feedback, system performance data, and findings from internal monitoring reviews (as described in Step 3). Particular attention should be paid to identifying any unintended consequences, equity concerns, or operational challenges experienced by members. The team should use an iterative refinement process to address issues promptly, making targeted adjustments to system elements (such as risk calibration logic, dashboard interfaces, triage rules, or training materials) as needed. Transparent communication of refinements to members should be maintained throughout. This step ensures that the system continuously improves during Initial Implementation and that members experience a responsive and supportive transition.

Timeline: Implement once system is live and continue throughout the duration of this phase

- Institute and maintain of rapid-cycle feedback and refinement

Challenges & Solutions: Initial Implementation Phase

Challenge	Solution
Technical complexity in linking personnel data across systems	Start with modular specifications; use role-based access and minimum necessary data principles
Concerns about overreach or privacy violations	Ensure robust legal oversight and stakeholder input and review; emphasize intent and limits of use
Early dashboards fail to meet user need	Benchmark external tools; gather structured feedback through rapid-cycle prototyping

Target Outcomes: Initial Implementation Phase

- ☐ Modernized compliance system fully transitioned to live operation across OPTN membership
- ☐ OPTN members supported through initial system adoption with targeted training, communications, and responsive support channels

- ☐ Member use of system components actively monitored, with insights on adoption trends and system performance collected and analyzed
- ☐ Initial implementation issues identified and addressed through iterative refinement, with updates communicated transparently to members

Full Implementation & Sustainability Phase

In this final phase, the re-engineered compliance monitoring system becomes fully operational across the OPTN network. Core tools and processes are embedded into routine oversight, and participating members adapt to the new expectations for transparency, responsiveness, and risk-based monitoring. The focus shifts to ensuring long-term sustainability by evaluating performance, refining procedures as needed, and reinforcing a culture of continuous improvement.

Personnel Involved

- HHS-DOT Compliance and Safety Office leadership and staff
- HHS-DOT system governance and oversight staff
- OPTN contractor leadership and technical staff
- Project management support
- OPTN contractor compliance operations staff
- OPTN contractor system monitoring and analytics staff
- Legal and regulatory staff
- Communications specialists
- MPIC members and OPTN member representatives

Resources Needed

- Staff time for HHS-DOT and OPTN contractor teams
- Project management tools and collaboration platforms
- Platforms for ongoing system monitoring and reporting
- Tools for annual review and refinement of risk framework, monitoring tools, and operational rules
- Resources to support governance processes and stakeholder engagement
- Budget for maintaining system technical infrastructure
- Resources for member communications and engagement
- Data governance and security resources

Step 1: Integrate Compliance System into OPTN Operations

With Initial Implementation complete and the modernized compliance system fully operational, the next priority is to integrate the system into ongoing OPTN operations as a routine part of member oversight and performance monitoring. The HHS-DOT Compliance and Safety Office and OPTN contractor should formally transition from an implementation posture to sustained

operational management, embedding the system's core components (risk-calibrated monitoring framework, automated monitoring tools and dashboards, updated site survey model, and operational rules and pathways) into standard workflows and governance processes. This includes ensuring that all routine compliance reviews, site surveys, and monitoring activities are conducted using the modernized tools and methodologies, and that internal policies, staffing, and resource allocations are aligned to support sustained system use. Integrating the system into ongoing operations establishes a stable foundation for long-term sustainability and enables the team to shift focus to continuous monitoring and improvement.

Timeline: Three to four months

- Establish routine use throughout the phase

Step 2: Monitor System Performance and Impact

With the modernized compliance system fully integrated into ongoing operations, the HHS-DOT Compliance and Safety Office and OPTN contractor should establish a routine process for monitoring the performance and impact of the system itself. This includes tracking key indicators of system functionality (e.g., dashboard performance, accuracy of automated monitoring outputs), process consistency (e.g., alignment of site survey findings with risk calibration), and member experience (e.g., clarity, transparency, and usability of system components). In addition, the team should monitor the system's broader impact on member performance and patient safety outcomes, using both quantitative data and qualitative feedback from members and stakeholders. Regular review of these insights will inform adjustments to system components and support a learning-oriented oversight culture, consistent with the goals of the OPTN modernization effort.

Timeline: Throughout duration of phase

- Establish a regular cadence of reviews occurring at least four times interspersed throughout the phase

Step 3: Update Risk Framework, Monitoring Tools, and Operational Rules

To maintain the effectiveness and relevance of the modernized compliance system, the HHS-DOT Compliance and Safety Office and the OPTN contractor should establish an ongoing process to continuously update the risk-calibrated monitoring framework, automated monitoring tools and dashboards, and operational rules and decision pathways. This process should be informed by insights gathered through routine system monitoring (Step 2), member feedback, and evolving best practices in healthcare oversight and risk management. Updates may include adjustments to risk calibration logic, enhancements to automated tools, refinements to triage protocols, and incorporation of new data elements or monitoring capabilities as the system matures. The update process should be transparent and structured, with defined cycles (e.g., annual review and revision) and opportunities for stakeholder input. Embedding this continuous improvement cycle ensures that the compliance system remains responsive to emerging risks, advances in technology, and the evolving needs of the OPTN community.

Timeline: Ongoing

- Should continue as long as this compliance framework is in place

Step 4: Establish and Maintain Governance for Stability

To ensure the long-term sustainability and continued evolution of the modernized compliance system, the HHS-DOT Compliance and Safety Office, in collaboration with the OPTN contractor, should establish clear governance structures and processes to oversee system operations, monitor impact, and guide continuous improvement. Governance should include defined roles and responsibilities for ongoing system management, risk framework stewardship, policy alignment, and member engagement. Mechanisms for regular stakeholder input, including from OPTN members, MPIC, and other relevant bodies, should be formalized to promote transparency and responsiveness. Resource planning is also essential; the team should ensure that staffing, technical capacity, and budget allocations remain sufficient to support system operations, monitoring, and improvement cycles over time. Embedding strong governance ensures that the modernized compliance system remains a dynamic and trusted tool for promoting accountability, transparency, and continuous quality improvement across the OPTN.

Timeline: Ongoing

- Review and refresh annually

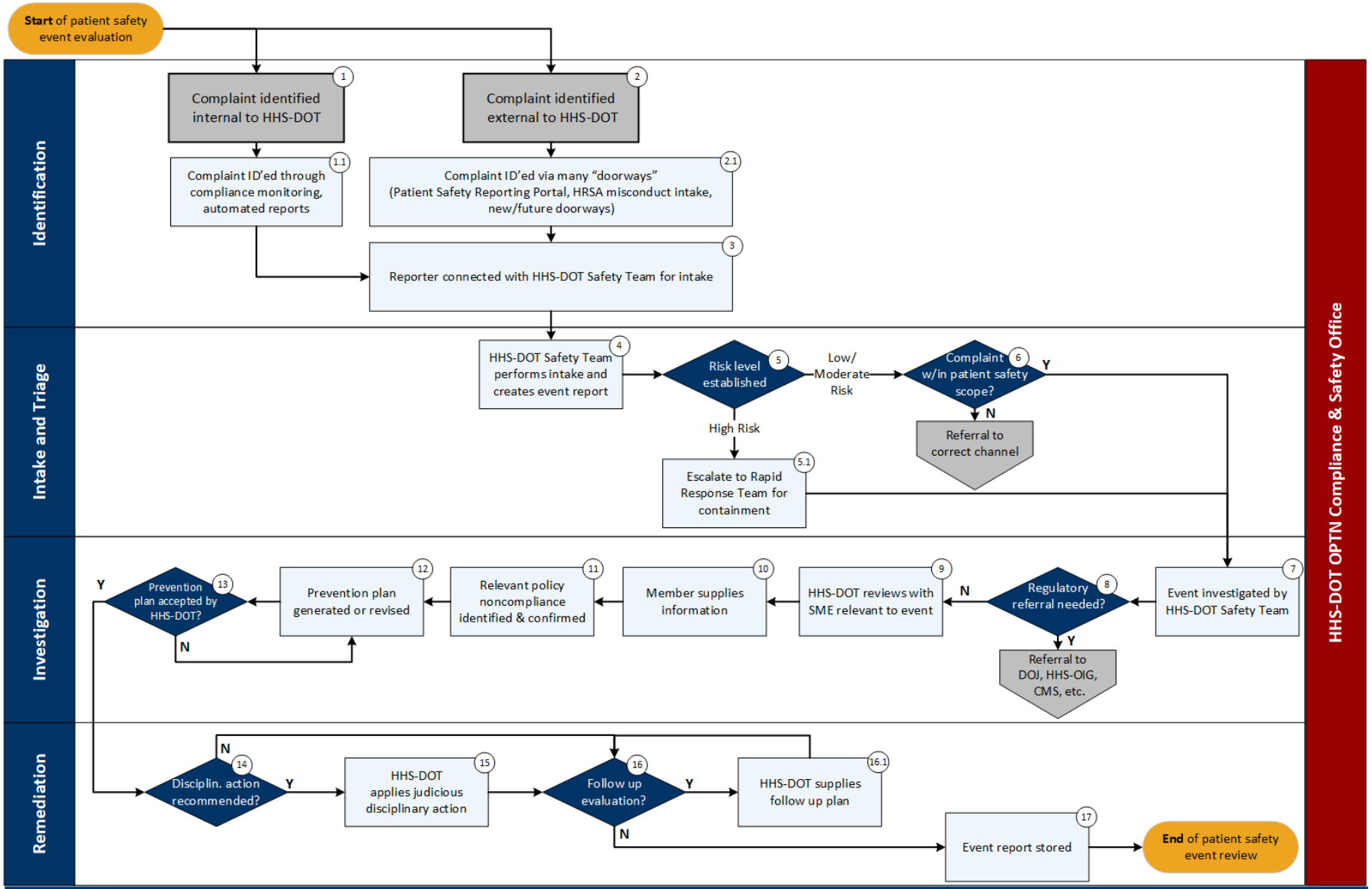
Challenges & Solutions: Full Implementation & Sustainability Phase

Challenge	Solution
Sustaining attention and resources for system operations as implementation focus shifts	Embed system maintenance and continuous improvement responsibilities into HHS-DOT and OPTN contractor operational plans, staffing, and budget cycles; formalize these commitments in governance structures.
Keeping the risk framework, monitoring tools, and operational rules current with evolving risks and best practices	Maintain a structured annual review and update process with cross-functional participation and stakeholder input; monitor emerging risks and external developments to inform updates.
Ensuring transparency and member trust in ongoing system operations	Continue regular, transparent communication of system updates, monitoring results, and governance processes to members; sustain active channels for member feedback and input.
Managing leadership or staff turnover in key roles affecting system governance and operations	Institutionalize system knowledge and governance processes through documentation, training, and onboarding for new leaders and staff; ensure continuity through well-defined roles and governance mechanisms.

Target Outcomes: Full Implementation & Sustainability Phase

- ☐ The modernized compliance system is fully integrated into routine OPTN operations, with all core components used consistently across oversight activities.
- ☐ Ongoing performance monitoring processes are established, with quarterly reviews of system functionality and process consistency, and annual reviews of system impact on member performance and patient safety outcomes.
- ☐ A continuous improvement cycle is operational, with annual review and refinement of the risk-calibrated monitoring framework, automated tools, and operational rules.
- ☐ Governance structures are in place to oversee system sustainability, with defined roles, stakeholder input mechanisms, and resource commitments to support long-term operations and improvement.
- ☐ Member engagement in system monitoring and improvement processes is sustained through transparent communication and opportunities for feedback and collaboration.
- ☐ The compliance system contributes to a broader culture of continuous learning, fairness, and transparency within OPTN member oversight.

Appendix 9: HHS-DOT safety investigation process map



OPTN Future State: Patient Safety Event Evaluation

Process Start/End | Decision Point | Process Step | Off-Page Reference

Step 2.1: Complaint intake includes anonymous reporting methods and patient facing "doorways."
Step 5: Complaint risk level reflects a future state of expanded "Wakefield Criteria" type events.
Step 5.1: A rapid response team coordinates rapid communication and harm reduction for addressable events.
Step 6: Complaints related to interpersonal events or non-safety issues are triaged to member systems
Step 11: A policy noncompliance connection ensures investigations identify gaps in system safeguards.

Appendix 10: Implementation Roadmap—Centralize Patient Safety Reviews within HHS-DOT (Sub-recommendation 1.2)

This implementation roadmap outlines the steps to establish a dedicated HHS-DOT OPTN Compliance and Safety Office, with a focus on the patient safety oversight arm. It supports the transition from a peer-driven case review model to a federally led system that emphasizes transparency, accountability, and learning. The roadmap centers on standardizing safety event definitions, implementing a tiered response framework, and enabling system-level learning through real-time data use. Importantly, it is predicated on the assumption that all activities under sub-recommendation 1.1 have been enacted. Implementation activities are organized into four phases, each grounded in change management principles and implementation science best practices (see the **Change Management Best Practices** section).

Roadmap Objectives

1. **Establish a centralized federal oversight structure** for patient safety that ensures consistent, timely, and accountable responses to safety events.
2. **Define a standardized framework for reportable safety events**, including "near misses," to enable early detection and prevention of harm.
3. **Replace the peer-review model with a learning-oriented approach** that emphasizes system-level insight, transparency, and continuous improvement.
4. **Implement a tiered response framework** that aligns interventions with the severity and systemic implications of reported events.
5. **Foster trust and participation** by creating responsive feedback loops, clear communication channels, and a strong emphasis on fairness.
6. **Leverage safety event data to drive proactive oversight**, enabling pattern recognition, real-time risk monitoring, and informed intervention.

Overview of Roadmap Steps by Implementation Phase

Phase	Steps
Exploration & Planning	1. Convene Implementation Team 2. Identify Internal and External Experts
Installation	1. Define and Validate Reportable Events and Thresholds 2. Develop Reporting Tools, Templates, and Processes 3. Develop Risk Classification and Triage Protocols 4. Develop Safety Even Review Processes and Criteria 5. Develop Member-Facing Guidance, Training, and Communication Materials 6. Pilot Test and Refine Safety Event and Review Process
Initial Implementation	1. Transition to Live Operation of Safety Event Reporting and Monitoring 2. Support Members Through Adoption

	3. Monitor System Use and Member Engagement 4. Identify and Address Implementation Issues
Full Implementation & Sustainability	1. Integrate Safety Event Reporting and Review into OPTN Operations 2. Monitor System Performance 3. Continuously Improve Tools, Protocols, and Processes 4. Establish and Maintain Governance Structure

Exploration & Planning Phase

This phase lays the groundwork for transitioning patient safety oversight to the HHS-DOT OPTN Compliance and Safety Office. Initial activities focus on forming the Implementation Team, reviewing current safety event processes, and developing shared definitions and design priorities, particularly around reportable events and system-level risk. While some foundational work has begun under the current contract, this phase formalizes the framework for a federal model that emphasizes transparency, consistency, and learning.

Personnel Involved

- HHS-DOT Compliance and Safety Office leadership and staff
- HHS-DOT staff with expertise in patient safety, compliance oversight, legal and regulatory affairs, data analytics, and human-centered design (as applicable)
- OPTN contractor leadership and technical staff
- Project management support
- External subject matter experts (to be identified), including experts in national patient safety frameworks (AHRQ, IHI), healthcare incident reporting systems, root cause analysis, and oversight models from analogous federal agencies (CMS, FAA, NTSB)
- OPTN member representatives and MPIC members with operational expertise in safety event reporting and review

Resources Needed

- Staff time for HHS-DOT and OPTN contractor team members
- Project management tools and collaboration platforms
- Meeting facilitation resources
- Tools for conducting expertise mapping and engagement planning
- Budget for engaging external consultants and subject matter experts
- Platforms to support stakeholder engagement (e.g., virtual workshops, focus groups)
- Tools and platforms for documenting findings and recommendations from early expert engagement

Step 1: Convene Implementation Team

The HHS-DOT Compliance and Safety Office should convene a dedicated implementation team to lead the planning and execution of the modernized safety event review system. This team should include representatives from HHS-DOT Compliance and Safety Office leadership and staff, OPTN contractor leadership and technical staff, and project management support. The team should establish clear roles and responsibilities, develop an internal project charter to guide its work, and define processes for coordinating with other key stakeholders, including the MPIC, OPTN BOD, and relevant clinical, operational, and patient safety experts. Once convened, the implementation team will lead all planning activities for the safety event review modernization effort, beginning with the identification and engagement of additional internal and external experts (Step 2).

Timeline: One to two months

- Team should be solidified before proceeding with next step

Step 2: Identify Internal and External Experts

To ensure that the modernized safety event review system reflects current best practices in patient safety and is aligned with evolving national frameworks, the HHS-DOT Compliance and Safety Office, in collaboration with the OPTN contractor, should identify key internal and external subject matter experts (SMEs) to inform system design. Internal experts may include HHS-DOT staff with expertise in patient safety, compliance oversight, legal and regulatory affairs, data analytics, and human-centered design. External experts should include, for example, individuals with experience in national patient safety frameworks (e.g., AHRQ, IHI), healthcare incident reporting systems, root cause analysis, and oversight models from analogous federal agencies (e.g., CMS, FAA, NTSB). OPTN member representatives and MPIC members with deep operational knowledge should also be included to ensure that the system design is practical, transparent, and trusted by members. The implementation team should conduct a mapping exercise to identify priority areas of expertise needed and coordinate with internal networks and external partners to engage appropriate experts. Early engagement of these experts will help ensure that system modernization efforts are grounded in best practices and aligned with the transparency, consistency, and trust-building goals articulated in this report.

Timeline: Three to four months (can be concurrent with previous step)

- Should be completed near the beginning of the planning period, to ensure expert input prospectively informs all subsequent design aspects.

Challenges & Solutions: Exploration & Planning Phase

Challenge	Solution
Defining clear roles and responsibilities across the implementation team	Establish an internal project charter during team formation that documents roles, responsibilities, and coordination processes; revisit and refine as needed throughout planning.

Identifying and engaging the right external experts to inform system design	Conduct a structured expertise mapping exercise early in the phase; consult HHS-DOT networks, external partners, and OPTN stakeholders to identify priority experts and initiate engagement.
Aligning modernization goals with evolving national patient safety frameworks	Engage external SMEs with current knowledge of national frameworks; structure early expert engagement sessions to explicitly address alignment questions and identify gaps.
Building trust and transparency with OPTN members regarding planned system changes	Include OPTN member representatives and MPIC members in the expert engagement process; prioritize clear, transparent communication about modernization goals and design principles from the outset.

Target Outcomes: Exploration & Planning Phase

- ☐ A dedicated implementation team is convened with clear roles, responsibilities, and an internal project charter to guide modernization of the safety event review system
- ☐ Priority internal and external experts are identified, with initial engagement planning completed to inform system design
- ☐ Initial alignment established between modernization goals and relevant national patient safety frameworks
- ☐ Internal project plan for Installation phase developed and endorsed by HHS-DOT Compliance and Safety Office leadership

Installation Phase

In the Installation Phase, the newly formed Implementation Team translate design concepts for federal oversight of patient safety into policy updates, response frameworks, and supporting tools. Activities include defining reportable safety events (especially “near misses”), updating investigation protocols, aligning penalties with systemic risk, and launching stakeholder communication. The HHS-DOT OPTN Compliance and Safety Office leads this work in partnership with contractor staff and safety experts to ensure that both infrastructure and cultural expectations are prepared for implementation.

Personnel Involved

- HHS-DOT Compliance and Safety Office leadership and staff
- HHS-DOT staff with expertise in patient safety, compliance oversight, legal and regulatory affairs, data analytics, and human-centered design (as applicable)
- OPTN contractor leadership and technical staff
- Project management support

- OPTN contractor staff with expertise in incident reporting systems, patient safety frameworks, and root cause analysis
- External subject matter experts (as identified in Planning phase), including experts in national patient safety frameworks, healthcare incident reporting systems, and oversight models from analogous federal agencies
- OPTN member representatives and MPIC members (as pilot participants and advisors)
- Communications and training specialists (for member-facing materials)
- Human-centered design specialists (as applicable — for tool design and refinement)

Resources Needed

- Staff time for HHS-DOT and OPTN contractor teams
- Project management tools and collaboration platforms
- Tools and platforms for developing reporting tools, templates, and intake processes
- Resources for developing and documenting risk classification, triage protocols, and review criteria
- Platforms for secure data exchange and pilot testing of reporting and review processes
- Legal and regulatory review support (to ensure alignment with NOTA, Final Rule, and privacy protections)
- Budget for engaging external subject matter experts
- Tools for developing and delivering member-facing guidance, training, and communication materials
- Resources for collecting and analyzing member feedback and system performance data during pilot testing
- Data governance and security resources

Step 1: Define and Validate Reportable Events and Thresholds

The first priority in the Installation phase is to develop clear, consistent definitions of reportable safety events, including near misses, and establish reporting thresholds that align with national patient safety frameworks. The HHS-DOT Compliance and Safety Office, in collaboration with the OPTN contractor and informed by internal and external experts identified during the Exploration & Planning phase, should translate findings from existing gap analyses and stakeholder engagement into an updated set of reportable event definitions and threshold criteria. This work should explicitly address known limitations of the current Wakefield Criteria and ensure alignment with modern healthcare safety frameworks (e.g., AHRQ Common Formats, IHI guidelines). Definitions and thresholds should promote clarity and consistency for members while enabling effective risk-based review of reported events. Initial validation should test the updated definitions and thresholds against historical event data and simulated case scenarios to assess clarity, feasibility, and alignment with system goals for transparency, trust-building, and improved safety learning. The validated definitions and thresholds will guide the design of reporting tools, intake processes, and review protocols in subsequent steps.

Timeline: Two to four months

- Validated definitions and thresholds need to be carried through all subsequent system design

Step 2: Develop Reporting Tools, Templates, and Processes

With updated definitions and reporting thresholds in place, the next priority is to develop reporting tools, templates, and intake processes that enable consistent and effective capture of safety event information across the OPTN membership. The HHS-DOT Compliance and Safety Office, in collaboration with the OPTN contractor and with input from internal and external experts, should design reporting tools and templates that reflect the validated event definitions and thresholds from Step 1 and are aligned with national patient safety reporting frameworks (e.g., AHRQ Common Formats). Tools should promote clarity, ease of use, and completeness of reporting, with attention to capturing key data elements needed to support subsequent risk classification, triage, and review. Intake processes should be designed to support timely submission, secure handling of sensitive information, and integration with existing OPTN systems where appropriate. Draft tools and processes should undergo user testing with OPTN member representatives to assess usability and ensure alignment with members' operational workflows. Finalized tools and processes will provide the foundation for risk-based triage and systematic safety event review in subsequent steps.

Timeline: Four to six months (sequential to previous step)

Step 3: Develop Risk Classification and Triage Protocols

The HHS-DOT Compliance and Safety Office, in collaboration with the OPTN contractor, should develop clear protocols that define how reported events will be initially assessed, how risk levels will be assigned, and how triage decisions will guide subsequent review pathways. The risk classification framework should reflect national patient safety principles, incorporate the updated event definitions and thresholds established in Step 1, and be aligned with the goals of transparency, trust-building, and system learning articulated in Sub-Rec 1.2. Triage protocols should define criteria and pathways for determining which events warrant full investigation, referral, escalation, or alternative handling (e.g., aggregation for trend analysis or learning). Draft classification and triage protocols should be tested using historical event data and simulated scenarios to ensure consistency, feasibility, and alignment with system goals. Final protocols will serve as the foundation for the development of review processes and criteria in Step 4.

Timeline: Four months (six sessions + framework development and review; can be concurrent with previous step)

Step 4: Develop Safety Even Review Processes and Criteria

Clear and consistent processes and criteria for the review of reported safety events will be developed in this step. These processes should define how events will be reviewed, who will

conduct the reviews, what review criteria will be applied, and how decisions regarding investigation, escalation, corrective actions, and closeout will be made. Review processes should align with national patient safety standards and draw on best practices in incident investigation (e.g., root cause analysis, contributing factors analysis), while ensuring transparency, fairness, and system learning. The team should also define processes for referral of events to external bodies as appropriate (e.g., DOJ, state agencies), consistent with legal and regulatory requirements. Draft processes and criteria should be tested using simulated cases and historical data to ensure clarity, consistency, and operational feasibility. Finalized processes will provide the foundation for consistent, transparent, and trusted safety event review under the modernized system.

Timeline: Two months (sequential to previous step)

- Can be initiated when risk classification and triage protocols are finalized. Must be fully fleshed out in preparation for member-facing guidance development.

Step 5: Develop Member-Facing Guidance, Training, and Communication Materials

To support consistent adoption of the modernized safety event reporting and review system, the HHS-DOT Compliance and Safety Office and the OPTN contractor should develop clear, accessible guidance documents, training materials, and communication products for OPTN members. These materials should explain the updated reportable event definitions and thresholds, reporting tools and processes, risk classification and triage protocols, and review processes and criteria developed in earlier steps. Development of materials should follow Change Management Best Practices outlined in this report, including alignment with the broader implementation plan and communications plan for the modernized office. Draft materials should be tested with OPTN member representatives and MPIC members to ensure clarity, usability, and alignment with members' operational workflows. Final materials should be prepared and approved in advance of pilot testing to support transparency, member understanding, and consistent reporting practices.

Timeline: Two months

- Materials need to be finalized to support member engagement before implementation can begin in earnest

Step 6: Pilot Test and Refine Safety Event and Review Process

The final activity in the Installation phase is to conduct integrated pilot testing of the modernized safety event reporting and review processes and refine them based on pilot results and stakeholder feedback. The HHS-DOT Compliance and Safety Office and the OPTN contractor should design and execute a structured pilot involving a subset of OPTN members, testing the full workflow from event reporting (using the new tools and definitions) through risk classification, triage, and review processes. Pilot participants should submit sample event reports using the new tools, engage with the reporting and intake processes, and participate in feedback sessions regarding usability, clarity, and perceived fairness of the system. Throughout the pilot, the team should collect both quantitative and qualitative feedback from members and internal reviewers to assess system

functionality, member experience, and alignment with system goals of transparency, trust, and improved learning. Pilot results should be systematically analyzed, and refinements to reporting tools, triage protocols, and review processes should be implemented before transition to Initial Implementation.

Timeline: Two to Four Months

- Must continue, regardless of it exceeds the expected time, before Initial Implementation can be started

Challenges & Solutions: Installation Phase

Challenge	Solution
Disagreement on near-miss thresholds or classification	Use Wakefield criteria and real-world examples to anchor discussion and build consensus
Interdependencies with compliance policy changes may delay updates	Track overlaps using a crosswalk; stagger rollout as needed while preserving coordination
Perception that federal oversight is punitive or removes professional autonomy	Emphasize learning-oriented goals, transparency, and member voice through clear messaging and early engagement

Target Outcomes: Installation Phase

- ☐ Definitions of reportable safety events and reporting thresholds validated and aligned with national patient safety frameworks
- ☐ Reporting tools, templates, and intake processes developed, tested, and ready for Initial Implementation
- ☐ Risk classification framework and triage protocols finalized to guide consistent and transparent handling of reported safety events
- ☐ Safety event review processes and criteria finalized, with clear pathways for investigation, escalation, referral, and closeout
- ☐ Member-facing guidance, training materials, and communication products developed, tested with members, and ready to support system adoption
- ☐ Integrated pilot testing of the modernized safety event reporting and review processes completed, with refinements implemented to support readiness for Initial Implementation

Initial Implementation Phase

This phase marks the beginning of the operational rollout of the redesigned safety event oversight system. Core components, such as real-time dashboards, triage workflows, and case tracking infrastructure, are developed, piloted, and refined in collaboration with end-users. The emphasis is

on ensuring tools are practical, transparent, and responsive to safety risks, while also surfacing early lessons to guide system-wide scaling and improvement.

Personnel Involved

- HHS-DOT Compliance and Safety Office leadership and staff
- OPTN contractor leadership and technical staff
- Project management support
- OPTN contractor staff supporting day-to-day safety event reporting and review operations
- OPTN contractor system monitoring and analytics staff
- Communications and training specialists (for ongoing member engagement)
- Helpdesk or user support staff (for member-facing support channels)
- OPTN member representatives and MPIC members (as feedback participants and advisors)
- Human-centered design specialists (as applicable — for iterative refinement based on early member feedback)

Resources Needed

- Staff time for HHS-DOT and OPTN contractor teams
- Project management tools and collaboration platforms
- Platforms for system monitoring and reporting (to track early system use and performance)
- Resources for delivering member training, refreshers, and ongoing communication
- Helpdesk or user support systems (for tracking and responding to member inquiries)
- Tools for collecting and analyzing member feedback and system performance data
- Resources to support iterative refinement of system components during Initial Implementation
- Data governance and security resources

Step 1: Transition to Live Operation of Safety Event Reporting and Monitoring

The Initial Implementation phase begins with the formal transition to live operation of the modernized safety event reporting and review system. The HHS-DOT Compliance and Safety Office, in collaboration with the OPTN contractor, should move all validated system components (updated reportable event definitions and thresholds, reporting tools and intake processes, risk classification and triage protocols, and review processes and criteria) into active use across the OPTN membership. This transition should follow a structured go-live plan, with clear deployment milestones, readiness checks, data submission cutover procedures, and communication protocols to inform members of key dates and expectations. The plan should also include procedures for tracking and addressing technical or operational issues that arise during early live operation. Successfully completing this step establishes the foundation for consistent member adoption and enables the team to shift focus to member support, system monitoring, and continuous refinement during Initial Implementation.

Timeline: One to Two Months

- Target the go-live date for two-months out from the commencement of this phase.

Step 2: Support Members Through Adoption

Following system go-live, it is critical to provide structured support to help OPTN members adopt and consistently use the updated safety event reporting and review processes. The HHS-DOT Compliance and Safety Office should implement a coordinated member support program, aligned with the Change Management Best Practices outlined in this report. Support activities should include delivering targeted training and refreshers, maintaining clear and timely communications about system features and expectations, and offering responsive support channels (e.g., helpdesk, office hours, FAQs) to address member questions and challenges. Special attention should be given to members with varying levels of readiness to ensure equitable support and consistent adoption. Throughout this step, the team should actively monitor member feedback and emerging questions to adapt support offerings as needed. Sustained member support during this early phase is essential to promote transparency, trust, and consistent reporting practices under the modernized system.

Timeline: Duration of Initial Implementation

- Begins with go-live date and runs continuously

Step 3: Monitor System Use and Member Engagement

Throughout Initial Implementation, the HHS-DOT Compliance and Safety Office and the OPTN contractor should actively monitor how members are engaging with the modernized safety event reporting and review system and how the system is performing in live operation. Key areas of monitoring should include member reporting activity (timeliness, completeness, and quality of submitted reports), system performance (accuracy of triage and review processes, processing times), and member engagement with training, support resources, and communications. The team should also track qualitative feedback from members regarding clarity, usability, and perceived fairness of the system. This monitoring will provide critical insights into system functionality, adoption trends, and areas needing refinement. Regular review of these insights should inform responsive adjustments and support a learning-oriented, trust-building oversight culture.

Timeline: Duration of Initial Implementation

- Begins with go-live date and runs continuously

Step 4: Identify and Address Implementation Issues

As the modernized safety event reporting and review system moves through its initial period of live operation, the HHS-DOT Compliance and Safety Office should maintain a structured process for identifying and addressing early implementation issues. This can include systematically collecting and reviewing member feedback, system performance data, and findings from internal monitoring reviews (as described in Step 3). Special attention should be paid to identifying any unintended consequences, equity concerns, or operational challenges experienced by members. The team

should use an iterative refinement process to address issues promptly, making targeted adjustments to system components (such as reporting tools, triage protocols, review criteria, or member-facing guidance) as needed. Transparent communication of refinements to members should be maintained throughout. This step is critical to promote member trust, support transparency, and ensure that the system is operating effectively and consistently before transition to Full Implementation.

Timeline: Duration of Initial Implementation

- Begins with go-live date and runs continuously, with emphasis place on rapid-cycle feedback and refinement to support system stabilization.

Challenges & Solutions: Initial Implementation Phase

Challenge	Solution
Ensuring consistent member understanding and adoption of updated reporting and review processes	Provide clear and accessible training, guidance, and support resources; monitor member feedback and questions to identify where additional clarification or support is needed.
Addressing variability in member readiness and operational capacity to implement the new processes	Offer targeted support to members with varying levels of readiness; prioritize equity of support and track adoption trends to identify members who may require additional assistance.
Identifying and resolving technical or operational issues during early system use	Establish structured processes for tracking member-reported issues and internal system performance data; use rapid-cycle feedback loops to implement timely refinements.
Maintaining member trust and transparency during early refinements of the system	Communicate openly with members about known limitations, refinements underway, and rationale for adjustments; sustain channels for ongoing member feedback and engagement.

Target Outcomes: Initial Implementation Phase

- ☐ The modernized safety event reporting and review system is fully transitioned to live operation across the OPTN membership
- ☐ OPTN members are supported through adoption of updated reporting tools, definitions, thresholds, and review processes, with targeted training and guidance in place
- ☐ Responsive member support channels (e.g., helpdesk, office hours, FAQs) are operational to assist members during system adoption
- ☐ Member reporting activity, system performance, and member engagement are actively monitored, with early trends and insights documented
- ☐ Initial implementation issues, including technical, operational, and adoption-related challenges, are identified and addressed through structured, transparent refinement cycles

- ☐ Member feedback is systematically collected and incorporated into early system adjustments, supporting transparency, trust, and system learning during Initial Implementation

Full Implementation & Sustainability Phase

This phase marks the full operational integration of the redesigned patient safety oversight system. Dashboards, triage workflows, and reporting tools are used routinely to support timely, transparent, and learning-oriented responses to safety events. The focus shifts to maintaining system responsiveness, identifying cross-cutting risks, and sustaining a culture of accountability and improvement across the OPTN network.

Personnel Involved

- HHS-DOT Compliance and Safety Office leadership and staff
- HHS-DOT system governance and oversight staff
- OPTN contractor leadership and technical staff
- Project management support
- OPTN contractor staff responsible for ongoing safety event reporting and review operations
- OPTN contractor system monitoring and analytics staff
- Legal and regulatory staff (to ensure ongoing alignment with NOTA, Final Rule, and privacy protections)
- Communications specialists (to maintain transparency and member engagement)
- OPTN member representatives and MPIC members (as ongoing stakeholders in system governance and continuous improvement)

Resources Needed

- Staff time for HHS-DOT and OPTN contractor teams
- Project management tools and collaboration platforms
- Platforms for ongoing system monitoring and reporting (quarterly and annual reviews)
- Tools to support continuous improvement cycles (annual reviews and targeted updates of reporting tools, triage protocols, and review processes)
- Resources to support governance processes (meeting support, stakeholder engagement, reporting to leadership and OPTN BOD)
- Budget for maintaining system technical infrastructure (reporting tools, intake platforms, monitoring dashboards)
- Resources for ongoing member communications, engagement, and transparency reporting
- Data governance and security resources (to support system evolution and compliance with federal standards)

Step 1: Integrate Safety Event Reporting and Review into OPTN Operations

With Initial Implementation complete and the modernized safety event reporting and review system fully operational, the next priority is to integrate the system into ongoing OPTN operations as a routine part of member oversight and safety monitoring. The HHS-DOT Compliance and Safety Office and the OPTN contractor should formally transition from an implementation stance to sustained operational management, embedding the system's core components (reporting tools and intake processes, risk classification and triage protocols, and review processes and criteria — into standard operational workflows, governance structures, and resource planning). This includes ensuring that routine safety event reviews, member interactions with reporting tools, and data monitoring processes are conducted consistently using the modernized system. Internal policies, staffing, and resource allocations should be reviewed and updated to support sustained system use. Successfully embedding the system into routine operations creates a stable foundation for ongoing transparency, trust-building, and continuous learning, consistent with the goals articulated in Sub-Rec 1.2.

Timeline: Ongoing

- Step can be considered complete when routine use has been established member-wide

Step 2: Monitor System Performance

As the modernized safety event reporting and review system becomes fully embedded in ongoing operations, a routine process should be implemented to monitor the performance of the system itself, member reporting activity, and the system's impact on member behavior and patient safety outcomes. Monitoring should include key indicators of reporting activity (volume, completeness, timeliness), triage and review consistency (alignment with protocols, fairness), and system performance (processing times, data quality). Additionally, the team should assess the system's broader impact, including whether the modernized processes are fostering transparency, trust, and learning-oriented behavior among members. Monitoring should incorporate both quantitative data and qualitative feedback from members and stakeholders. Regular reviews of these insights should inform continuous improvement cycles (Step 3) and be reported to governance structures to support ongoing transparency and trust.

Timeline: Started within first two months of the phase; ongoing with a regular cadence

- Quarterly reviews
- Annual impact review

Step 3: Continuously Improve Tools, Protocols, and Processes

To maintain the effectiveness and relevance of the modernized safety event reporting and review system, the HHS-DOT Compliance and Safety Office should establish an ongoing process for continuous improvement of key system components. This includes regularly reviewing and updating the reporting tools and templates, risk classification and triage protocols, and review processes and criteria based on insights from system monitoring (Step 2), member feedback, and

evolving national patient safety frameworks. Updates should be informed by emerging risks, trends in reported events, advancements in patient safety practices, and input from OPTN members and stakeholders. The update process should follow a structured improvement cycle, with annual comprehensive reviews and interim targeted updates as needed. Embedding this continuous improvement cycle ensures that the safety event review system remains responsive, trusted, and aligned with the goals of transparency, fairness, and system learning.

Timeline: Ongoing

- Annual comprehensive review and update cycle
- Targeted interim updates as needed, typically every three to six months

Step 4: Establish and Maintain Governance Structure

To ensure the long-term sustainability of the modernized safety event reporting and review system, the HHS-DOT Compliance and Safety Office should establish and maintain clear governance structures to oversee ongoing system use, performance monitoring, and continuous improvement. Governance responsibilities should include stewardship of reporting tools and processes, alignment with evolving national patient safety frameworks, management of continuous improvement cycles, and oversight of member engagement and transparency practices. Mechanisms for ongoing stakeholder input, including participation from OPTN members, MPIC, and external patient safety experts, should be formalized to ensure responsiveness and trust. Governance processes should also include regular reporting to HHS-DOT leadership and the OPTN BOD on system performance, member engagement, and progress toward transparency and learning goals. Establishing strong governance is critical to sustaining member trust, system learning, and alignment with broader patient safety goals over time.

Timeline: Ongoing

- Initiate governance structure and stakeholder engagement – one to two months
- Fully operational governance in place – up to six months
- Annual review and refresh of governance processes and resources commitments – annually

Challenges & Solutions: Final Implementation & Sustainability Phase

Challenge	Solution
Sustaining attention and resources for ongoing system operations and continuous improvement as the initial implementation focus shifts	Embed system stewardship responsibilities and resource commitments into HHS-DOT and OPTN contractor operational plans, staffing, and budget cycles; formalize these commitments in governance structures.
Keeping system components aligned with evolving national patient safety frameworks and emerging best practices	Maintain structured annual review cycles with participation from external patient safety experts and key stakeholders; regularly scan national frameworks and update system components accordingly.

Maintaining member trust and engagement in the safety event review system over time	Sustain transparency practices through regular reporting to members, clear communication of system updates, and ongoing stakeholder input mechanisms; prioritize responsiveness to member feedback in governance processes.

Target Outcomes: Full Implementation & Sustainability Phase

- ☐ The modernized safety event reporting and review system is fully integrated into routine OPTN operations, with consistent use of updated reporting tools, triage protocols, and review processes
- ☐ Ongoing system monitoring processes are established, with quarterly reviews of system performance and member reporting activity, and annual reviews of system impact and member engagement
- ☐ Continuous improvement processes are operational, with annual review and refinement cycles for reporting tools, triage protocols, and review processes, and targeted interim updates as needed
- ☐ Governance structures are established and operational, providing oversight of system performance, transparency practices, and continuous improvement activities
- ☐ Mechanisms for ongoing stakeholder input, including OPTN members, MPIC, and external patient safety experts, are formalized and integrated into governance processes
- ☐ Member trust, transparency, and system learning are sustained and strengthened through ongoing governance, monitoring, and continuous improvement of the safety event reporting and review system

Appendix 11: Implementation Roadmap - Re-brand the MPSC as the Membership and Performance Improvement Committee (MPIC) (Sub-Recommendation 2.1, Part 1)

This implementation roadmap outlines the steps to rebrand the Membership and Professional Standards Committee (MPSC) as the Membership and Performance Improvement Committee (MPIC), with a updated roles and clearly defined responsibilities. The rebranding marks a structural and cultural shift within the OPTN, reinforcing the MPIC's forward-looking role in member support, performance improvement, and proactive engagement. This transition also includes the transfer of compliance and safety oversight responsibilities to the HHS-DOT Compliance and Safety Office, enabling the MPIC to focus on transparency, education, and quality enhancement. Implementation activities are organized across four phases and are grounded in change management and governance best practices (see the **Change Management Best Practices** section). The roadmap emphasizes stakeholder engagement, policy and bylaw alignment, and trust-building among members concerned about oversight transitions.

Roadmap Objectives:

- **Clarify the new identity and scope of the MPIC**, positioning it as a leadership body focused on member performance improvement and support, distinct from compliance enforcement.
- **Transition compliance and safety responsibilities to HHS-DOT**, allowing the MPIC to center its work on developmental guidance, peer support, and early intervention.
- **Revise OPTN policies, Management and Membership Policies, and bylaws** to reflect the rebranded committee's responsibilities and remove outdated references to MPSC roles.
- **Build stakeholder understanding and acceptance** through clear messaging, structured engagement, and ongoing communication throughout the transition.
- **Maintain continuity and legitimacy** by preserving core membership oversight functions within the OPTN structure, while reinforcing the committee's new, proactive posture.

Overview of Roadmap Steps by Implementation Phase:

Phase	Steps
Exploration & Planning	1. Convene Implementation Team 2. Develop Initial Implementation and Communication Plans
Installation	1. Draft and Review Governance Revisions 2. Launch Communication and Engagement Activities
Initial Implementation	1. Submit Policy and Bylaw Changes for Review and Comment 2. Revise and Finalize Changes Based on Feedback 3. Maintain Transparent, Ongoing Communication
Full Implementation & Sustainability	1. Launch MPIC Operations and Reinforce New Identity 2. Evaluate Member Understanding and Alignment 3. Sustain the Shift Toward Performance Improvement

Exploration & Planning Phase

This phase establishes the foundation for successfully rebranding the MPSC as the MPIC and redefining its scope within the OPTN. Activities focus on convening a cross-functional implementation team, setting the vision for the restructured committee, and developing an initial implementation and communication strategy. Early alignment around goals, terminology, and transition messaging is essential to ensure stakeholder buy-in and minimize resistance during later policy and bylaw revisions. Although groundwork has been initiated under the current contract, this phase formalizes the planning process and prepares for the broader cultural and structural changes that follow.

Personnel involved

- Five to seven implementation team members with experience in OPTN policy change, governance transitions, and change management
- HHS-DOT COR and SMEs to support strategic alignment, federal oversight context, and message development
- MPSC/MPIC and OPTN BOD members to lend historical insight, policy continuity, and stakeholder credibility
- Optional: external contractor staff to provide facilitation, perceived neutrality, and planning infrastructure

Resources needed

- Templates and examples from change management best practices
- Secure collaboration platform for drafting, review, and version control
- Messaging materials endorsed by HHS-DOT to explain:
    - The rationale for rebranding the MPSC
    - The scope and responsibilities of the future MPIC
    - The separation of compliance/safety functions from membership performance oversight
- Examples of effective communication strategies used in prior policy or governance transitions
- Full text of current OPTN policies, Management and Membership Policies, and INVEST bylaws

Step 1: Convene Implementation Team

Assemble a balanced, cross-functional team of five to seven experts in OPTN policy, governance transitions, and change management to guide planning, engage stakeholders, and shape the transition roadmap. Ideally implementation team members will have experience with the OPTN policies and the role and scope of the MPSC. This team should establish clear roles and

responsibilities, develop an internal project charter to guide their work, and define processes for coordinating with other key stakeholders (such as the OPTN BOD).

Timeline: Six weeks

- Identify/invite members for Implementation team: Two weeks (If competitive contracting is required, allow up to six months)
- Internal orientation and onboarding sessions: Four weeks

Step 2: Develop Initial Implementation and Communication Plans

Draft planning documents to outline the rebranding strategy, core messages, key milestones, and communication channels. The implementation and communications plan should focus on why the scope of the MPSC should change and the rationale for retaining membership criteria with the rebranded MPIC. Plans should be structured as living documents to adapt to emerging needs.

Timeline: Two to three months sequential to the previous step

- Develop initial drafts: One month
- Ongoing refinement throughout subsequent phases based on stakeholder feedback: Two to three months

Challenges & Solutions: Exploration & Planning Phase

Challenge	Solution
Resistance from OPTN members concerned about changes in committee authority	Develop clear, consistent messaging early and test it with key stakeholders; reference change management best practices and emphasize continuity of mission
Communication plan may not address all concerns or anticipate emerging issues	Treat plans as iterative; gather stakeholder feedback and adjust messaging throughout implementation
Limited bandwidth or expertise to manage complex governance transitions	Engage external facilitators or change management contractors for technical support and continuity

Target Outcomes: Exploration & Planning Phase

- ☐ Implementation Team established with defined roles, onboarding completed, and shared understanding of transition objectives
- ☐ Initial draft of the Implementation Plan completed, aligned with change management best practices and reviewed by HHS-DOT and OPTN leadership
- ☐ Initial Communication Plan drafted, including:
    - Target audiences and tailored messaging
    - Communication cadence and engagement channels
    - Draft FAQs and support materials

- ☐ Internal feedback loops in place to refine plans as resistance or confusion emerges
- ☐ Structured messaging prepared to distinguish MPIC's new identity and purpose from legacy MPSC responsibilities

Installation phase

The Installation Phase operationalizes the planning work completed during the earlier phase. Activities include drafting and reviewing policy and bylaw revisions to reflect the MPIC's redefined scope, deploying structured communication strategies, and engaging OPTN members in discussion and feedback. A deliberate and transparent approach is essential to build confidence in the committee's new identity, ensure clarity in governance responsibilities, and minimize disruption across the broader OPTN community.

Personnel involved

- Implementation Team members with expertise in OPTN policy structure, bylaws, and change management
- HHS-DOT COR and SMEs to ensure alignment with federal policy, regulatory expectations, and strategic messaging
- MPSC/MPIC and OPTN BOD to participate in policy drafting, internal review, and public engagement
- Legal experts with specific experience in OPTN governance and INVEST bylaws
- OPTN community stakeholders engaged through communication sessions, comment periods, and feedback channels

Resources needed

- OPTN Policies, Management and Membership Policies, and INVEST Bylaws
- Draft Implementation and Communication Plans developed during the planning phase
- Communication supports, including:
    - Webinar platforms
    - Slide decks and handouts
    - FAQs, comparison tools, and structured feedback collection mechanisms
- Policy drafting templates, version control tools, and comment tracking systems
- Internal review guidance from HHS-DOT and OPTN leadership

Step 1: Draft and Review Governance Revisions

Develop proposed changes to all relevant OPTN policies and bylaws to align with the MPIC's new scope and structure.

- The OPTN Policies[40] include five references to the MPSC. Each reference needs to be reviewed considering the changing scope of the committee. Most references will be updated to refer cases to HHS-DOT for compliance or safety event investigations. As

specified in the OPTN Management and Membership Policy E,[30] changes to OPTN policies must be approved by the OPTN BOD, which includes a public comment period.

- The Management and Membership Policies[30] include many references to the MPSC which need to be reviewed and updated in light of the changing scope of the MPSC.
- The INVEST Bylaws[41] specify that the OPTN Board of Directors' Vice President serves as a non-voting member of the MPSC. Given the change in scope, that may no longer be necessary. Changes to OPTN bylaws must be approved by a majority vote of a quorum of OPTN members present at its annual meeting.
- Conduct internal reviews with committees, BOD, and HHS-DOT.

Timeline: Three to six months

- Have the draft materials vetted internally and undergo legal review: Five months
- Prepare final materials for public comment: One month

Step 2: Launch Communication and Engagement Activities

During the initiation phase it is critical to build awareness and support for the intended change. Launch the communication strategy developed in the previous phase, engage stakeholders in structured outreach, explain rationale for change, and address anticipated concerns.

Timeline: Six to twelve months concurrent with the previous step

- Ongoing outreach aligned with policy comment periods
- Live engagement events and written materials distributed throughout the network

Challenges & Solutions: Installation Phase

Challenge	Solution
Volume and complexity of policy references require careful coordination	Use structured review templates and tracking logs to ensure consistency across documents and streamline version control.
Resistance from members concerned about dilution of oversight	Emphasize the MPIC's redefined role as a performance improvement body, distinct from enforcement functions now housed at HHS-DOT. Reinforce the continued importance of membership oversight within the OPTN structure.
Confusion about what is changing versus what remains	Develop clear, side-by-side comparison tools and talking points to distinguish changes in scope, process, and accountability from elements that will remain consistent (e.g., retention of proposing OPTN membership criteria within the MPIC).

Target Outcomes: Installation Phase

- ☐ Draft revisions completed for:
- ☐ OPTN Policies (references to MPSC updated to reflect MPIC role)
- ☐ OPTN Management and Membership Policies (restructured to reflect oversight transition)
- ☐ INVEST Bylaws (updated composition and committee responsibilities)
- ☐ Internal reviews conducted by OPTN committees, BOD, and HHS-DOT advisors
- ☐ Communication strategy activated, including:
- ☐ Webinars and briefing sessions for OPTN members
- ☐ Updated messaging materials and FAQs distributed
- ☐ Feedback mechanisms in place and monitored
- ☐ Stakeholder questions and concerns logged and addressed
- ☐ Broad awareness of proposed changes established across the OPTN community

Initial implementation phase

This phase marks the formal transition of the MPSC to the MPIC. Activities focus on advancing proposed policy and bylaw changes through the OPTN review and public comment process, while sustaining clear, consistent communication with the OPTN community. Member feedback is used to refine the proposed changes, strengthen understanding of the MPIC's new scope, and prepare the transplant community for the operational shift in oversight responsibilities.

Personnel involved

- Implementation Team to support policy revisions, manage feedback, and coordinate outreach
- HHS-DOT COR and SMEs to ensure regulatory compliance and message alignment
- MPIC and OPTN BOD to sponsor and shepherd the proposed changes through internal review and public engagement
- OPTN policy committees to review and respond to proposed revisions during comment periods
- OPTN community members and public stakeholders engaged in formal review and feedback processes

Resources needed

- Finalized draft versions of:
    - OPTN Policies
    - OPTN Management and Membership Policies
    - INVEST Bylaws

- Communication tools and engagement platforms, including:
  - Webinar software
  - Digital fact sheets and FAQs
  - Comment tracking systems and revision logs
- Public comment infrastructure provided through the OPTN policy development process
- Staff and technical support to manage comment synthesis, revisions, and version control

Step 1: Submit Policy and Bylaw Changes for Review and Comment

Formally present the proposed changes to HHS-DOT and the OPTN BOD. HHS-DOT will also review the policies to ensure they follow legal and regulatory requirements. After incorporating input from the OPTN BOD and HRSA-DOT, the proposed policies will be posted for public comment to allow interested individuals to review and respond.

Timeline: Two to three months (longer if multiple comment cycles are required)

- Additional time allocated for revision and possible reposting if changes are significant

Step 2: Revise and Finalize Changes Based on Feedback

At the conclusion of the comment period, review stakeholder input, adjust policy language as needed, and prepare final versions for OPTN BOD approval. If the changes are significant, the revised policy may again be released for public comment. In writing revisions, ensure that all changes are responsive to concerns raised during comment periods. Finally, the OPTN BOD will review and vote on the policy changes.

Timeline: One to two months post-comment period

- Final vote by the OPTN BOD concludes this phase

Step 3: Maintain Transparent, Ongoing Communication

Continue outreach efforts in parallel with policy review. Keep stakeholders informed of progress, clarify points of confusion, and reinforce the rationale behind the MPIC transition. Given the structured policy review process within the OPTN, there is already built-in steps for communicating these changes to the OPTN community and public.

Timeline: Ongoing throughout the implementation phase

Challenges & Solutions: Initial Implementation Phase

Challenge	Solution
Significant stakeholder resistance or confusion during the public comment period	Prioritize real-time response to concerns. Provide clear, direct messaging and clarify what is/is not changing through FAQs, live sessions, and side-by-side comparisons.
Policy revisions require extensive changes based on feedback	Allocate time and resources for a second round of comments if needed. Emphasize transparency and document how feedback was incorporated.

Communication gaps persist across OPTN member types or settings	Diversify outreach channels (e.g., email, meetings, social media). Enlist MPIC and OPTN BOD members as ambassadors to reinforce key messages within their networks.

Target Outcomes: Initial Implementation Phase

- ☐ Policy and bylaw proposals submitted to the OPTN BOD and HHS-DOT for internal review
- ☐ Public comment period completed with community engagement tracked and feedback logged
- ☐ All comments synthesized and reviewed by the Implementation Team and MPIC
- ☐ Revisions made to policy language, or second comment cycle launched if needed
- ☐ Final vote held by the OPTN BOD to adopt the updated MPIC structure and scope
- ☐ Communication Plan maintained throughout, with:
    - Regular stakeholder updates
    - Updated FAQs and talking points
    - Participation in webinars, briefings, or Q&A sessions
- ☐ Member sentiment and questions monitored to inform future refinement or education efforts

Full implementation & sustainability phase

This phase finalizes the MPIC transition and ensures the committee's new roles, responsibilities, and governance structure are fully embedded in OPTN operations. With policies and bylaws officially adopted, the focus turns to institutionalizing the MPIC's performance improvement role, monitoring the effectiveness of communications, and supporting long-term engagement across the OPTN network. Continuous feedback is used to assess understanding, address residual confusion, and reinforce the MPIC's position as a trusted, forward-looking body.

Personnel involved:

- MPIC members in their new capacity to operationalize the committee's redefined responsibilities
- OPTN policy and governance staff to provide support and ensure consistency across committee processes
- HHS-DOT oversight team to monitor adherence to federal expectations and support continued stakeholder education
- OPTN communications staff and stakeholder engagement leads
- Optional: external evaluators or member survey contractors to assess understanding and impact of the change

Resources needed:

- Final adopted versions of:
  - OPTN policies reflecting the MPIC structure
  - Management and Membership Policies
  - INVEST Bylaws
- Communications and education materials, including:
  - Slide decks for onboarding new members and external partners
  - Updated web content, FAQ documents, and MPIC charter
- Member sentiment data from surveys, Q&A sessions, and feedback channels
- Meeting agendas and workplans for the MPIC's first year under the new structure
- Performance improvement tools and learning resources aligned with the MPIC's new mission

Step 1: Launch MPIC Operations and Reinforce New Identity

Begin committee work under the MPIC name, roles and responsibilities. Update public-facing materials, web pages, and documentation. Reinforce identity in external communications.

Timeline: Immediately upon OPTN BOD adoption

- Continue for three to six months post-implementation to reinforce understanding

Step 2: Evaluate Member Understanding and Alignment

Assess stakeholder awareness and perception of the MPIC's new role through surveys, structured interviews, or informal check-ins with key OPTN constituencies.

Timeline: Three to six months post-implementation (concurrent with previous step)

- Use results to inform future communications and clarify any persistent misunderstandings

Step 3: Sustain the Shift Toward Performance Improvement

Embed performance improvement strategies into MPIC operations, including onboarding, agenda planning, and interaction with other OPTN committees. Continue monitoring how the MPIC interacts with the broader ecosystem and evolves in practice.

Timeline: Ongoing

- Reviewed semi-annually by HHS-DOT or OPTN BOD for alignment and improvement opportunities

Challenges & Solutions: Full Implementation & Sustainability Phase

Challenge	Solution
Lingering confusion about MPIC's role or its separation from compliance functions	Continue messaging through multiple channels, using concrete examples of what the MPIC does and does not do. Incorporate visual guides and real scenarios in briefings.

Skepticism that the committee's new orientation is meaningful or sustained	Make early MPIC work visibly aligned with performance improvement (e.g., launch a learning collaborative or early intervention pilot). Highlight these efforts publicly.
Inconsistent adoption of new terminology or references to the MPIC	Build automatic language updates into templates, onboarding materials, and policy documents. Create a brief style guide to support staff and partners in using the correct language.

Target Outcomes: Full Implementation & Sustainability Phase

- ☐ MPIC fully operational with updated charter, workplans, and committee materials
- ☐ MPIC web pages and documentation updated and publicly available
- ☐ External communications consistently use and reinforce new name and scope
- ☐ Member surveys or interviews completed, showing increased understanding of the MPIC's role
- ☐ At least one refinement cycle completed to adjust FAQs, guidance, or messaging based on real-world feedback
- ☐ Early MPIC activities reflect its proactive, member-supportive orientation (e.g., development of tools, peer learning sessions)
- ☐ MPIC establishes clear boundaries between its performance role and HHS-DOT-led compliance/safety functions

Appendix 12: Implementation Roadmap - Engage the MPIC to review and recommend membership criteria (Sub-Recommendation 2.1, Part 2)

This implementation roadmap outlines the steps needed to formally charge the MPIC with reviewing and recommending OPTN membership criteria. This marks a strategic opportunity to modernize, clarify, and strengthen membership standards in line with evolving expectations for OPTN member quality and accountability. By shifting this responsibility from the MPSC to the rebranded MPIC, the OPTN reinforces the committee's renewed focus on transparency, learning, and system performance. The roadmap includes four phases of work, beginning with scoping and planning, and culminating in a sustainable process by which the MPIC continually evaluates and updates membership criteria to ensure alignment with best practices and national needs (see the **Change Management Best Practices** section).

Roadmap Objectives:

1. **Transfer responsibility for proposing membership criteria from the MPSC to the MPIC,** aligning with the rebranding and governance reengineering efforts.
2. **Clarify and document the scope of the MPIC's role in reviewing,** recommending, and periodically updating OPTN membership standards.
3. **Develop a transparent process for evaluating membership criteria,** informed by stakeholder feedback and evidence-based practices.
4. **Ensure consistency and rigor across all program types,** while allowing space for flexibility and innovation in how standards are met.
5. **Establish a review cycle** that allows membership criteria to evolve in response to changes in procurement or transplantation practice, policy priorities, and system performance data.

Overview of Roadmap Steps by Implementation Phase:

Phase	Steps
Exploration & Planning	1. Confirm Scope and Develop Review Framework 2. Conduct Environmental Scan and Gap Analysis
Installation	1. Draft Revised Membership Criteria 2. Conduct Stakeholder Engagement and Vetting 3. Prepare Final Drafts for Public Comment
Initial Implementation	1. Launch and Monitor Public Comment Period 2. Synthesize Feedback and Provide Implementation Support 3. Finalize and Prepare for OPTN BOD Approval
Full Implementation & Sustainability	1. Roll out Final Criteria and Support Member Adoption 2. Monitor Adoption and Collect Feedback 3. Codify Review Process

Exploration & Planning Phase

This phase establishes the foundation for formally transitioning oversight of OPTN membership criteria to the MPIC as part of its redefined role. Activities focus on clarifying the MPIC's mandate for proposing membership criteria, developing a transparent governance structure for this responsibility, and conducting a comprehensive assessment of existing membership criteria across all OPTN member types. The MPIC will engage in an environmental scan to identify best practices from analogous credentialing and accreditation models, while also analyzing current OPTN criteria to surface gaps, inconsistencies, or outdated requirements. Early stakeholder engagement is prioritized to ensure that the review process reflects the needs of diverse OPTN members, supports equity, and fosters trust in how membership standards are applied and updated.

Personnel involved:

- MPIC members, OPTN BOD and HHS-DOT COR to jointly clarify scope and establish initial priorities
- OPTN policy and membership staff to provide historical documentation and subject-matter context
- Legal and regulatory advisors to ensure consistency with federal mandates and the Final Rule
- Optional: external advisors with experience in credentialing, quality standards, or equity-driven membership models
- Representatives from all OPTN member types to contribute stakeholder insights

Resources needed:

- Current OPTN membership criteria by entity type, including any unpublished internal guidance
- Meeting summaries or historical memos from prior MPSC membership criteria discussions
- Applicable Final Rule language and HHS-DOT guidance
- Documentation from analogous credentialing or standard-setting organizations
- Collaboration tools for drafting, tracking input, and documenting rationale behind revisions

Step 1: Confirm Scope and Develop Review Framework

Clarify what aspects of membership criteria fall under MPIC review and how that review will be structured (e.g., one-time revision vs. rolling process). Establish guiding principles (e.g., transparency, relevance, feasibility, equity).

Timeline: 1–2 months

- Deliverable: MPIC Membership Criteria Review Framework

Step 2: Conduct Environmental Scan and Gap Analysis

Compare existing OPTN membership criteria across OPTN member and program types. Identify inconsistencies, outdated requirements, or areas lacking specificity. Include review of best practices from other accreditation bodies.

Timeline: Two to three months (sequential to previous step)

- Deliverable: Gap analysis and scan summary to inform the installation phase

Challenges & Solutions: Exploration & Planning Phase

Challenge	Solution
Lack of clarity about where MPIC's role ends and HHS-DOT or OPTN BOD authority begins	Clearly define the committee's charge as "review and recommendation" and establish a review and approval chain with the BOD and federal oversight
Membership criteria vary widely by entity type and may be viewed as sensitive or political	Emphasize consistency, fairness, and quality. Use stakeholder input and a principled framework to guide decision-making and messaging.
Limited institutional memory around past changes to membership criteria	Engage policy staff and legacy MPSC members to reconstruct rationale where needed; document all new changes going forward

Target Outcomes: Exploration & Planning Phase

- ☐ MPIC formally charged with membership criteria oversight and scope confirmed with HHS-DOT
- ☐ Draft review framework completed, including:
  - Guiding principles
  - Review cadence (e.g., annual or rolling)
  - Documentation and transparency standards
- ☐ Gap analysis completed, including:
  - Mapping of current criteria across member types
  - Identification of inconsistent, burdensome, or outdated elements
  - Opportunities for harmonization or modernization
- ☐ Stakeholder input gathered on initial concerns, values, and expectations related to membership standards

Installation phase

This phase translates planning into action by formally integrating the MPIC into the process for reviewing and recommending membership criteria. The MPIC will develop proposed revisions based on the gap analysis and review framework from the planning phase, supported by policy and technical staff. This includes aligning criteria across member types where appropriate, eliminating outdated or burdensome requirements, and introducing language that reflects system performance goals and equity considerations. Engagement with OPTN stakeholders remains a top priority throughout.

Personnel involved:

- MPIC members to lead review and deliberation of criteria by member type
- OPTN policy staff to draft and refine proposed revisions, manage internal review, and track feedback
- HHS-DOT COR and legal advisors to ensure alignment with regulatory requirements and federal oversight
- Representatives from transplant hospitals, OPOs, labs, and other OPTN member types to provide feedback
- Optional: subject matter experts in accreditation, performance measurement, and/or equity

Resources needed:

- Gap analysis and review framework developed in the prior phase
- OPTN data to inform where criteria may exclude or disadvantage members without improving quality
- Policy development infrastructure (templates, internal comment processes, version control tools)
- Communication materials (FAQs, slides, side-by-side comparisons) for use during internal and public review
- Engagement platforms for listening sessions, focus groups, and/or written comment

Step 1: Draft Revised Membership Criteria

Using the review framework and gap analysis, develop proposed updates to existing criteria for all OPTN member types. Ensure consistency in structure, clarity in expectations, and alignment with broader goals of transparency and quality.

Timeline: Five to six months

- Internal review by MPIC and OPTN policy staff throughout

Step 2: Conduct Stakeholder Engagement and Vetting

Present proposed criteria revisions to OPTN committees, the OPTN BOD, and relevant stakeholders. Conduct listening sessions and/or focus groups to gather real-time feedback, particularly from impacted member types.

Timeline: Two to three months (sequential to previous step)

- Materials revised in response to feedback before formal public comment

Step 3: Prepare Final Drafts for Public Comment

Refine language and prepare for public posting. Ensure documentation includes rationale for changes, response to stakeholder input, and summary of expected impacts.

Timeline: One month (sequential to previous step)

- Phase concludes with launch of public comment period

Challenges & Solutions: Installation Phase

Challenge	Solution
Pushback from members who view revisions as overreach or misaligned with practice realities	Emphasize MPIC's collaborative, evidence-informed approach. Use stakeholder stories and examples to demonstrate the need for revisions and their potential value.
Difficulty achieving consistency across diverse member types with unique operational needs	Where standardization is not feasible, allow for tiered or context-specific criteria. Clearly articulate the rationale for any differences.
Limited awareness or engagement from members during the internal review period	Use multiple channels for engagement (e.g., webinars, standing committee meetings, written summaries). Offer opportunities for both live and asynchronous feedback.

Target Outcomes: Installation Phase

- ☐ Full draft of revised membership criteria completed for all relevant member types
- ☐ Revisions reflect:
  - Harmonization where possible across programs
  - Removal of obsolete or burdensome requirements
  - Introduction of equity- and performance-informed elements
- ☐ Structured review and vetting conducted with:
  - At least three stakeholder engagement sessions
  - Feedback documented and synthesized
- ☐ Final draft versions prepared and approved for public comment
- ☐ Communication materials prepared to support rollout and transparency

Initial implementation phase

This phase advances the revised membership criteria developed by the MPIC through the OPTN's formal public comment and review process. Activities focus on responding to stakeholder input, refining policy language as needed, and preparing for adoption and implementation. The MPIC continues to serve as the steward of the criteria during this phase, helping to ensure transparency, consistency, and responsiveness to member concerns.

Personnel involved:

- MPIC members to review and incorporate public comment
- OPTN policy staff to manage the public comment process, track feedback, and coordinate revisions
- HHS-DOT COR and legal advisors to provide oversight and ensure regulatory compliance
- OPTN BOD to review final versions and vote on adoption
- Transplant community stakeholders engaged through comment, feedback sessions, and implementation planning

Resources needed:

- Final draft membership criteria and supporting rationale documents
- OPTN's public comment platform and tools for synthesizing input
- Communication materials for use during and after comment (e.g., one-pagers, side-by-side comparisons, FAQs)
- Tracking system for documenting and responding to stakeholder feedback
- Templates for implementation guidance (e.g., member readiness checklists)

Step 1: Launch and Monitor Public Comment Period

Publish the proposed membership criteria updates for public comment. Monitor engagement, respond to questions, and provide clarification as needed.

Timeline: Two months (standard OPTN public comment cycle)

Step 2: Synthesize Feedback and Provide Implementation Support

After the comment period closes, summarize and categorize feedback. Identify areas of strong support or concern, and draft recommendations for how to revise policy language accordingly.

Timeline: One to two months (started during previous step)

- MPIC votes on whether to revise or advance as drafted

Step 3: Finalize and Prepare for OPTN BOD Approval

Incorporate necessary revisions and prepare the final version of the criteria, along with a summary of how feedback was addressed. Submit to the OPTN BOD for formal adoption.

Timeline: One to two months (sequential to previous step)

- Phase ends with vote by OPTN Board

Challenges & Solutions: Initial Implementation Phase

Challenge	Solution
High volume of conflicting feedback from diverse stakeholders	Prioritize transparency and principled reasoning in how feedback is addressed. Where compromise is not possible, clearly explain tradeoffs.
Delays in OPTN BOD approval due to lingering questions or legal concerns	Engage OPTN BOD members and HHS-DOT advisors early. Provide redlines, side-by-side versions, and decision memos to aid review.
Insufficient understanding among members about how new criteria will affect them	Begin parallel development of implementation guidance and educational materials during this phase. Offer drop-in Q&A sessions or webinars to improve clarity and preparedness.

Target Outcomes: Initial Implementation Phase

- ☐ Public comment period completed, with participation tracked across stakeholder types
- ☐ Feedback synthesized and discussed by MPIC
- ☐ Revised membership criteria finalized, with:
  - Clear documentation of rationale
  - Explanation of changes based on input
  - Final versions formatted and ready for adoption
- ☐ OPTN BOD vote scheduled and supporting materials submitted
- ☐ Member education and readiness resources drafted in parallel with policy finalization

Full Implementation & Sustainability Phase

This phase finalizes the adoption of updated membership criteria and supports OPTN members in adapting to the new standards. The MPIC's new role as steward of membership criteria becomes institutionalized through regular review cycles, monitoring of implementation challenges, and feedback loops. Emphasis is placed on transparency, member education, and ensuring that criteria remain relevant and equitable as the procurement and transplantation system evolves.

Personnel involved:

- MPIC members to oversee implementation fidelity and establish a recurring review schedule
- OPTN policy staff to support criteria adoption logistics and member-facing guidance
- HHS-DOT COR and legal advisors to monitor compliance and ensure alignment with federal regulations

- OPTN Member Quality and Membership staff to respond to member questions and provide technical support
- Members from all OPTN entity types to participate in post-implementation feedback and future refinement cycles

Resources needed:

- Final, OPTN BOD-approved membership criteria and public-facing documentation
- Implementation guidance for members, including:
    - Checklists
    - FAQs
    - Recorded training/webinars
- Feedback mechanisms, such as:
    - Member surveys
    - Listening sessions
- Email helpdesk or virtual office hours
- Documentation outlining the review/update cadence (e.g., every three to five years or as needed)
- Ongoing policy tracking tools to monitor when standards may become outdated

Step 1: Roll out Final Criteria and Support Member Adoption

Publish final membership criteria and share with the OPTN community via multiple channels. Provide implementation guidance, training sessions, and individualized technical support as needed.

Timeline: Immediately after OPTN BOD approval; support ongoing activities for six to twelve months

Step 2: Monitor Adoption and Collect Feedback

Track implementation experiences and gather member feedback to identify common challenges or areas needing clarification. Use this feedback to inform potential mid-course adjustments or future updates.

Timeline: Six to twelve months post-rollout

- Includes both proactive outreach and reactive support

Step 3: Codify Review Process

Formalize a regular cadence for reviewing and updating membership criteria. Define roles, timing, and triggers for revisiting specific elements. Ensure MPIC has the tools and resources needed to fulfill this function on an ongoing basis.

Timeline: Ongoing; initiated during the first-year post-implementation

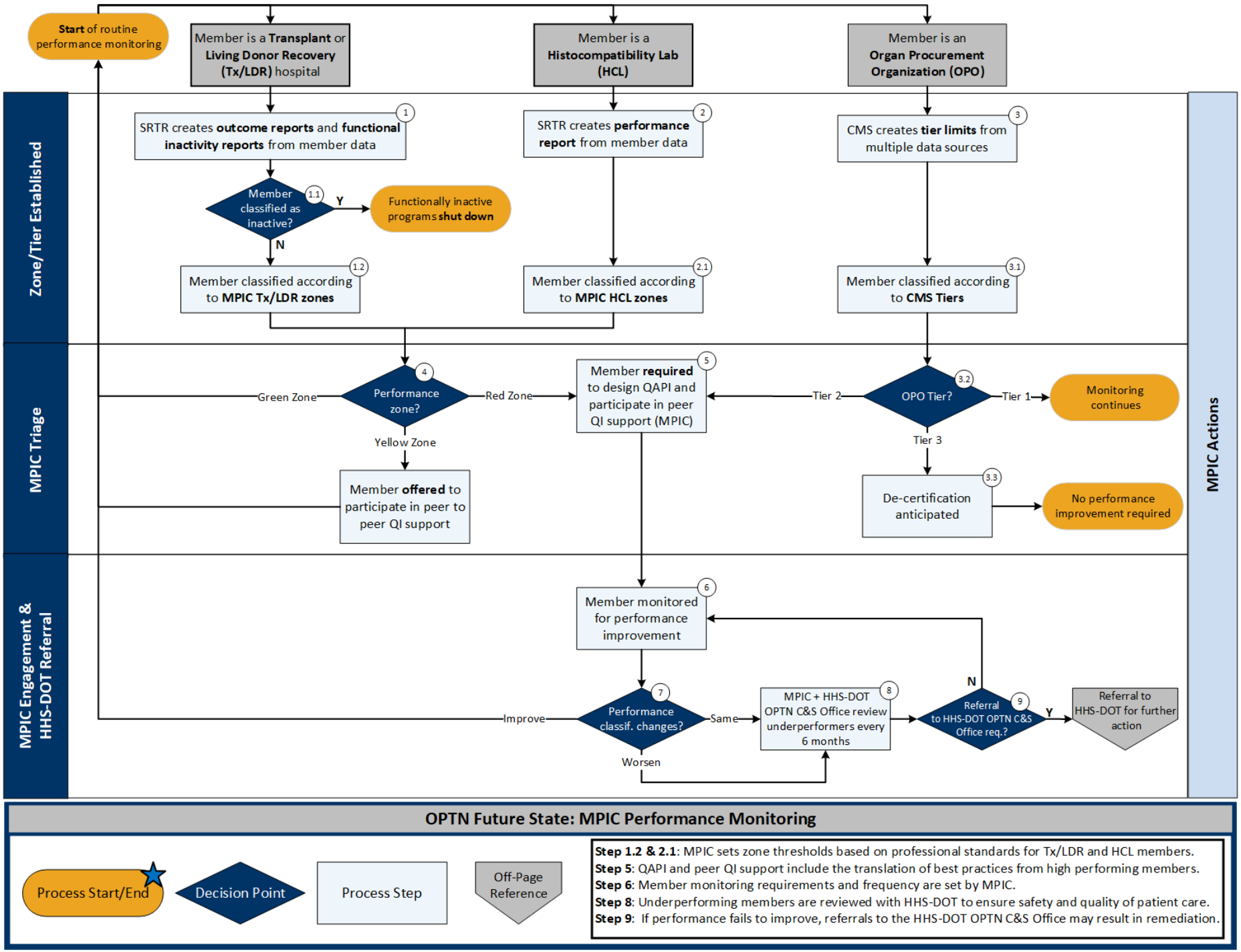
Challenges & Solutions: Full Implementation & Sustainability Phase

Challenge	Solution
Variation in how quickly different member types adopt new criteria	Offer tailored support by member type. Monitor adoption patterns and prioritize outreach to lagging groups.
Confusion about how new criteria will be evaluated or enforced	Clearly communicate the link between membership standards and monitoring practices. Provide examples and case scenarios during training.
Risk that criteria become outdated without structured review	Embed a formal review schedule into MPIC's annual workplan. Assign staff support to track regulatory, scientific, and operational developments that may trigger interim updates.

Target Outcomes: Full Implementation & Sustainability Phase

- ☐ Final membership criteria distributed and accessible to all OPTN members
- ☐ Implementation guidance materials available in multiple formats (written, visual, recorded)
- ☐ Live and recorded support sessions conducted, with attendance tracked
- ☐ Feedback channels activated and monitored
- ☐ Implementation challenges logged and synthesized
- ☐ MPIC adopts a formal schedule and process for ongoing review and update of criteria
- ☐ First review cycle planning initiated within 12–18 months

Appendix 13: OPTN performance monitoring process map



Appendix 14: OPTN member performance improvement process measures

Organ procurement organization process measures

Donor

- **Potential Donor Identification Rate:** Percentage of eligible deaths (where donation is possible) that are identified as potential donors
- **Donor Referral Rate:** Rate at which potential donors are referred to an organ procurement organization (OPO).
- **Onsite Referral Time:** The time it takes for an OPO representative to arrive at the hospital unit where the potential donor is.
- **Conversion Rates** (Nondonor to donor): Percentage of donors/donor families that identified as eligible that change from “no” to “yes”
- **Authorization Rate:** Rate at which consent for organ donation is obtained.
- **Donor Management Time:** Duration of time spent optimizing the donor's condition to improve organ viability.
- **Donor-to-Recipient Match Quality:** Measures of the compatibility between donor and recipient, including blood type and other factors.
- **Donor Optimization Strategies:** Monitoring the use of established protocols and practices to maintain organ viability and function.
- **Yield Measures:** Monitoring the number of organs transplanted per donor, how many organs are used for research, discard rate, and utilization rate.

Organs

- **Organ Retrieval Time:** The time it takes to retrieve organs after a donor is declared dead.
- **Organ Transport Time:** The time it takes to transport organs from the donor hospital to the transplant hospital.
- **Organ Preservation Quality:** Metrics related to the cooling and storage of organs to maintain their function during transport.
- **Organ Distribution within the Donor Service Area (DSA):** The percentage of organs that are transplanted within the OPO’s DSA.
- **Organ out of sequence rate:** The percentage of organs that are transplanted out of sequence.

Transplant hospital process measures

Donor

- **Living Donor Evaluation:** Timeliness and efficiency of evaluating potential living donors.

Organs

- **Hours from First Electronic Offer to Donor Cross Clamp Time:** A measure of how quickly organs are offered to and accepted by transplant hospitals

Recipient

- **New patient referrals:** Count of referrals per month (referral is when the transplant hospital receives the patient referral form)
- **Waitlist volume:** Count of patients listed per month. Total number and by patient characteristics
- **Wait List Management:** Time from referral to evaluation, waitlist enrollment, and notification of waiting list status.
- **Waitlist Mortality Rate:** This measures the percentage of patients on the waitlist who die before receiving a transplant.
- **Surgery Measures:** Adherence to best practices during the transplant surgery, including antibiotic prophylaxis, ABO verification, and surgical techniques.
- **Post-operative Care:** Timely initiation of post-operative care, including medication management, and monitoring for complications.
- **Rejection Prevention:** Adherence to immunosuppressant protocols and monitoring for signs of rejection.
- **Follow-up Care:** Adherence to follow-up schedules and timely address of any post-transplant complications.
- **Patient Education:** Ensuring patients receive adequate education about their condition, medications, and post-transplant care.

Histocompatibility laboratory process measures

Donor

- **Donor-to-Recipient Match Quality:** Measures of the compatibility between donor and recipient, including blood type and other factors.

Operations

- Time from collection of compatibility sample to report of compatibility result
- Time from receipt of compatibility sample to report of compatibility result
- Time from compatibility result to receipt by OPO or transplant hospital
- Time of last sample used for compatibility testing to time of organ transplantation
- Proficiency testing results and interpretation upon receipt from ASHI, CAP, or CLIA for compatibility relevant testing

Appendix 15: Implementation Roadmap – Create a Data Submission and Reporting Process (Sub-Recommendation 2.2, Part 1)

This roadmap outlines the steps needed to develop and implement a structured process for OPTN member data submission and reporting, supporting transparency, benchmarking, and system-wide quality improvement. Though OPTN members already submit data for various purposes, there is no consistent, centralized mechanism for collecting and analyzing data related to process measures, early performance concerns, or learning system participation. This roadmap supports the creation of such a mechanism, grounded in principles of fairness, burden reduction, and meaningful use of data. The implementation is organized across four phases, progressing from scoping and consensus-building to full integration into OPTN operations and oversight processes (see the **Change Management Best Practices** section).

Roadmap Objectives

1. **Develop a standardized framework for member data submission** related to quality improvement, performance benchmarking, and process measure reporting.
2. **Ensure alignment with existing OPTN and SRTR data collection requirements**, minimizing duplication and administrative burden on members.
3. **Establish clear expectations and protocols** for what data is collected, how it is submitted, and how it will be used.
4. **Enable real-time or near-real-time performance insights** through dashboards, summary reports, or benchmarking tools available to members and oversight bodies.
5. **Promote transparency, fairness, and learning** by using submitted data to identify promising practices and early signals of performance risk.

Overview of Roadmap Steps by Implementation Phase

Phase	Steps
Exploration & Planning	1. Establish Vision and Guiding Principles 2. Map Existing Data Flows and Minimize Gaps
Installation	1. Draft Submission Requirements and Technical Specifications 2. Build and Test Submission Interface 3. Finalize Guidance Materials and Pilot Support Model
Initial Implementation	1. Launch Pilot Submission Process 2. Monitor Submission Experience and Identify Pain Points 3. Analyze Submitted Data and Disseminate Benchmarking Report
Full Implementation & Sustainability	1. Scale Submission Process to All OPTN Members 2. Active Reporting and Feedback Mechanism 3. Codify Oversight, Maintenance, and Iterations

Exploration & Planning Phase

This phase focuses on defining the vision, scope, and structure of a new data submission and reporting process. The process will support OPTN-wide learning, quality improvement, and performance monitoring through timely and structured data collection from members. Key activities include mapping current data flows, identifying gaps and overlaps, and engaging stakeholders to co-develop a framework that supports both accountability and capacity-building, without unintentionally creating more burden.

Personnel Involved

- HHS-DOT COR and data policy advisors to set federal expectations and boundaries
- OPTN policy, IT, and data systems staff to map current capabilities and limitations
- SRTR representatives to ensure alignment with existing analytic infrastructure
- OPTN members from each entity type (transplant programs, OPOs, labs) to offer user perspectives
- Optional: external consultants with experience in health system performance measurement, data governance, or digital infrastructure

Resources Needed

- Inventory of existing OPTN and SRTR data collection processes, timelines, and platforms
- Documentation on past member feedback regarding data burden, transparency, and usability
- Examples from external systems (e.g., CMS QIP, AHRQ quality reporting, NSQIP)
- Collaboration tools for co-design and feedback tracking
- Change management best practices related to IT infrastructure and user adoption

Step 1: Establish Vision and Guiding Principles

Develop a shared understanding of why a new data submission process is needed and how it will be used. Align stakeholders around core principles such as data minimization, actionable insights, equity, and trust.

Timeline: One to two months

- Includes two to three workshops or design sessions that includes representatives from all OPTN members types

Step 2: Map Existing Data Flows and Minimize Gaps

Document all data currently submitted by OPTN members, including purposes, timing, and recipients. Identify where current systems are redundant, burdensome, or lack key information needed for performance improvement.

Timeline: Two to three months (sequential to previous step)

- Culminates in a gap analysis and technical assessment

Challenges & Solutions: Exploration & Planning Phase

Challenge	Solution
Stakeholders anticipated fatigue over concerns about increasing data burden	Engage members early, co-develop principles of burden minimization, and show how submitted data will be used to support, not penalize, participants.
Fragmentation across OPTN, SRTR, and external systems	Use mapping to surface duplication and gaps. Work toward interoperability and shared dashboards where possible.
Lack of clarity about how data will be used or protected	Develop transparent governance rules and use agreements early. Build in data access transparency and opt-in pilots where feasible.

Target Outcomes: Exploration & Planning Phase

- ☐ Vision and principles document created and endorsed by HHS-DOT, MPIC, and OPTN BOD
- ☐ Initial stakeholder group convened with representation across OPTN member types
- ☐ Comprehensive data flow map completed, including:
  - Source systems
  - Frequency and format of submission
  - End-users and decision-making contexts
- ☐ Gap analysis identifies:
  - Missing data elements needed for process or performance measures
  - Redundant or burdensome reporting steps
  - Technical limitations of current platforms
- ☐ Preliminary use cases drafted (e.g., for QI dashboards, risk monitoring, or peer benchmarking)

Installation Phase

This phase translates planning into action by building the infrastructure, documentation, and workflows needed to operationalize the new data submission and reporting process. Core activities include drafting and testing submission requirements, integrating them into existing systems where possible, and developing accessible guidance for OPTN members. The focus remains on clarity, efficiency, and usability—ensuring members know what to submit, when, and why, while minimizing additional burden. Stakeholder engagement continues through user testing and refinement cycles.

Personnel Involved

- OPTN IT and data operations teams to design submission interfaces and automate data capture where possible
- Policy and analytics staff to define required data elements and reporting logic
- MPIC and HHS-DOT advisors to confirm alignment with performance monitoring and improvement goals
- Member representatives to test workflows and offer feedback
- Optional: external usability experts or data governance consultants

Resources Needed

- Gap analysis and principles document from the planning phase
- Existing OPTN and SRTR data platforms and APIs
- Prototype interfaces and mock data templates
- Testing environment and feedback collection tools
- Draft communication materials (FAQs, quick-start guides, training decks)

Step 1: Draft Submission Requirements and Technical Specifications

Translate identified data needs into clear reporting templates, including submission frequency, formatting standards, and documentation requirements. Design for automation where possible.

Timeline: Two to three months

- Includes internal vetting and crosswalk with existing data feeds

Step 2: Build and Test Submission Interface

Develop or modify the OPTN member portal to accept the new data elements. Conduct testing with dummy data and engage three to five member organizations from each relevant member type in usability testing and feedback.

Timeline: Three months (sequential to previous step)

- Iterative design with at least two rounds of feedback

Step 3: Finalize Guidance Materials and Pilot Support Model

Create user-facing documentation and train OPTN support staff to assist members with the submission process. Prepare for a soft pilot launch.

Timeline: Concurrent with previous step

Challenges & Solutions: Installation Phase

Challenge	Solution
Difficulty integrating new submissions with members' existing IT systems	Offer multiple submission options (e.g., manual entry, flat file upload, API); provide templates and support early.
Lack of clarity or consistency in how data will be used	Pair rollout with clear documentation and educational sessions that explain use cases and safeguards.
Risk of early non-compliance due to confusion or onboarding issues	Implement a "grace period" during pilot rollout; use that time to fine-tune requirements and support workflows.

Target Outcomes: Installation Phase

- ☐ Draft technical specifications completed and approved by HHS-DOT and MPIC
- ☐ Submission templates and formatting guides developed
- ☐ Submission portal functionality built and tested
- ☐ Usability testing completed with at least three entity types (e.g., OPOs, transplant programs, labs)
- ☐ Member guidance materials drafted, including:
  - Submission instructions
  - Visual walkthroughs
  - Troubleshooting tips
- ☐ Support model in place, with OPTN staff trained to field questions and track pain points

Initial Implementation Phase

This phase activates the new data submission and reporting process by launching it with a small cohort of OPTN members, monitoring early implementation, and making refinements based on real-world feedback. The focus is on identifying and addressing usability issues, improving documentation, and building member confidence in the system. This is also the phase during which downstream outputs, for instance dashboards or analytic summaries, begin to take shape to demonstrate the value of participation.

Personnel Involved

- OPTN member services and technical support staff to onboard pilot participants and troubleshoot issues
- Analytics staff to begin processing submitted data and testing its utility for internal and member-facing reporting
- MPIC and HHS-DOT to monitor participation, assess usefulness of early outputs, and guide adjustments

- Pilot participants across member types to serve as early adopters and feedback sources
- Communications staff to begin preparing public-facing updates and onboarding materials for broader rollout

Resources Needed

- Submission portal and backend analytics environment
- Training materials, submission templates, and user support channels
- Pilot feedback collection tools (e.g., surveys, office hours, structured debrief forms)
- Data security protocols and access logs to track system use and safeguard member data
- Draft mock-ups of proposed benchmarking or feedback reports

Step 1: Launch Pilot Submission Process

Invite five to ten OPTN members (across entity types) to participate in the first wave of submissions. Provide hands-on onboarding and support.

Timeline: Two months

- Includes rolling enrollment and technical assistance as needed

Step 2: Monitor Submission Experience and Identify Pain Points

Track what works, what breaks, and what's unclear. Host debrief sessions and gather structured feedback from users and OPTN support staff.

Timeline: One to two months (concurrent with previous step)

- Daily to weekly feedback loops encouraged during this phase

Step 3: Analyze Submitted Data and Disseminate Benchmarking Report

Begin processing submitted data to test visualizations, identify outliers, and evaluate whether the data is supporting early insights. Prepare internal use cases and member-facing feedback reports.

Timeline: Ongoing. Concurrent with previous steps and continues into next phase.

- Deliver draft dashboard or scorecard mock-ups for review

Challenges & Solutions: Initial Implementation Phase

Challenge	Solution
Technical difficulties submitting or formatting data	Provide one-on-one onboarding, template validators, and live help sessions during pilot
Submitted data is incomplete, inconsistent, or lacks interpretability	Conduct initial quality review with feedback to members; adjust templates and documentation to clarify requirements
Members don't see the benefit of participating	Share early wins (e.g., visualizations or insights from the pilot), and solicit testimonials from early adopters for use during scale-up

Target Outcomes: Initial Implementation Phase

- ☐ Pilot launch completed with representation from multiple OPTN member types
  - 75% of pilot participants successfully complete first data submission
- ☐ System usability issues documented and categorized
- ☐ Feedback collected from at least three types of stakeholders (submitters, support staff, data analysts)
- ☐ Data quality checks performed and early analytic use cases tested
- ☐ First drafts of dashboards or benchmarking summaries created and shared internally

Full Implementation & Sustainability Phase

This phase brings the data submission and reporting process to full operational status across all OPTN member types. Activities focus on onboarding all members, supporting adoption at scale, and institutionalizing the submission process within OPTN oversight and quality improvement operations. With foundational workflows in place, the emphasis shifts to data use, system learning, and iterative improvements. Reporting outputs such as dashboards, benchmarking summaries, and feedback loops are activated to promote engagement, transparency, and value.

Personnel Involved

- OPTN staff to manage ongoing data collection, user support, and system maintenance
- MPIC and HHS-DOT to integrate data into performance review, policy development, and learning activities
- Member organizations to routinely submit data and engage with resulting insights
- Analytics teams to maintain and refine dashboards, performance flags, or quality signals
- Optional: independent evaluators to assess utility and burden of ongoing data submission process

Resources Needed

- Fully functional data submission portal integrated into the OPTN member platform
- Scalable training materials and communication products
- User support infrastructure (ticketing system, helpdesk, knowledge base)
- Public and member-facing data products (dashboards, scorecards, reports)
- Governance documentation and revision triggers for data submission requirements

Step 1: Scale Submission Process to All OPTN Members

Roll out the finalized process across all member types, using lessons learned from the pilot to streamline onboarding and technical assistance.

Timeline: Three to six months

- Phased or entity-specific rollout may be used

Step 2: Activate Reporting and Feedback Mechanisms

Publish or provide access to dashboards, benchmarking tools, and feedback reports that translate submitted data into actionable insights. Promote use through regular communication and optional learning sessions.

Timeline: Ongoing. Concurrent with previous step; continues indefinitely

- Regular update cycle and feedback loop established

Step 3: Codify Oversight, Maintenance, and Iterations

Develop a process for regularly reviewing submission requirements, updating templates, and phasing in new data elements. Embed submission compliance into routine member expectations.

Timeline: Ongoing. Begins in parallel with full rollout; formalized in Year 1 post-rollout

Challenges & Solutions: Full Implementation & Sustainability Phase

Challenge	Solution
Sustaining member participation and data quality over time	Embed feedback loops, provide real value through reporting, and periodically highlight use cases that demonstrate impact
Risk of the system becoming outdated or disconnected from policy and clinical realities	Establish regular review cadence; include standing agenda item at MPIC and policy committee meetings to consider updates
Fragmentation of data use or lack of coordination across OPTN and SRTR	Develop shared reporting goals and technical alignment strategies; seek opportunities to co-develop outputs and analytics tools

Target Outcomes: Full Implementation & Sustainability Phase

- ☐ 90%+ of OPTN members onboarded and actively submitting data by end of rollout period
- ☐ Submission success rates tracked and technical issues reduced over time
- ☐ Member-facing reporting tools launched, with usage metrics tracked (e.g., logins, downloads)
- ☐ Routine analytic use of data embedded into MPIC oversight, learning collaboratives, or early warning systems
- ☐ Maintenance and iteration plan adopted, including:
    - Review of submission elements every one to two years
    - User feedback surveys
    - Sunset or revision criteria for data elements
- ☐ Evaluation plan initiated to assess impact, burden, and areas for improvement

Appendix 16: Implementation Roadmap – Develop a Peer-to-Peer Performance Review Process Led by the MPIC (Sub-Recommendation 2.2, Part 2)

This roadmap outlines the creation of a structured, MPIC-led peer-to-peer performance review process designed to support OPTN members exhibiting signs of performance risk. The process provides a confidential, collegial space for members to receive constructive input from experienced peers, identify opportunities for improvement, and access tailored technical assistance, before compliance actions become necessary. By facilitating collaborative learning and early intervention, the MPIC will help foster a more responsive and equitable oversight ecosystem, reduce stigma associated with underperformance, and build a shared commitment to quality improvement across the transplant community. The roadmap is organized across four implementation phases and emphasizes principles of transparency, psychological safety, and system-level learning (see the **Change Management Best Practices** section).

Roadmap Objectives

1. **Design a structured peer-to-peer review process** for OPTN members exhibiting early signs of risk or opportunity for growth.
2. **Recruit and train a diverse pool of peer reviewers** with expertise in transplant operations, performance improvement, and systems thinking.
3. **Develop transparent referral criteria and selection protocols** to ensure fairness, clarity, and appropriate match between reviewers and reviewed programs.
4. **Pilot the review process in a small cohort** to refine workflows, documentation practices, and participant experience.
5. **Embed the process into the broader OPTN performance improvement framework**, positioning the MPIC as a trusted support partner and learning convener.

Overview of Roadmap Steps by Implementation Phase

Phase	Steps
Exploration & Planning	1. Define Process Objectives and Use Cases 2. Identify Roles, Responsibilities, and Qualifications of the MPIC Quality Improvement Peers 3. Develop the processes and materials to be used in the peer-to-peer sessions
Installation	1. Recruit and Train Peer Reviewers 2. Finalize Review Process Materials and Test Workflows 3. Identify and Confirm Pilot Participants
Initial Implementation	1. Conduct Pilot Peer Reviews 2. Gather and Analyze Feedback 3. Refine Process Based on Pilot Results

Full Implementation & Sustainability	1. Launch Full Program Rollout 2. Embed Process into OPTN Operations 3. Evaluate, Iterate, Sustain

Exploration & Planning Phase

This phase establishes the conceptual and structural foundation for launching a peer-to-peer performance review process under the leadership of the MPIC. The goal is to design a process that facilitates early, non-punitive support for OPTN members showing signs of underperformance or systemic strain. Early efforts center on identifying use cases, establishing trust-building principles, determining how members will be selected for review, and clarifying the qualifications, training, and protections for peer reviewers. The process must be voluntary (or invitation-based with member consent), confidential, and clearly distinguished from compliance enforcement mechanisms. Planning will draw from successful models used in other health system peer review programs and integrate feedback from potential participants.

Personnel Involved

- MPIC leadership to define process goals, referral criteria, and oversight structure
- HHS-DOT advisors to clarify scope and alignment with federal goals and non-punitive boundaries
- OPTN policy and operations staff to document existing member support mechanisms
- Transplant program and OPO representatives to offer user perspectives and inform design
- Optional: external advisors with experience in peer learning, just culture, or academic detailing

Resources Needed

- Examples of peer review models in health care (e.g., clinical coaching, academic detailing, NIH study section principles)
- OPTN and SRTR performance data to identify early indicators of strain or variation
- Legal and policy guidance to ensure confidentiality and define data-sharing parameters
- Stakeholder engagement materials (e.g., strawman process flows, referral scenarios, interview guides)

Step 1: Define Process Objectives and Use Cases

Clarify what types of concerns would trigger a peer review invitation (e.g., falling into the red or yellow performance zone for transplant programs/CMS' tier 2 for OPOs; self-referral; other persistent quality issues). Define how the process will support improvement rather than discipline.

Timeline: One to two months

- Includes internal strategy sessions and external stakeholder interviews

Step 2: Identify roles, responsibilities, and qualifications of the MPIC quality improvement peers

Outline the responsibilities of the MPIC members who will serve as quality improvement peers, and needs for additional experts to support as needed; determine how the peers reviewers will be recruited and trained, and what safeguards (e.g., conflict of interest, confidentiality) will be built into the process.

Timeline: Two to three months (sequential to previous step)

- Includes focus groups or surveys with potential reviewers and review recipients

Step 3: Develop the processes and materials to be used in the peer-to-peer sessions

Develop standardized agendas and documentation for the peer-to-peer quality improvement sessions; develop training materials to support MPIC peer reviewers.

Timeline: Two to three months (sequential to previous step)

Challenges & Solutions: Exploration & Planning Phase

Challenge	Solution
Misperception that peer review is punitive or reputationally damaging	Brand the process as supportive, separate from compliance, and rooted in collegial coaching. Include participant testimonials in future communications.
Difficulty recruiting qualified reviewers from diverse practice settings	Offer stipends, recognition, and structured onboarding. Build a reviewer pool that reflects a range of geographies, program sizes, and roles.
Concerns about data use or confidentiality	Clearly define data protections and limits. Use de-identified or aggregate-level data when possible. Implement non-disclosure agreements for all reviewers.

Target Outcomes: Exploration & Planning Phase

- ☐ MPIC formally charged with developing and piloting peer review function
- ☐ Process goals and referral use cases clearly defined, including:
- ☐ Characteristics of “early risk” or coaching opportunities
- ☐ Triggers for invitation to review
- ☐ Boundaries between this process and compliance action
- ☐ Draft reviewer role description and qualifications established
- ☐ Initial reviewer training principles and ethical safeguards identified
- ☐ Engagement conducted with at least two to three types of OPTN members to gather input on design

Installation Phase

This phase focuses on operationalizing the peer-to-peer performance review process through the development of infrastructure, recruitment of peer reviewers, and drafting of all materials and workflows needed to support the pilot. Emphasis is placed on making the process structured but flexible, respectful of participants' time and reputations, and deeply aligned with the MPIC's learning and support mission. Activities include developing templates, training modules, reviewer onboarding processes, and communications to ensure clarity, transparency, and usability for all participants.

Personnel Involved

- MPIC and OPTN policy staff to finalize referral and review protocols
- Legal and compliance advisors to establish confidentiality protections and role boundaries
- OPTN communications staff to develop participant-facing materials
- Recruited peer reviewers to undergo training and provide feedback on the process design
- Review participants (members selected for review) to assist in co-designing feedback experience
- Optional: third-party facilitator or coaching consultant to support training and process refinement

Resources Needed

- Finalized peer review protocol (including referral pathways, reviewer assignment logic, and communication timeline)
- Reviewer recruitment plan, screening process, and onboarding materials
- Training curriculum for reviewers (including role expectations, confidentiality, communication skills)
- Participant-facing guidance (e.g., welcome letter, what to expect, timeline overview)
- Templates for:
    - Referral forms
    - Reviewer observations
    - Feedback memos or discussion guides
- IT tools for scheduling, documentation, and secure communication

Step 1: Recruit and Train Peer Reviewers

Launch the MPIC reviewer pool with a targeted recruitment effort across OPTN member types. Onboard volunteers with structured training that emphasizes confidentiality, systems thinking, and nonjudgmental communication.

Timeline: Two to three months

- Aim for diversity across geography, experience, and entity type

Step 2: Finalize Review Process Materials and Test Workflows

Refine and test each step of the process with simulated cases. Ensure clarity, consistency, and usability of all tools. Conduct tabletop exercises or dry runs with reviewers and staff.

Timeline: Two months (concurrent with previous step)

Step 3: Identify and Confirm Pilot Participants

Select two to three member organizations (with consent) for initial reviews. Walk them through expectations, ensure consent, and schedule sessions.

Timeline: One month (sequential to previous steps)

- Pilot launch begins at end of this phase

Challenges & Solutions: Installation Phase

Challenge	Solution
Difficulty creating a safe, trusting environment for reviewed members	Emphasize confidentiality, include preview materials, and offer opportunity to shape the process. Position MPIC and reviewers as coaches, not auditors.
Reviewer burnout or lack of follow-through.	Offer scheduling flexibility, clear time expectations, and recognition for service. Consider rotating terms or caps on number of reviews per year
Low clarity or inconsistent execution during early reviews	Provide tightly structured templates and scripts. Debrief after each review to improve tools and expectations iteratively.

Target Outcomes: Installation Phase

- ☐ Peer reviewer pool established, trained, and documented
- ☐ Reviewer toolkit finalized, including:
  - Role guidelines
  - Communication templates
  - Observation and documentation tools
- ☐ Member-facing materials created and tested with user input
- ☐ End-to-end workflow tested through at least one dry run
- ☐ Consent process and referral logic operationalized
- ☐ Pilot participants selected and briefed for initial implementation

Initial Implementation Phase

This phase launches the peer-to-peer review process with a small, diverse group of OPTN member organizations, providing the first real-world test of how the system functions and how it is experienced by participants. MPIC members, peer reviewers, and OPTN staff observe the effectiveness of workflows, review quality, communication tone, and member reception. Structured debriefs and process tracking ensure that lessons from the pilot are captured to refine and scale the program in future phases.

Personnel Involved

- Trained peer reviewers to conduct the performance review sessions and draft feedback
- OPTN staff to facilitate scheduling, support logistics, and monitor process adherence
- MPIC members to provide oversight and adjudicate any necessary process improvements
- Reviewed members (OPTN organizations selected for the pilot) to offer feedback on clarity, tone, and usefulness
- HHS-DOT advisors to observe and assess alignment with learning health system goals

Resources Needed

- Fully functioning process documentation (e.g., referral pathway, review agenda, confidentiality forms)
- Tracking tools for reviewer-participant interactions, scheduling, and feedback completion
- Participant experience survey and interview guides
- Debrief templates for peer reviewers
- Summary dashboard or shared document for capturing real-time lessons learned

Step 1: Conduct Pilot Peer Reviews

Facilitate the first round of peer reviews with two to three OPTN members. Follow structured workflows, ensure reviewer preparation, and collect post-review feedback.

Timeline: Two to three months

- Includes reviewer preparation, session execution, and post-review documentation

Step 2: Gather and Analyze Feedback

Collect structured input from reviewers, reviewed organizations, and support staff. Analyze where breakdowns occurred, what worked well, and what needs clarification or revision.

Timeline: One to two months (concurrent with previous step)

- Includes debrief meetings, feedback surveys, and content analysis

Step 3: Refine Process Based on Pilot Results

Use findings to revise reviewer materials, member-facing documentation, and overall process workflows. Make changes before moving to full-scale implementation.

Timeline: One month (sequential to previous steps)

- Updated version of the process is prepared for broader rollout

Challenges & Solutions: Initial Implementation Phase

Challenge	Solution
Members feel defensive or unclear about the goals of the review	Use introductory sessions and clear communications to frame the review as supportive, confidential, and improvement-focused
Reviewers feel unsure about how candid or directive to be	Provide debriefs, reflective tools, and case-based training to guide tone and content of feedback
Valuable suggestions from the pilot get lost or underprioritized	Use a centralized feedback tracker, and schedule a formal MPIC review session to act on pilot findings before scale-up

Target Outcomes: Initial Implementation Phase

- ☐ Two to three peer review sessions completed using structured protocols
- ☐ All reviewed members complete post-review feedback surveys/interviews
- ☐ Reviewers submit structured debriefs documenting insights and areas of confusion
- ☐ Issues tracked across all reviews (e.g., documentation gaps, tone concerns, unclear roles)
- ☐ Process refinement plan created and adopted by MPIC
- ☐ Updated templates and guidance produced for future implementation

Full Implementation & Sustainability Phase

This phase scales the peer-to-peer review process to full operational capacity, ensuring that it becomes a recognized, trusted component of the OPTN performance improvement framework. The focus is on normalizing participation, maintaining a diverse and skilled reviewer pool, and institutionalizing continuous feedback mechanisms to improve the process over time. As this model matures, it also serves as a key tool for early detection of system risks, dissemination of promising practices, and strengthening a shared culture of accountability and support.

Personnel Involved

- MPIC leadership to oversee process quality, trends in participation, and learning loops
- OPTN staff to coordinate review logistics, support communication, and track engagement metrics
- Peer reviewers to conduct reviews and participate in continuous training and evaluation
- Reviewed members to share experiences and contribute to system learning
- HHS-DOT advisors to ensure alignment with national oversight and improvement goals

Resources Needed

- Finalized, publicly available documentation outlining review goals, process steps, and confidentiality protections
- Sustained reviewer training and recruitment processes (e.g., annual onboarding cycle, refresher training)
- Knowledge management system to track trends, emerging themes, and impact
- Feedback loops for reviewers and reviewed members to suggest improvements
- Optional: integration with learning collaboratives, improvement coaching, or dashboard tools

Step 1: Launch Full Program Rollout

Require peer-to-peer review for a set of OPTN members (i.e., red performance zone for transplant programs/CMS' tier 2 for OPOs). Offer peer-to-peer services to others (e.g., yellow performance zone for transplant programs, those who self-refer, others with performance concerns).

Timeline: Three to six months

- Ongoing availability after launch

Step 2: Embed Process into OPTN Operations

Integrate review outcomes into broader learning system components (e.g., quality dashboards, MPIC learning reviews). Maintain reviewer pool capacity and track system-level insights.

Timeline: Ongoing

- Updated annually or as needed

Step 3: Evaluate, Iterate, and Sustain

Use structured evaluation to monitor process impact, member experience, and reviewer feedback. Refine materials, training, and referral criteria over time to preserve effectiveness and relevance.

Timeline: Ongoing with annual reviews

- May include member surveys, case studies, and impact summaries

Challenges & Solutions: Full Implementation & Sustainability Phase

Challenge	Solution
Process may be viewed as duplicative or redundant over time	Regularly revisit use cases and update value proposition based on participant feedback and system needs
Risk of reviewer drift or inconsistency in tone, approach, or feedback quality	Provide case-based refresher training and peer learning for reviewers; audit and debrief review sessions periodically
Sustaining engagement from members with limited resources or low trust	Highlight success stories, provide flexible participation options, and ensure tangible value (e.g., coaching, insights, tools)

Target Outcomes: Full Implementation & Sustainability Phase

- ☐ 10+ OPTN members complete peer reviews within first year of rollout
- ☐ Reviewer pool maintained with appropriate diversity and annual refresher training
- ☐ Participation satisfaction rates exceed 80% among both reviewers and reviewed organizations
- ☐ Common improvement themes tracked and fed into learning collaboratives, guidance materials, or OPTN policy discussion
- ☐ Annual review and refinement cycle adopted by MPIC
- ☐ Process becomes part of OPTN's broader performance improvement and system learning strategy

Appendix 17: Implementation Roadmap – Develop and Launch an OPTN Performance Improvement Learning System (Sub-Recommendation 2.2, Part 3)

The OPTN Performance Improvement Learning System will serve as a key mechanism for supporting the OPTN's transition to a more proactive, system-oriented approach to accountability, transparency, and continuous improvement. The OPTN Learning System is intended to provide a platform for data-driven learning, member-to-member sharing, and collaborative quality improvement across the organ procurement and transplantation community. Development of the OPTN Learning System will proceed in a phased manner, beginning with shared system-wide components (such as the OPTN Learning System platform, governance structures, and foundational learning resources), while enabling the concurrent development of audience-specific learning streams. To ensure long-term success, the OPTN Learning System will be built through a process that balances federal leadership with strong bottom-up engagement: member-driven innovations, participant champions, and stakeholder co-creation will be actively supported and encouraged. The OPTN Learning System will also draw on best practices from national learning system frameworks to ensure alignment with current healthcare quality improvement approaches. Through this structure, the OPTN Learning System will promote a culture of continuous learning, foster trust and transparency, and enable sustainable improvement across OPTN functions.

Roadmap Objectives

1. **Establish foundational Learning System platform** and governance structures to support data-driven learning, member-to-member sharing, and collaborative quality improvement
2. **Develop a phased, audience-aware Learning System architecture** that enables concurrent but differentiated learning streams for OPOs, transplant programs, and potential future collaborative learning initiatives
3. **Foster bottom-up engagement, participant ownership, and member-driven innovation** by supporting participant champions and co-creation of OPTN Learning System components
4. **Embed continuous learning processes** that promote accountability, transparency, trust, and quality improvement across OPTN functions
5. **Align Learning System components** with national learning system frameworks and best practices in healthcare quality improvement
6. **Establish mechanisms for ongoing stakeholder** input, feedback loops, and iterative refinement to ensure the Learning System remains responsive, valued, and sustainable

Overview of Roadmap Steps by Implementation Phase:

Phase	Steps
Exploration & Planning	1. Define Vision and Scope 2. Convene Member Specific Workgroups 3. Conduct Stakeholder Engagement and Needs Assessments 4. Develop Implementation and Communication Plan 5. Facilitate Review and Buy-in
Installation	1. Develop and Launch Learning System Platform 2. Launch Learning Collaboratives 3. Launch Initial Learning Activities and Resources 4. Refine Learning System Components 5. Establish Governance Structures
Initial Implementation	1. Expand Data Reporting and Dashboards 2. Broaden Learning Collaborative Offerings 3. Establish Regular Learning Events and Communities of Practice 4. Strengthen Dissemination and Feedback Loops
Full Implementation & Sustainability	1. Sustain and Evolve 2. Strengthen Integration 3. Support Continuous Refinement 4. Monitor System Impact

Exploration & Planning Phase

The Exploration & Planning phase establishes the foundation for the OPTN Learning System. This phase focuses on defining the system's vision, scope, and governance, commissioning member type learning streams, and engaging members to identify priorities and potential champions. Early planning is structured to promote member-driven innovation, foster ownership, and ensure that the OPTN Learning System reflects the needs of its participants.

Personnel Involved

- Members of the OPTN Learning System Steering Group
- OPTN contractor leadership and project management staff
- Member type–specific working group members (OPO Learning System Working Group, Transplant Program Learning System Working Group, and any cross-cutting learning groups as commissioned)
- External quality improvement experts (as advisors or working group participants)
- Identified member champions within each member type
- Stakeholder engagement specialists (to support needs assessment and member input processes)
- Communications specialists (to support early planning for engagement and transparency)

Resources Needed

- Staff time for Learning System Steering Group members and OPTN contractor staff
- Staff time for member type–specific working groups
- Platforms and tools to support stakeholder engagement activities (interviews, surveys, listening sessions)
- Tools to support collaborative planning (e.g., project management and document sharing platforms)
- Budget to support participation of external quality improvement experts
- Resources for drafting and refining initial implementation and communication plans
- Resources to support two-phase review and buy-in processes, including meeting support and member communications

Step 1: Define Vision and Scope

Convene a OPTN Learning System steering committee comprised of a small number of representatives drawn from the OPTN contractor(s), MPIC members, external quality improvement experts, and OPTN member types. The role of the committee is to provide strategic oversight and guide phased OPTN Learning System development and to define the system's vision, scope, and guiding principles, consistent with Sub-Recommendation 2.2. This framing will clarify the intended purpose of the Learning System, its core values (transparency, trust, continuous improvement), and its structural approach, balancing system-wide components with member specific learning streams. This high-level framework will ensure that stream-specific planning efforts proceed within a clear, shared understanding of the OPTN Learning System architecture.

Timeline: Four to six weeks

- Must be completed before member specific learning streams commence

Step 2: Convene Member Specific Workgroups

The OPTN Learning System steering committee formally commissions member-specific working groups tasked with conducting bottom-up planning for their respective learning streams, in alignment with the overall OPTN Learning System vision and architecture, to lead planning for their respective learning streams. At a minimum, this should include groups for transplant hospitals, organ procurement organizations (OPOs), and histocompatibility labs, with the potential for additional working groups to support cross-cutting collaborative learning activities as appropriate. Each working group should be composed primarily of representatives of the member type it serves, with participation from identified member champions, quality improvement experts, and other key stakeholders. This structure is intended to promote trust, member ownership, and responsive design for each stream.

Timeline: One month (sequential to previous step)

- Light coordination from Steering Committee allows groups to launch in parallel

Step 3: Conduct Stakeholder Engagement and Needs Assessments

Each member specific working group should conduct its own stakeholder engagement and needs assessment to inform the design of its learning stream. Using methods such as interviews, surveys, and facilitated listening sessions, each working group should identify: (1) the types of learning activities members value most; (2) barriers to participation in learning collaboratives; (3) priority topics and improvement areas; and (4) preferred formats and platforms for learning. In addition, each working group should seek to identify potential member champions to help lead and promote learning activities within their member type.

Timeline: Two to three months (sequential to previous step)

- Includes time at the end for analysis and synthesis of findings

Step 4: Develop Implementation and Communication Plan

Based on the results of their stakeholder engagement and needs assessment, each member type-specific working group should develop an initial implementation and communication plan for its learning stream. Each plan should include: (1) timeline and milestones; (2) roles and responsibilities; (3) required resources and budget; (4) communication and engagement strategies to build member awareness, buy-in, and participation; and (5) metrics to monitor progress and impact. Developing these plans at the stream level will allow each member type to move at an appropriate pace and to tailor learning activities to their specific needs and context.

Timeline: One to two months (sequential to previous step)

- Conducted in parallel across streams
- Includes time for review and refinement with working groups and Steering Committee

Step 5: Facilitate Review and Buy-in

To build the broad support necessary for a successful OPTN Learning System, each member specific working group should facilitate a two-phase review and buy-in process for its initial implementation and communication plan to ensure alignment between member-driven innovation and federal leadership. Phase 1 should focus on member-level review and input within the respective member type community. This will foster bottom-up ownership and ensure that plans reflect the needs and perspectives of those who will participate. Phase 2 should present the refined plans to HHS-DOT leadership and the OPTN BOD for review, input, and formal approval to proceed.

Timeline: Six to eight weeks (sequential to previous step)

- Phase 1 (member-level review/input): Three to four weeks
- Phase 2 (OPTN BOD review/input): Three to four weeks

Challenges & Solutions: Exploration & Planning Phase

Challenge	Solution
Risk of misalignment between Steering Group vision and member type–specific needs and priorities	Establish clear two-way communication between the Steering Group and member type–specific working groups; use iterative feedback loops to refine the OPTN Learning System vision and scope based on member input.
Difficulty securing active participation from members and champions during the planning phase	Leverage stakeholder engagement processes to identify and recruit trusted member champions; clearly communicate the value of participation and the opportunity to shape the OPTN Learning System development.
Perception that the OPTN Learning System planning is too top-down or not sufficiently responsive to member needs	Conduct stream-specific planning and needs assessments led by member type–specific working groups; prioritize transparency and member-driven innovation throughout planning activities.
Challenges coordinating planning timelines across multiple member type–specific working groups	Use the Steering Committee to provide light-touch coordination and promote shared understanding, while allowing member type–specific working groups to proceed at appropriate, asynchronous paces.

Target Outcomes: Exploration & Planning Phase

- ☐ The vision, scope, and guiding principles for the OPTN Learning System are clearly defined and documented by the Steering Committee
- ☐ Member type–specific working groups (e.g., for OPOs, transplant hospitals, histocompatibility labs) are formally commissioned and launched
- ☐ Initial stakeholder engagement and needs assessments are completed for each member type, with findings documented and used to inform learning stream design
- ☐ Potential member champions are identified and engaged to support planning and future implementation
- ☐ Initial stream-specific implementation and communication plans are developed and refined through member-driven planning
- ☐ A two-phase review and buy-in process is conducted for each learning stream, securing both member-level and leadership-level support for phased OPTN Learning System implementation

Installation Phase

In the Installation phase, the initial infrastructure of the OPTN Learning System is built and early learning activities are launched within each member type learning stream. The focus is on standing

up core components, piloting key elements, and supporting member ownership through evolving governance structures. Communication and engagement remain central to building participation and trust.

Personnel Involved

- Members of learning stream working groups
- Member champions and active participants in learning collaboratives and other OPTN Learning System activities
- OPTN contractor staff supporting platform development, data infrastructure, and learning activities
- OPTN contractor staff supporting dissemination and member engagement
- Learning System Steering Committee members (as advisors during the transition to member-driven governance)
- External quality improvement experts (to support learning design and facilitation)

Resources Needed

- Platform development resources to support OPTN Learning System infrastructure
- Data collection and analysis resources to support embedded measurement within learning collaboratives
- Facilitation resources for learning collaboratives and one-off learning activities
- Communications resources to support member engagement, dissemination, and trust-building
- Resources to support transition to member-driven governance, including governance design and member leadership development
- Tools to support continuous feedback and iterative refinement of OPTN Learning System components

Step 1: Develop and Launch Learning System Platform

As an early priority in the Installation phase, the OPTN contractor should develop and launch the OPTN Learning System platform to support both member specific learning streams and cross-cutting learning activities ***and*** provide the technical foundation for OPTN Learning System activities. The platform should host data dashboards, learning resources, and collaboration spaces, and may leverage existing OPTN platforms or external systems, as appropriate. Initial platform development should emphasize usability, member accessibility, and support for iterative refinement based on member feedback.

Timeline: Three to four months

- Includes time for member input, usability testing, and initial launch
- Platform can continue evolving in later phases

Step 2: Launch Learning Collaboratives

Each member specific working group, with support from the OPTN contractor, should design and launch initial learning collaboratives focused on priority topics identified in the previous phase. Learning collaboratives should be structured to foster member-to-member learning, collaborative quality improvement, and continuous system learning, using an iterative approach such as Plan-Do-Study-Act (PDSA). As part of the collaborative process, participating members should collaboratively define and refine key process measures and data collection priorities to support learning and improvement goals. Data collection and reporting should evolve in parallel with collaborative activities, ensuring that data is meaningful to participants and supports actionable learning.

Timeline: Two to three months (sequential to previous step)

- Time built in for early PDSA cycles and participant feedback

Step 3: Launch Initial Learning Activities and Resources

In parallel with the launch of initial learning collaboratives, member type-specific working groups and the OPTN contractor should initiate one-off learning activities and resources to broaden participation and support flexible learning. These may include learning bulletins, targeted reports, webinars, workshops, case studies, community forums, or other learning opportunities identified through early member input. Offering a range of one-off and flexible learning opportunities ensures that members can engage with the OPTN Learning System in ways that align with their needs and capacity. Early activities should be designed to build awareness, demonstrate value, and foster trust among members, while providing additional channels for member-driven innovation and continuous learning,

Timeline: Two to three months (concurrent with previous step)

- Should be launched early enough to support member engagement during Installation

Step 4: Refine Learning System Components

Throughout the Installation phase, the OPTN Learning System Steering Committee, member specific working groups, and the OPTN contractor should work collaboratively to refine components based on feedback from initial learning collaboratives, one-off activities, and platform use. Feedback should be gathered from participating members, member champions, and working group participants through structured and informal channels. Refinement may include updates to OPTN Learning System platform features, data collection processes, collaborative models, and learning resources. Embedding iterative refinement at this stage helps ensure the OPTN Learning System remains responsive to member needs, supports member ownership, and aligns with evolving priorities

Timeline: Two to three months (concurrent with previous steps)

Step 5: Establish Governance Structures

As the OPTN Learning System matures, it is critical to establish member-driven governance structures to support its ongoing sustainability and evolution. The Steering Committee should work with member specific working groups, member champions, and the OPTN contractor to define a governance model that ensures the OPTN Learning System remains responsive to member needs, owned by participants, and aligned with broader OPTN goals. Governance structures should include mechanisms for ongoing member input, shared decision-making, and transparent communication about OPTN Learning System priorities and activities. This transition from initial Steering Committee oversight to member-driven governance will promote trust, engagement, and long-term relevance of the OPTN Learning System. Finalizing the governance prepares OPTN Learning System for long-term sustainability.

Timeline: Two to three months (concurrent with previous steps)

Challenges & Solutions: Installation Phase

Challenge	Solution
Difficulty aligning platform functionality with evolving member needs	Engage members early in platform design and testing; use iterative feedback loops to refine features and usability.
Variation in readiness across member type learning streams	Allow learning streams to proceed at appropriate paces; provide flexible supports and coordination through governance structures.
Limited member capacity to engage in initial learning activities	Design learning collaboratives and one-off activities to be flexible and responsive to member time and resource constraints.
Challenges in transitioning to member-driven governance	Provide leadership development and facilitation support; engage member champions to build ownership and trust in new governance structures.

Target Outcomes: Installation Phase

- ☐ Learning System platform is developed and launched to support member type learning streams
- ☐ Initial learning collaboratives are launched within each member type learning stream
- ☐ One-off learning activities and resources are initiated to broaden participation and engagement
- ☐ Learning System components are refined based on early feedback from members
- ☐ Member-driven governance structures are established to guide ongoing Learning System development and ownership

Initial Implementation Phase

The Initial Implementation phase focuses on scaling the OPTN Learning System across member types and embedding learning processes into broader OPTN culture. Member type learning streams expand their activities and deepen integration with OPTN processes, while maintaining flexibility and responsiveness to member needs. Strengthened feedback loops and member-driven governance help sustain engagement and alignment with improvement goals.

Personnel Involved

- Members of member specific OPTN Learning System working groups
- Member champions and participants within each Learning System stream
- OPTN contractor staff supporting OPTN Learning System platform operations, data analysis, and facilitation of learning activities
- OPTN contractor staff supporting dissemination and feedback loops
- Members of OPTN Learning System governance structures (transitioning to member-driven governance during this phase)
- External collaborators and quality improvement experts (as needed to support stream-specific initiatives)
- OPTN committee liaisons (as appropriate for integrating OPTN Learning System learnings into broader OPTN work)

Resources Needed

- Expanded OPTN Learning System platform capacity to support broader participation and enhanced data visualization
- Data analysis resources to support evolving reporting needs and collaborative learning goals
- Facilitation resources for expanded learning collaboratives and communities of practice
- Ongoing communications resources to support dissemination and member engagement
- Resources to support governance functions, member feedback mechanisms, and iterative refinement of OPTN Learning System components
- Project management and collaboration tools to coordinate stream-specific and cross-stream OPTN Learning System activities
- Resources to support joint learning opportunities where cross-stream sharing adds value

Step 1: Expand Data Reporting and Dashboards

As Initial Implementation begins, each member specific OPTN Learning System stream should expand its data reporting and dashboards to support broader participation and more advanced learning goals. This may include scaling data collection efforts piloted during Installation, adding new process and outcome measures identified through learning collaboratives, and broadening dashboards to serve both members and external stakeholders (where appropriate). Importantly,

data expansion should continue to be member-driven, with key measures and dashboard features refined collaboratively within each OPTN Learning System stream to ensure they remain meaningful and actionable for participants.

Timeline: Three to four months

- Builds upon data collection and platform development completed during the Installation phase

Step 2: Broaden Learning Collaborative Offerings

During this step, each OPTN Learning System stream should broaden its learning collaborative offerings to engage a wider range of members and address a diverse set of priority topics. Building on early successes from the Installation phase, new collaboratives should be launched within each OPTN Learning System stream, informed by member input, ongoing feedback, and evolving system priorities. Where appropriate, multi-disciplinary or cross-member-type collaboratives may also be explored, but these should be developed collaboratively and intentionally, rather than forced through broad, system-wide consensus processes.

Timeline: Three to five months (concurrent with previous step)

Step 3: Establish Regular Learning Events and Communities of Practice

Each member specific OPTN Learning System stream should establish a regular cadence of learning events and support the development of communities of practice that promote ongoing member-to-member learning and collaborative improvement. Event calendars should be defined within each OPTN Learning System stream, allowing topics, formats, and pacing to reflect the specific needs and interests of the member type. Potential activities may include webinars, workshops, peer discussions, case reviews, and community forums. Communities of practice should emerge organically, supported by member champions and facilitators, and should provide members with trusted spaces for sharing experiences, lessons learned, and innovations.

Timeline: Three to four months (concurrent with previous step)

Step 4: Strengthen Dissemination and Feedback Loops

Each OPTN Learning System stream should strengthen its dissemination practices and formalize feedback loops to promote continuous improvement and broader impact. Within each stream, dissemination efforts may include Learning Bulletins, case studies, practice updates, and contributions to OPTN committee work where appropriate. Feedback mechanisms should track how OPTN Learning System participation informs practice changes, policy discussions, and member-level improvements. Though primary dissemination and feedback processes should remain member type–specific, opportunities for cross-stream sharing should also be explored, for example, through joint learning forums or shared dissemination channels, when they add value without forcing alignment across all streams. This approach ensures that each OPTN Learning System stream remains responsive to its members, while contributing to broader system learning,

in alignment with Sub-Recommendation 2.2 and the reviewer's guidance on preserving stream autonomy and member-driven innovation.

Timeline: Two to three months (concurrent with previous step)

Challenges & Solutions: Initial Implementation Phase

Challenge	Solution
Risk of uneven progress across member type–specific OPTN Learning System streams	Allow each OPTN Learning System stream to progress at its own pace while maintaining light-touch coordination and cross-stream sharing through OPTN Learning System governance.
Difficulty maintaining member engagement as OPTN Learning System activities scale	Leverage member champions, ensure learning activities remain relevant and responsive, and offer flexible opportunities for participation.
Potential for misalignment between data collection and member priorities	Embed data development in member-driven learning collaboratives to ensure data remains meaningful and actionable.
Challenges integrating OPTN Learning System learnings into broader OPTN processes	Strengthen feedback loops to OPTN committees and leadership; highlight examples of OPTN Learning System impact on practice and policy.

Target Outcomes: Initial Implementation Phase

- ☐ Expanded data reporting and dashboards within each member type–specific OPTN Learning System stream
- ☐ Broader learning collaboratives launched across diverse topics in each OPTN Learning System stream
- ☐ Regular learning events and communities of practice established within each OPTN Learning System stream
- ☐ Strengthened dissemination and feedback loops informing practice, policy, and OPTN committee work
- ☐ Increased member ownership and leadership of OPTN Learning System activities through evolving governance
- ☐ Cross-stream learning and dissemination opportunities implemented where valuable

Full Implementation & Sustainability Phase

Member type learning streams are fully operational and continuously evolving. Learning System insights are integrated into OPTN processes, and system impact is regularly monitored. Member

ownership and trust remain central, ensuring that the Learning System continues to deliver value and drive ongoing improvement.

Personnel Involved

- Members of governance structures
- Member champions and active participants in learning collaboratives and communities of practice
- OPTN contractor staff supporting platform maintenance, data analysis, and learning activities
- OPTN contractor staff supporting dissemination and integration with OPTN processes
- External collaborators and quality improvement experts (as needed for continued learning innovation)
- OPTN committee liaisons (to support ongoing integration of Learning System insights into OPTN work)

Resources Needed

- Platform maintenance and enhancement resources to support evolving learning needs
- Data analysis and reporting resources to monitor Learning System impact and support continuous improvement
- Facilitation and coordination resources for learning collaboratives, communities of practice, and governance activities
- Communications resources to support dissemination, transparency, and member engagement
- Evaluation resources to track Learning System impact on practice, policy, and performance
- Resources to support member-driven governance functions and sustain member ownership over time

Step 1: Sustain and Evolve

During the Full Implementation & Sustainability phase, each member type learning stream should continue to sustain and evolve its collaborative learning activities, events, and communities of practice. Learning collaboratives should remain responsive to member priorities, with topics and formats evolving based on member feedback and emerging system needs. Communities of practice should continue to serve as trusted spaces for peer learning and innovation. By this phase, learning streams should be fully embedded in the operational culture of each member type, with members viewing the OPTN Learning System as a valued and essential part of their quality improvement efforts. Sustaining this alignment with member needs and maintaining member ownership will be critical to long-term success.

Timeline: Ongoing

- No fixed “completion”; this is a continuous activity supported by governance and member champions

Step 2: Strengthen Integration

Each member type learning stream should work to further integrate OPTN Learning System insights into broader OPTN processes, including committee discussions, policy development, and performance improvement initiatives. Learning collaboratives, communities of practice, and dissemination activities should include clear pathways for sharing emerging best practices and lessons learned with OPTN leadership and relevant committees. Facilitating this integration helps ensure that member-driven learning continues to shape system-level improvements and reinforces the value of the OPTN Learning System as a driver of both practice and policy evolution. Streams should retain autonomy in how they identify and share insights, allowing each to contribute in ways that reflect its members' needs and priorities.

Timeline: Ongoing

- Initial four to six months of strengthening effort

Step 3: Support Continuous Refinement

Each member type learning stream, in collaboration with the OPTN Learning System governance structures, should engage in ongoing refinement of components, including platform features, learning models, data priorities, and member engagement strategies. Governance processes should continue to be member-driven, ensuring that changes reflect evolving member needs and system priorities. Regular feedback from learning collaboratives, communities of practice, and governance participants should inform updates to the OPTN Learning System's structure and operations. Maintaining this continuous improvement cycle will help the OPTN Learning System remain relevant, trusted, and valuable to members over time.

Timeline: Ongoing

- Initial 6 months of structured refinement leading to embedded continuous governance function

Step 4: Monitor System Impact

Each member type learning stream should establish processes to monitor the impact of OPTN Learning System activities on practice, policy, and performance outcomes. Governance structures should oversee this monitoring, with results shared regularly with members to reinforce transparency and trust. Member feedback should continue to inform priorities and guide future improvements. Sustaining a strong sense of member ownership is essential at this stage; learning streams must continue to provide clear value to participants and remain aligned with their evolving needs. Maintaining this dynamic relationship will help ensure the long-term relevance and effectiveness of the OPTN Learning System.

Timeline: Ongoing

- Initial six to nine months to establish monitoring process

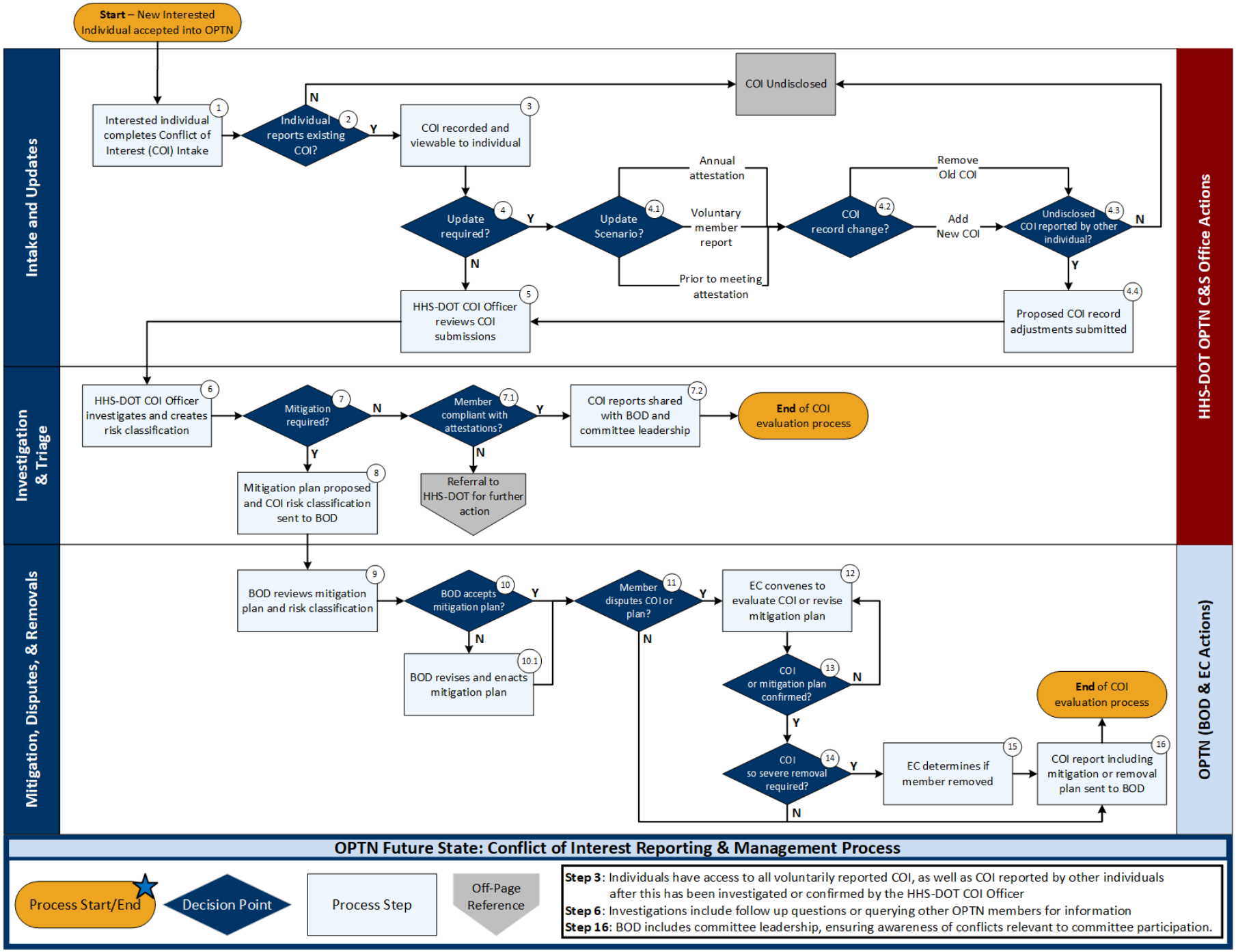
Challenges & Solutions: Full Implementation & Sustainability Phase

Challenge	Solution
Risk of declining member engagement over time	Continuously evolve learning activities to reflect member priorities; maintain clear value proposition and strong member ownership through governance.
Difficulty sustaining alignment between Learning System insights and OPTN processes	Strengthen integration pathways through regular collaboration between learning streams, OPTN committees, and leadership
Potential challenges in monitoring long-term system impact	Establish clear evaluation metrics and feedback loops; ensure results are transparent and shared with members to reinforce trust and accountability.

Target Outcomes: Full Implementation & Sustainability Phase

- ☐ Member type learning streams are sustained and continuously evolving based on member priorities
- ☐ Learning System insights are regularly informing OPTN processes, including committee work and policy development
- ☐ Learning System components and governance are refined through ongoing member feedback and participation
- ☐ System impact is monitored and shared with members to maintain transparency and trust
- ☐ Member ownership of the Learning System is reinforced, ensuring long-term relevance and sustainability

Appendix 18: PTN Conflict of Interest Reporting Process Map



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