

OPTN Board Support Contract Industry Day

November 9, 2023

- Suma Nair, Associate Administrator, Health Systems Bureau
- Alexandra “Bonnie” Garcia, HRSA Head of Contracting Activity
- Manjot Singh, OPTN Modernization Lead, Health Systems Bureau





Welcome

Alexandra “Bonnie” Garcia, HRSA Head of Contracting Activity



JULY 2023 – INDUSTRY DAY

- Shared information on OPTN modernization and preliminary transition contract approach with **300+** businesses, non-profits, academic institutions, and patient advocates
- Presentation and related materials:
<https://sam.gov/opp/31973befa4de49a8a41f5db99f516d40/view#general>
- List of attendees available on HRSA's FOIA Electronic Reading Room.
<https://www.hrsa.gov/foia/electronic-reading>



OVERVIEW

- **Background**
 - OPTN Modernization
 - Modernization Approach
 - OPTN Board
- **OPTN Board Support**
 - Requirements
 - Timelines
- **Questions & Answers**



Modernizing the Organ Procurement and Transplantation Network

Suma Nair, Associate Administrator, Health Systems Bureau



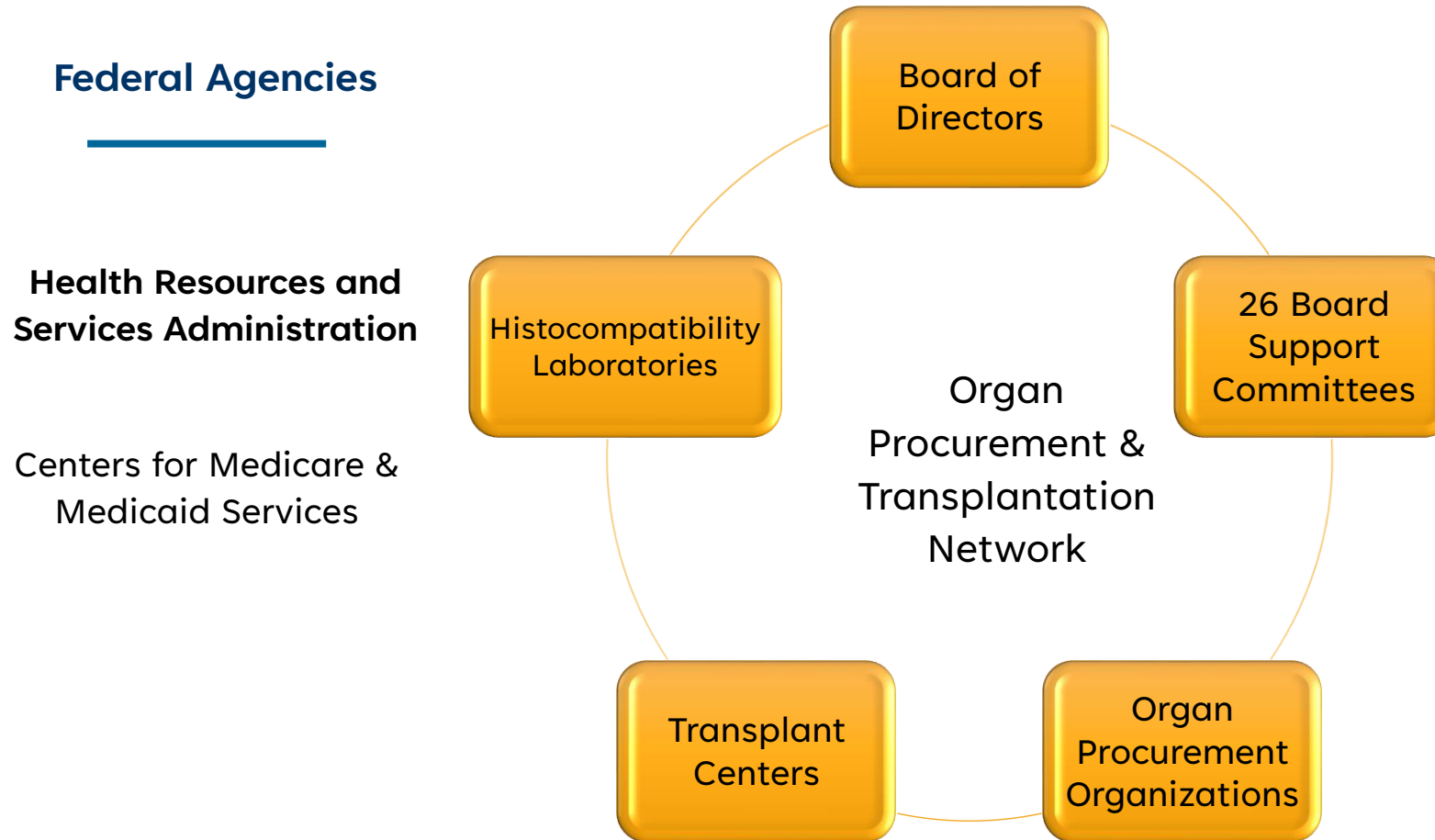
WHAT IS THE OPTN?

The Organ Procurement and Transplantation Network (OPTN) is a **unique public-private partnership** that links medical professionals, patients, and other stakeholders involved in the U.S. organ donation and transplantation system.

- Established by National Organ Transplant Act
- OPTN members, as required by law, include all U.S. transplant centers and Organ Procurement Organizations. OPTN members also include histocompatibility laboratories, public organizations, medical and scientific organizations, businesses, and individuals.
- OPTN responsibilities include:
 - operate and monitor an equitable system for allocating organs;
 - work to increase the supply of donated organs;
 - establish OPTN membership criteria;
 - monitor compliance with federal laws and OPTN policies;
 - and manage OPTN data.



OPTN: A UNIQUE PUBLIC/PRIVATE PARTNERSHIP



OPTN OPPORTUNITIES

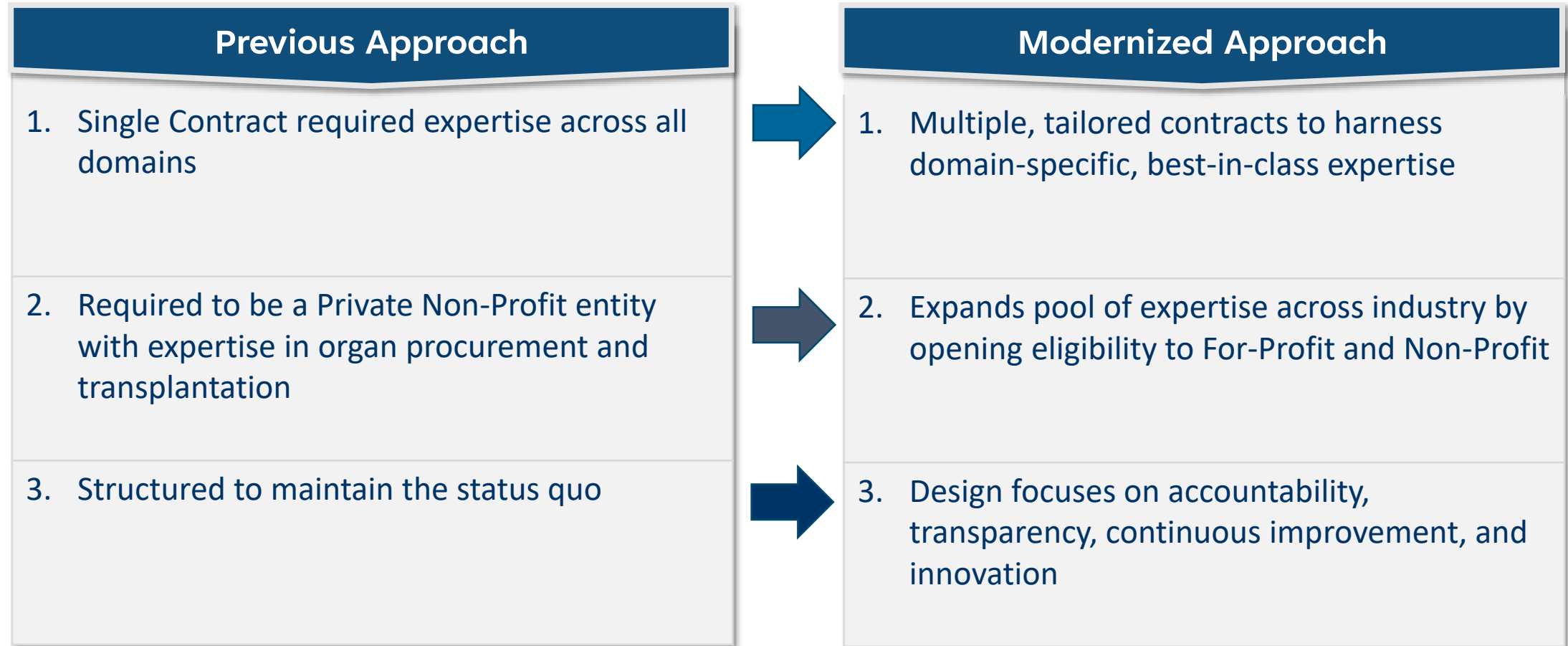


OPTN MODERNIZATION INITIATIVE

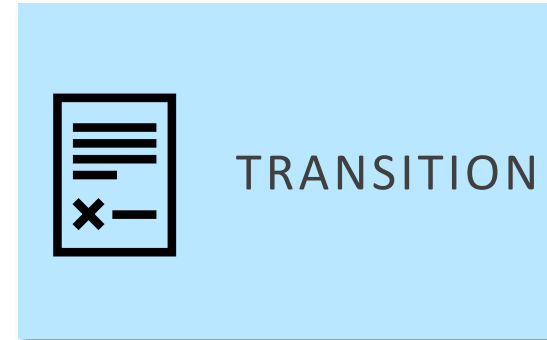
The **OPTN Modernization Initiative** is centered on putting **patients first**, prioritizing **information flow to clinicians**, promoting **innovation**, and enhancing **transparency and accountability**.



MODERNIZATION APPROACH



MODERNIZATION APPROACH

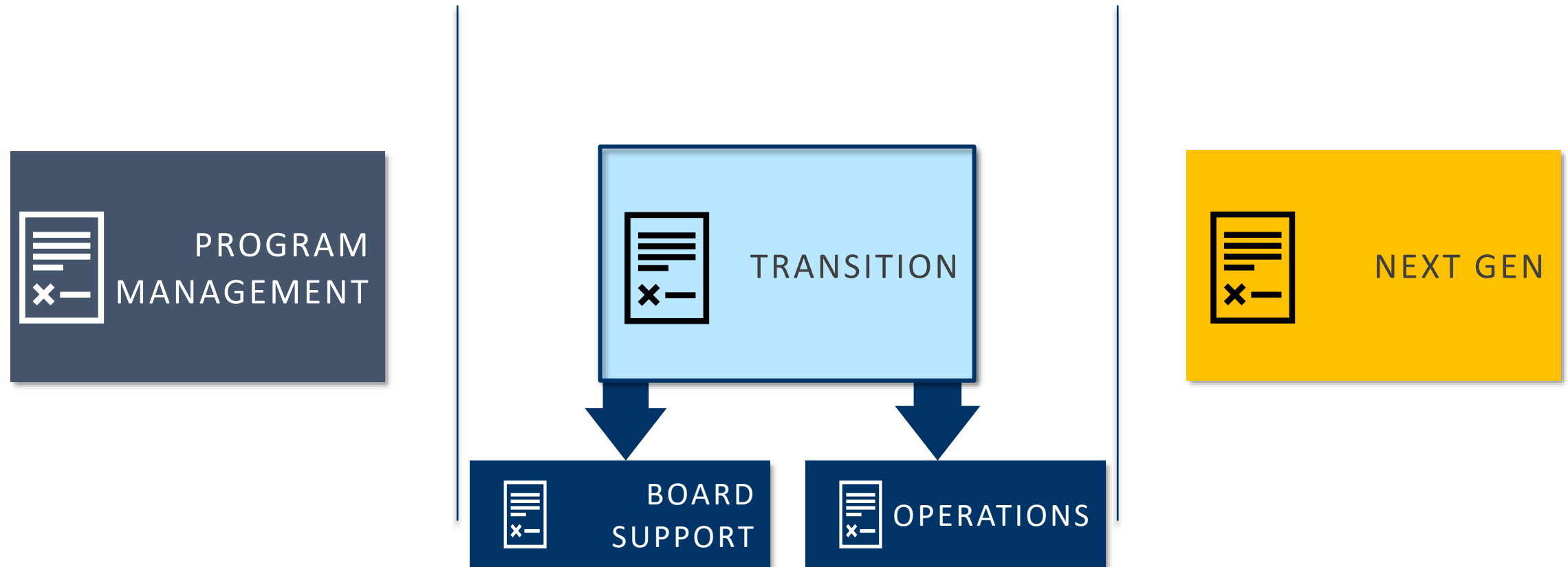


SECURING THE U.S. ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK ACT

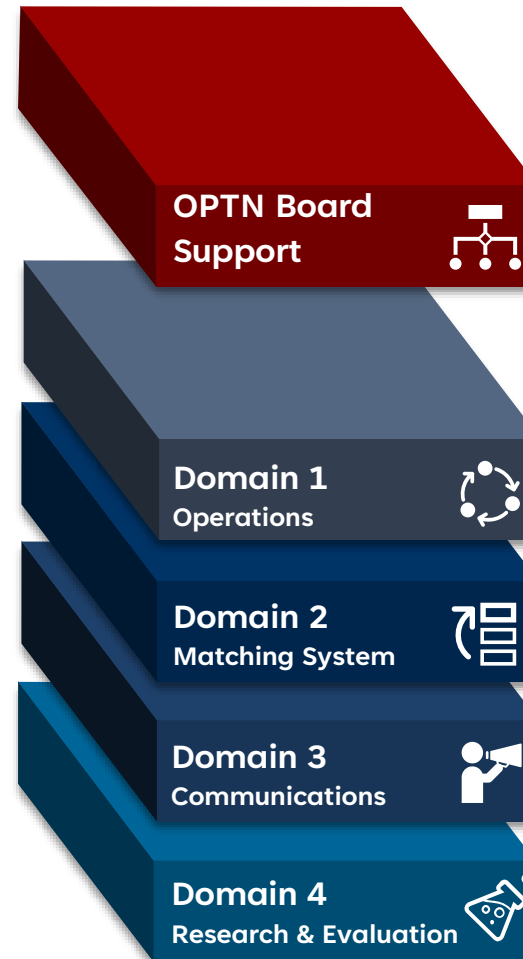
- Signed into law on September 22, 2023
- Removes the appropriations cap in National Organ Transplant Act of 1984
- Expands the pool of eligible entities and award mechanisms to support the OPTN
- Requires a separate organization to support the OPTN board from the organizations that support OPTN operations



MODERNIZATION APPROACH



TRANSITION CONTRACTS



Single Vendor Contract
(Non-Profit)

Multiple Vendor
Transition Contracts
(For-Profit & Non-Profit)

OPTN GOVERNING BOARD ROLES & RESPONSIBILITIES

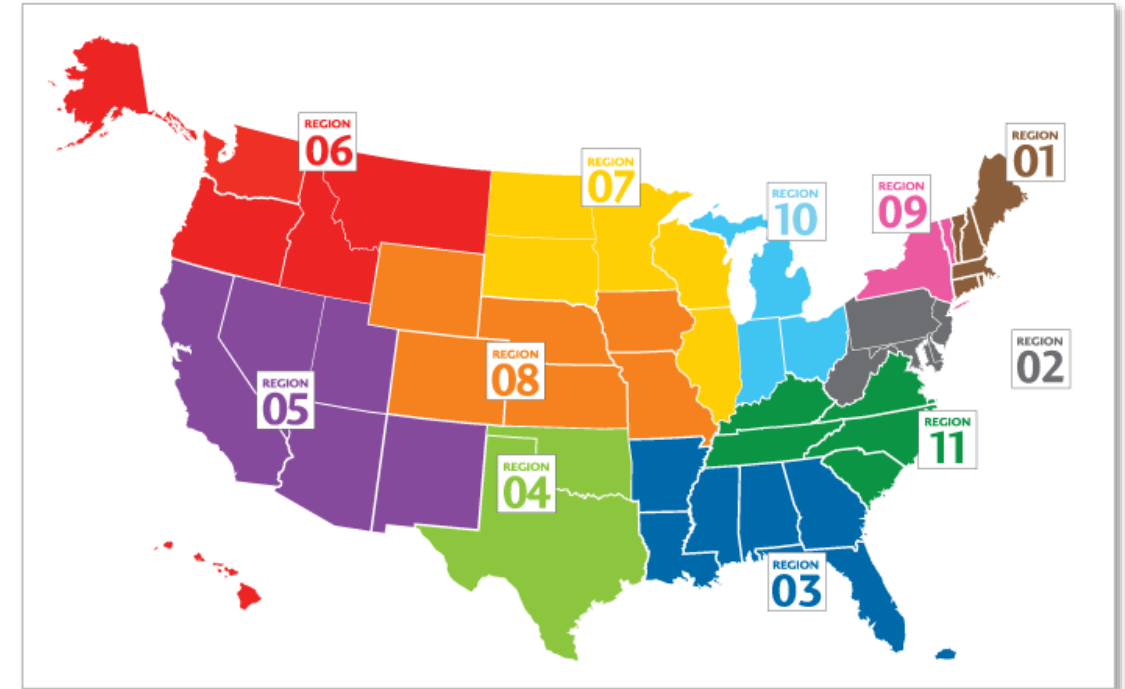
- Develops, reviews, approves, and enforces policies for organ allocation, procurement, and transplantation;
- Establishes committees as necessary to perform the duties of the OPTN;
- Oversees OPTN system operational functions and OPTN committee nominations;
- Supports, establishes, and enforces OPTN membership criteria and transplant and OPO program requirements; and
- Conducts reviews and evaluations of OPTN members and takes actions as approved by the HHS Secretary or designee that are consistent with the OPTN Final Rule and OPTN Bylaws for OPTN member non-compliance



WHO IS CURRENTLY ON THE OPTN BOARD?

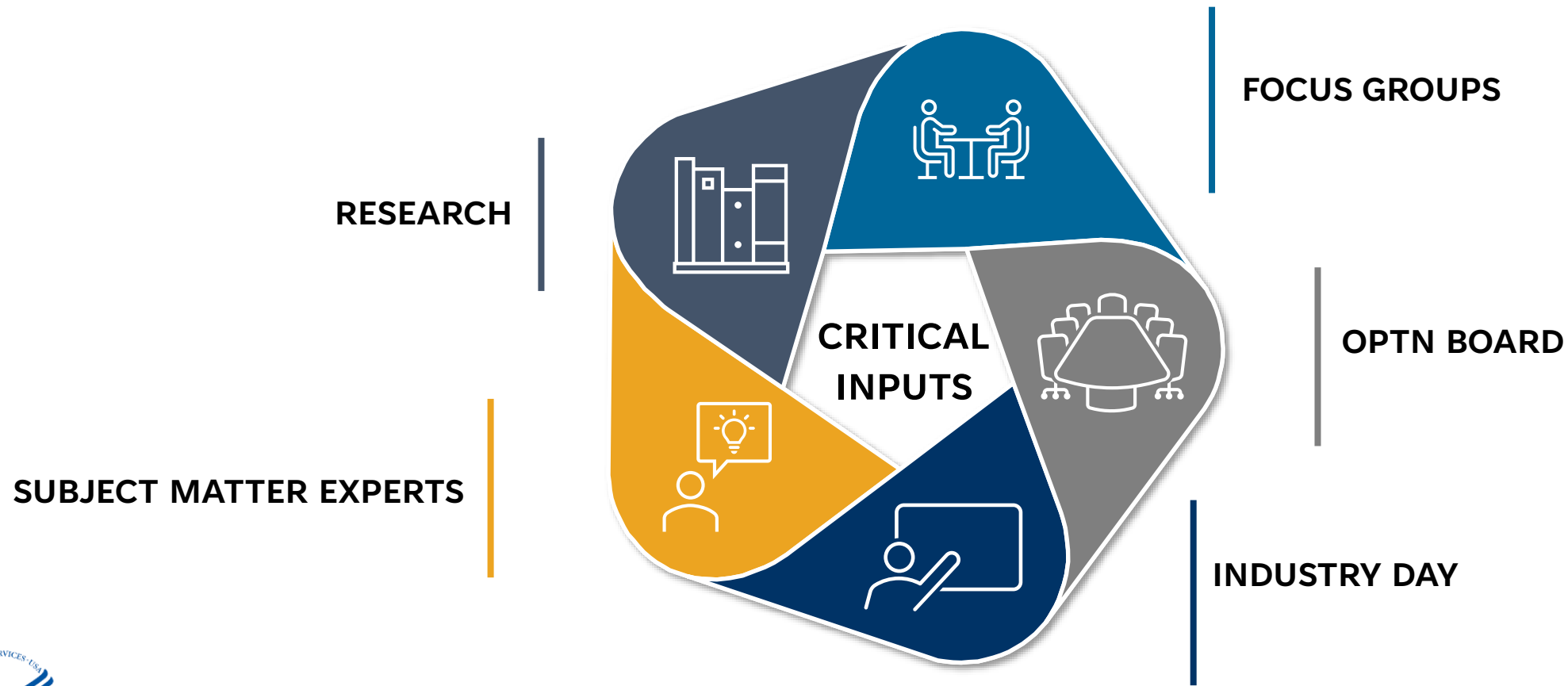
The Board of Directors is a group of 41 elected members, consisting of:

- 11 OPTN regional councilors
- transplant surgeons, physicians
- histocompatibility experts
- transplant coordinators
- organ procurement organizations (OPOs)
- voluntary health organizations
- medical/scientific membership organizations
- members of the general public, including:
 - transplant candidates and recipients
 - living donors
 - donor family members
 - recipient & patient family members



There are currently 11 OPTN regions

DEVELOPING REQUIREMENTS FOR OPTN BOARD SUPPORT

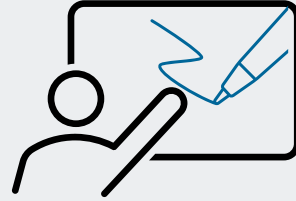


DEVELOPING REQUIREMENTS FOR OPTN BOARD SUPPORT



Deconstructed Board Operations

Deconstructed the Board Governance operations down to the **NOTA level** and rebuilt comprehensive list based on **functions**, **authorities**, and **legislation**



Identified Core vs. Support Functions

Identified functions and activities which can be performed in support of the Board to **minimize conflicts** between OPTN Board and operational support contractors



Developed Draft PWS¹

Developed **draft PWS¹ content** to reflect the support functions which enable the core OPTN Board activities, stakeholder feedback and market research



Essential Expertise

Vendors would ideally be mission-driven **non-profits** with experience in supporting accountable, transparent governance.

OPTN Board Support Contract

Manjot Singh, OPTN Modernization Lead, Health Systems Bureau



PURPOSE

- Support the Board with its **policy development and decision-making of the OPTN committees** – which drive who, when, where, and how Americans receive and give the gift of organs
- Assist the Board in its **structure and mechanism to provide equitable access to high quality, timely organ transplantation** to everyone in need
- Facilitate the Board's ability to rapidly and effectively **communicate, research, and achieve consensus on policy and enforcement decisions** that impact the lives and legacy of organ recipients and donors



KEY BOARD SUPPORT REQUIREMENTS



Administrative Services

Administrative, logistics, and other professional services to support Board of Directors (BOD) operations



BOD Member and Executive Director Management

Services necessary for the BOD to manage BOD member and Executive Director positions



BOD Governance

Services necessary for the BOD to effectively perform and govern itself

High Performing, Independent OPTN Board

OPTN Governance and Functional Oversight



Services necessary for the BOD to perform its OPTN-wide governance and oversight functions

General Requirements



Services to support coordination and collaboration amongst OPTN, HRSA, HHS and other HRSA Contractors.

TASK AREA 1 – ADMINISTRATIVE SERVICES

- Facilitate meeting and event logistics
- Prepare agendas and presentation materials
- Facilitate discussions and presentations
- Provide document and content management platforms and repositories
- Manage email and correspondence
- Facilitate and coordinate internal and external communications
- Draft information for dissemination
- Compile information to support BOD decision making

TASK AREA 2 – BOARD MANAGEMENT

- Provide the services necessary for BOD oversight of BOD member recruitment
- Provide education, training, and other services to ensure BOD members can fulfill their responsibilities
- Obtain, provide, and manage indemnification insurance for the BOD members
- Develop, implement, and continually revise a plan to monitor and address potential or actual conflicts of interest
- Maintain rosters of members of the BOD, their professional affiliations, contact information, and indication of their BOD compositional category
- Develop and implement processes for the recruitment, selection, performance evaluation, and dismissal of the OPTN Executive Director
- Establish and manage the process to hire and compensate OPTN Executive Director

TASK AREA 3 – BOARD GOVERNANCE

- Coordinate and collaborate between the BOD and other actors (e.g. HRSA, operations contractors, etc.)
- Ensure effective program and project management
- Support BOD access to specialized information and subject matter experts
- Support BOD processes and policies management
- Ensure continuity of BOD operations, performance metrics and monitoring, and risk management

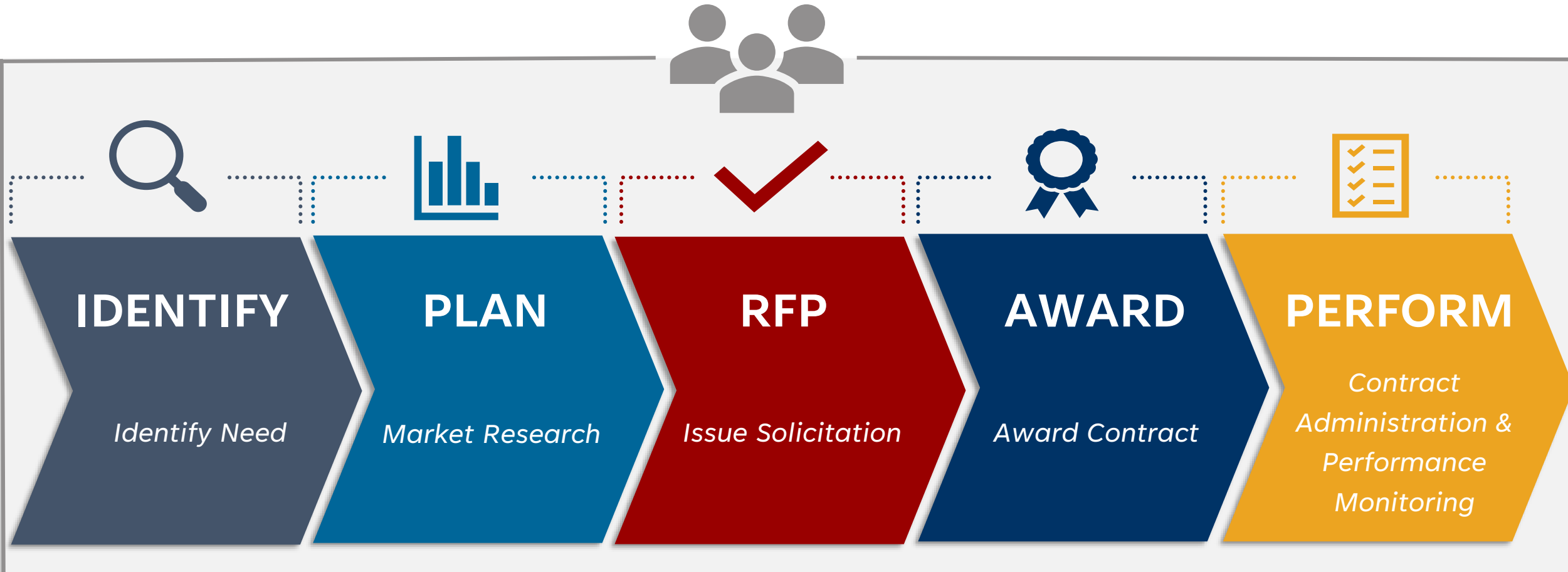
TASK AREA 4 – OPTN GOVERNANCE AND FUNCTIONAL OVERSIGHT

- Monitor and facilitate update of the OPTN charter and bylaws
- Support the Board in developing, implementing and evaluating OPTN policies
- Facilitate internal and external reviews
- Provide independent evaluation and financial analysis
- Provide access to technical expertise needed to review, approve, implement, and monitor strategic plans and other policies

ACQUISITION PROCESS



PHASES OF PROCUREMENT



OPTN TRANSITION CONTRACTS

Transition Contracts

Board Support Contract
Indefinite Delivery, Indefinite Quantity Contract

Operations Support Contracts
Indefinite Delivery, Indefinite Quantity Contract

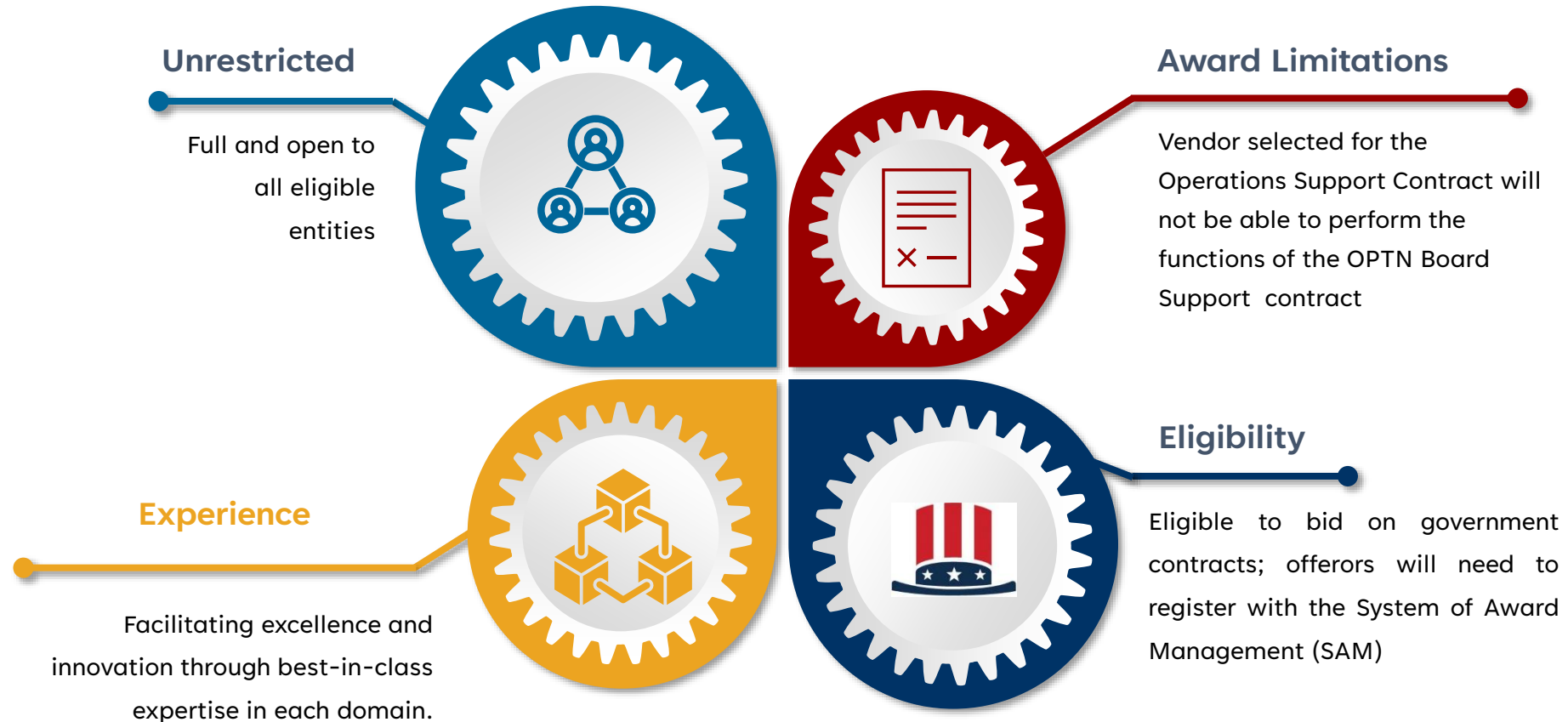
Tasks

- Administrative Services
- BOD Member and Executive Director Management
- BOD Governance
- OPTN Governance and Functional Oversight
- General Requirements

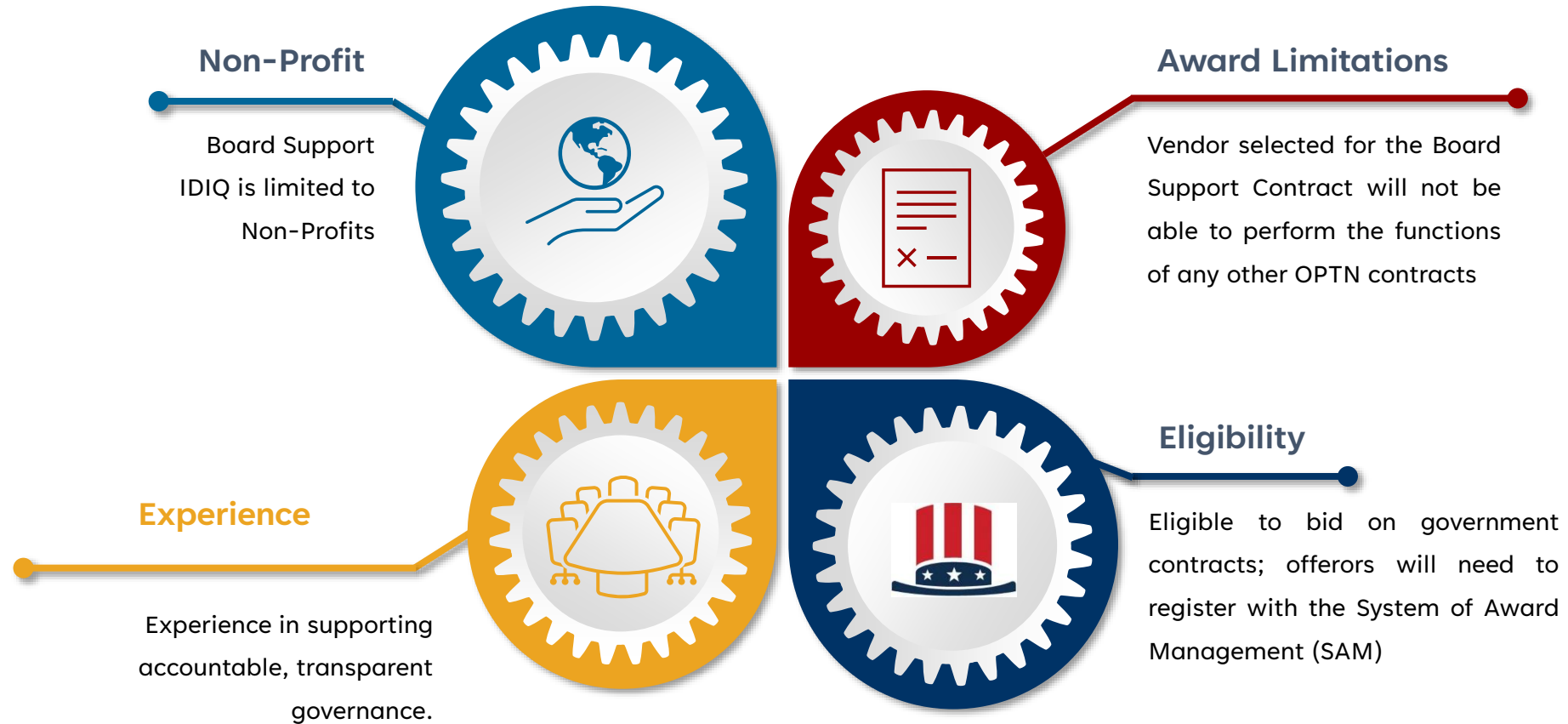
Domains

- Operations (Selected Vendors)
- Communications (Selected Vendors)
- Matching System (Selected Vendors)
- Research & Evaluation (Selected Vendors)

OPERATIONS SUPPORT CONTRACT ANTICIPATED VENDOR REQUIREMENTS



BOARD SUPPORT CONTRACT ANTICIPATED VENDOR REQUIREMENTS



ESTIMATED BOARD SUPPORT IDIQ TIMELINE



Q&A

- Suma Nair, Associate Administrator, Health Systems Bureau
- Alexandra “Bonnie” Garcia, HRSA Head of Contracting Activity
- Manjot Singh, OPTN Modernization Lead, Health Systems Bureau



CONTACT US



Via Web

Provide feedback on the OPTN
Modernization Initiative at
<https://www.hrsa.gov/optn-modernization>

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www.HRSA.gov



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