Performance Work Statement (PWS)

for

**Organ Procurement and Transplantation Network (OPTN) Next Generation (NextGen)
Information Technology (IT)
Multiple Award Blanket Purchase Agreement (MA-BPA)**

October 21, 2024

I. BACKGROUND

Health Resources and Services Administration (HRSA), an agency of the U.S. Department of Health and Human Services (HHS), implements the Organ Procurement and Transplantation Network (OPTN), as authorized by the National Organ Transplant Act of 1984 (42 USC 273 *et seq.*) and recently amended by Public Law 118-14. (Also see 42 CFR part 121). In March 2023, HRSA launched the HRSA Organ Procurement and Transplantation Network Modernization Initiative to strengthen accountability and performance in the organ donation and transplantation system by focusing on critical areas such as improved technology, governance, and operations. The approach to improving technology will encompass a combination of off-the-shelf (OTS) solutions with some level of new development and/or customization(s) to optimize both time-to-value and ensure the overall solution meets the needs of HRSA and the OPTN while keeping patient safety paramount.

The Health Resources and Services Administration (HRSA) oversees the Organ Procurement and Transplantation Network (OPTN). The OPTN was established by Congress nearly four decades ago and consists of a comprehensive network of transplant professionals and community members charged with increasing organ donation and operating and overseeing a fair and accountable system for allocating and transplanting organs in the United States. HRSA has worked to strengthen the OPTN to better meet the urgent needs of the more than 100,000 people on the organ transplant waitlist and their families.

II. PURPOSE

HRSA has a need for a streamlined and common contracting vehicle to support the research, design, development, configuration, customization, and deployment of modern IT solutions to the OPTN system. Once deployed, HRSA will have a need for ongoing enhancements and production support for solutions. While meeting the Modernization Initiative objectives and ensuring uninterrupted services for organ transplantation in the United States, HRSA requires access to expert services in the areas of product management, human-centered design (HCD), agile application development, Application Programming Interface (API) development, systems security, database management and security, accessibility and 508 Compliance, automated testing, cloud infrastructure design and management, continuous integration/continuous delivery (CI/CD), and/or Development, Security and Operations (DevSecOps) services.

III. SCOPE

Using modern, human-centered design practices and delivery methodologies, the OPTN NextGen IT MA-BPA (hereinafter referred to as NextGen IT MA-BPA) includes the services necessary for research, design, development, testing, and piloting of modules leading to modernized, secure, and flexible OPTN software solutions and information technology. The contractor, acting as an independent contractor and not as an agent of the government, shall furnish all materials, personnel, facilities, support and management necessary to provide the services and solutions as set forth in the Scope of Work below.

IV. PERIOD AND PLACE OF PERFORMANCE

The base award will be for one, three-year ordering period. The work will be performed offsite at the Contractor's location, unless specified otherwise at the task order level.

V. TASK AREAS

This MA-BPA encompasses services in support of OPTN Modernization Initiative technology solutions. This includes the incorporation of Agile methodologies and ceremonies into work, such as (but not limited to) sprint planning, daily scrum, sprint review, sprint retrospective, backlog grooming, and estimating activities. Where applicable, a Human Centered Design approach that actively involve users in the design and development of solutions will be incorporated. This includes incorporating best practices for user research and usability testing, such as (but not limited to) creating user personas, defining the problem space, developing affinity maps, designing user flow diagrams, wireframes, information architecture diagrams, prototypes and comprehensive user research plans. All work outlined in Tasks Areas are required to meet expectations outlined in Task Area 7: Coordination Among All Entities Supporting the OPTN.

Task Area 1: Software Development and Agile Teams

The objective of this task area is to develop customized software applications, database applications, and provide access to agile teaming arrangements for a variety of OPTN IT systems and Modernization Initiative efforts. Work in this task area includes performing deep dive research and discovery on existing processes and OPTN technologies, defining technology architecture that will enable industry standard or better ease of performance, refactoring of legacy systems, navigating code with complex interdependencies to break out business logic and decrease risks, evaluation and testing of products, creation of automated testing suites, collaborative and cross-functional implementation, and management of agile teaming arrangements.

Specific technologies to be used (if known) will be communicated at the Task Order level but will commonly include industry-standard web programming languages and frameworks such as JavaScript, Ruby, Java, and .NET; or Commercial Off-The-Shelf (COTS) products and platforms that can be used or adapted to meet HRSA's OPTN needs. Specific capabilities to be delivered by a team will be defined at the Task Order level and may include (but are not limited to) developing/modifying responsive web applications, developing/modifying REST APIs, and developing/modifying native mobile applications. Activities may include (but are not limited to) writing custom software, configuring Software as a Service (SaaS) platforms, or configuring COTS products to support specific objectives. This includes procurement of small quantities of non-production licenses for discovery and prototyping. Software developed under this MA-BPA shall be covered by automated unit and integration tests, and all software and configurations created under the MA-BPA shall be developed in a modern software version control system specified by HRSA. Contractors shall use both code reviews and automated checks to ensure software quality. The Contractor shall monitor industry trends and propose suitable technologies to HRSA to implement requested functionality. The Contractor shall meet work and requirements to cooperate and collaborate with all entities supporting the OPTN as outlined in Task Area 7: Coordination Among All Entities Supporting the OPTN. The Contractor shall incorporate Agile methodologies and ceremonies such as (but not limited to) sprint planning, daily scrum, sprint review, sprint retrospective, backlog grooming, and estimating activities as part of this work.

A comprehensive, but not limited, sampling of work to be performed under this task area is shown below:

a. Discovery
b. Engineering
c. Refactoring of Legacy Systems
d. Usability Testing
e. Data Science and Analytics
f. Deployment
g. Security and Operations (DevSecOps)
h. Automated Testing Suite
i. User Research and Design
j. Agile Teaming
k. Project Metrics Reporting and Analytics
l. Standards Development for Health IT Services
m. Business Intelligence
n. Web Development and Support
o. IT Strategic Planning
p. Requirements Analysis, Design, Coding, and Testing
q. Application Prototyping
r. Multimedia Software for Patient/Staff Education
s. Program Evaluation Software
t. Administrative and General Decision Support Software
u. Business Intelligence and Analytics
v. GIS-Enhanced Planning and Program Evaluation Software
w. Web 2.0 Development and Management
x. Database Development and Management
y. Clinical Protocol and Quality Assurance Decision Support Software
z. Customer Support

Task Area 2: Product, User Research, and Design Support

The objective of this task area is to provide the support for the product management lifecycle and human-center design process. This includes leveraging a range of qualitative and quantitative user research methods to determine people's goals, needs, and behaviors to develop user personas to drive product strategy, requirements, and metrics of success. It involves synthesizing user research and usability testing to create a product roadmap to drive a

technical strategy. Product road-mapping incorporates an iterative, phased approach to continuously re-assess product direction and prioritization based on user feedback and data.

Specific technologies to be used (if known) will be communicated at the Task Order level but will commonly include industry-standard product management and design tools such a Jira, Confluence, Figma, Mural, Miro etc. Specific capabilities to be delivered by a team will be defined at the Task Order level and may include (but are not limited to) product requirement documentation, project management and project status updates, wireframes, service designs, prototypes and other diagrams/visuals, interview guides, research briefs, and training materials. The Contractor shall meet work and requirements to cooperate and collaborate with all entities supporting the OPTN as outlined in Task Area 7: Coordination Among All Entities Supporting the OPTN. The Contractor shall incorporate Agile methodologies and ceremonies such as (but not limited to) sprint planning, daily scrum, sprint review, sprint retrospective, backlog grooming, and estimating activities as part of this work.

A comprehensive, but not limited, sampling of work to be performed under this task area is shown below:

    a. Discovery

    b. User Research including engagement plans and interview guides

    c. User research analyses and recommendations

    d. Project Management

    e. Product Road-mapping and Prioritization

    f. Product Strategy

    g. Product Definition, Scoping, and Requirements

    h. Identifying and defining Key Success Metrics

    i. Metrics Tracking, Reporting, and Analytics

    j. Human-Centered Design

    k. Plain-Language Content Writing

    l. Usability Testing

    m. Cross-Functional Collaboration

    n. Go-to-market planning and launch support

    o. Prototyping

    p. Inclusive Design/Accessibility/Section 508 Compliance

    q. Wireframing

    r. Service blueprints

    s. Information Architecture Design

t. Training materials (i.e. Customer Support Manual, Statement of Processes Documentation)

u. Workflow design

Task Area 3: Integration Services

The objective of this task area is to support the development and deployment of integrated information systems, which includes the integration of technical components, information technology components, organizational components and documentation. The Contractor shall integrate open source, COTS, Government Off the Shelf (GOTS) and/or SaaS solutions into existing, custom built, or new systems and provide configuration, customization and implementation services. The Contractor shall also integrate with other government systems using modern standards-based communication protocols and data formats. The Contractor shall meet work and requirements to cooperate and collaborate with all entities supporting the OPTN as outlined in Task Area 7: Coordination Among All Entities Supporting the OPTN. The Contractor shall incorporate Agile methodologies and ceremonies such as (but not limited to) sprint planning, daily scrum, sprint review, sprint retrospective, backlog grooming, and estimating activities as part of this work.

A comprehensive, but not limited, sampling of work to be performed under this task area is shown below:

a. Infrastructure Engineering, Development, Implementation, Integration

b. Enterprise Application Integration

c. Gap Analysis and Benchmarking

d. Integration of Health Systems Across Federal Agencies and Public and Private Healthcare Systems, such as Epic, Cerner.

e. Data Migration and Integration

f. Open Source Integration

g. Enterprise Data Management

h. Collaboration Tools

i. Business Process Reengineering

j. Test and Evaluation Services

k. Financial Analysis

l. Feasibility Studies

m. Requirements Analysis

n. System Design Alternative (SDA) Studies

o. Systems Engineering

p. Architecture Validation and Verification

q. Risk Assessment

r. Hardware Integrations

Task Area 4: Critical Infrastructure Protection and Information Assurance

The objective of this task area is to support the protection of critical infrastructure, assurance of agency information, and operations that protect and defend information and information systems by ensuring confidentiality, integrity, availability, accountability, restoration, authentication, non- repudiation, protection, detection, monitoring, and event react capabilities. The Contractor shall meet work and requirements to cooperate and collaborate with all entities supporting the OPTN as outlined in Task Area 7: Coordination Among All Entities Supporting the OPTN. The Contractor shall incorporate Agile methodologies and ceremonies such as (but not limited to) sprint planning, daily scrum, sprint review, sprint retrospective, backlog grooming, and estimating activities as part of this work.

A comprehensive, but not limited, sampling of work to be performed under this task area is shown below:

  a. Cyber Security
  b. Information Assurance of Critical Infrastructure
  c. Risk Management (Vulnerability Assessment and Threat Identification)
  d. Information Systems Security
  e. Application Security
  f. Disaster Recovery
  g. Incident Response Planning and Execution
  h. Security Certification and Accreditation
  i. Federal Information Security Management Act (FISMA) Implementation Support
  j. Health Insurance Portability and Accountability Act Implementation Support
  k. Record Management

Task Area 5: IT Operations and Maintenance

The objective of this task area is to support the operation and maintenance of IT systems, keeping IT systems viable with supported vendor releases or off-the-shelf applications software upgrades. Operations and maintenance on IT systems shall include all software and hardware associated with mainframes, client/server, web-based applications, and networking. The Contractor shall meet work and requirements to cooperate and collaborate with all entities supporting the OPTN as outlined in Task Area 7: Coordination Among All Entities Supporting the OPTN. The Contractor shall incorporate Agile methodologies and ceremonies such as (but not limited to) sprint planning, daily scrum, sprint review, sprint retrospective, backlog grooming, and estimating activities as part of this work.

A comprehensive, but not limited, sampling of work to be performed under this task area is shown below:

a. Operational Support

b. Software Maintenance and Upgrades

c. Telecommunications Maintenance (Data, Voice, Images, including Wireless)

d. Infrastructure Management Services (IMS)

e. Configuration Management

f. Network/Hardware Support

g. Resource Management

h. Backup and Recovery Management

i. Installation, Configuration, and Tuning

j. Electronic Software Licensing Services including license: deployment, management, tracking, upgrading, etc.

k. System Management

l. IT Training and Coaching

m. IT Operation and Maintenance Planning

n. Data Quality Management

o. Transformation Services

p. Continual Service Improvement

q. Balanced Scorecard for Operations

r. IT Infrastructure Optimization

Task Area 6: IT Management Services

The objective of this task area is to provide the Information Technology (IT) infrastructure and IT services required to assume management and operations of government IT resources and IT business functions. The Contractor shall meet work and requirements to cooperate and collaborate with all entities supporting the OPTN as outlined in Task Area 7: Coordination Among All Entities Supporting the OPTN. The Contractor shall incorporate Agile methodologies and ceremonies such as (but not limited to) sprint planning, daily scrum, sprint review, sprint retrospective, backlog grooming, and estimating activities as part of this work.

A comprehensive, but not limited, sampling of work to be performed under this task area is shown below:

a. Program Management

b. Program Management Office Support

c. IT Service Management

d. IT Portfolio Analysis

e. Risk Management

f. Capital Planning and Investment Control Support

g. Help Desk/IT Support

h. Management of Call Centers

i. Network Operations and Web Management Support

j. Leasing of Hardware and Software

k. Tools and Applications (including Application Service Provider)

l. Hardware/Software Maintenance

m. Transition Planning

n. Data Base Administration and Data Storage Management

o. Production Control and Management

p. Asset Management (including Radio Frequency Identification [RFID] Tracking)

q. Managed IT Services Support

r. IT Impact Analyses

s. Workflow Management

t. Implementation of Standards (e.g., International Organization for Standardization

u. (ISO) 9000, Capability Maturity Model Integration (CMMI), IT Services Management)

v. Solution Leasing

w. Software-as-a-service

x. Accessibility Services (508 and 504 compliance)

Task Area 7: Coordination Among All Entities Supporting the OPTN

This task area encompasses work and requirements to cooperate and collaborate with all entities supporting the OPTN.

The Contractor shall:

1. Meet on a regular basis to report on the status of deliverables and action items and shared metrics, conduct strategic planning, collaborate on innovative reforms, identify and address risks, and implement the HRSA OPTN Modernization Initiative.

2. Enter into data use agreements for OPTN data with other entities contracted to support the OPTN, as necessary and at the direction of HRSA.

   a) Implement all appropriate privacy and security protections for OPTN-related materials, as outlined in the appendices and future task orders.

   b) Share all data and information necessary to enable OPTN and all entities supporting the OPTN to successfully perform. This includes assisting with access to OPTN data, process and procedure documentation, and other data necessary to complete OPTN activities. NOTE: Any potential restrictions on the part of contractors to sharing data and necessary information must be identified at the time of task order award.

3. Report to HRSA all data, information, and other requested OPTN-related materials to support HRSA's oversight and congressional, statutory, regulatory, financial and other reporting requirements and oversight function.

4. Continually monitor, manage, and adjust processes, procedures, and functionality to integrate work with other entities supporting the OPTN.

5. Continually monitor, identify, and mitigate risks and proactively inform HRSA of any issues that prevent performance or successful implementation of efforts.

6. Conduct and participate in retrospectives to work collaboratively with other entities supporting the OPTN to identify issues and achievements, develop recommendations for improvement, and report on outcomes.

7. Incorporate Agile methodologies and ceremonies such as (but not limited to) sprint planning, daily scrum, sprint review, sprint retrospective, backlog grooming, and estimating activities as part of this work.

Task Area 8: Transition Activities

This task area encompasses services required to enable the transition of any contract activities from incumbent contractors to other entities, including HRSA, the OPTN, HRSA contractors, and other entities supporting the OPTN. This includes both transition-in at the start of performance and transition-out at the end of performance. The Contractor shall meet work and requirements to cooperate and collaborate with all entities supporting the OPTN as outlined in Task Area 7: Coordination Among All Entities Supporting the OPTN. The Contractor shall incorporate Agile methodologies and ceremonies such as (but not limited to) sprint planning, daily scrum, sprint review, sprint retrospective, backlog grooming, and estimating activities as part of this work.

At the direction of the COR, the Contractor shall:

1. Develop a transition plan for HRSA review and approval outlining the details of any transition (including applicable implementation roadmaps, risk management, privacy, back-up protocols, document transfer and processes) and implement approved plans to ensure successful transition.

2. Coordinate and implement the transition of any existing function or activity (including but not limited to processes, protocols, data collection or analyses, templates, systems) in such a way that ensures users have a seamless experience. This may include collaboration, coordinating, and training for multiple entities supporting the OPTN.

Task Area 9: General Requirements

<u>9.1 Branding, Media, and Reporting</u>

9.1.1 Branding

Contractors shall brand all OPTN products produced under contracts associated with this MA-BPA as OPTN products. OPTN products can only contain OPTN branding. Contractors shall not brand any OPTN product as a product of the entity supporting the OPTN or as joint OPTN products. No contractor shall brand any product not produced or approved to support the OPTN as an OPTN product. Additionally, contractors will ensure a consistent look, feel, and voice across all user-facing sites and services.

9.1.2 Media Inquiries and Public Release of Information

Contractors must work through the COR to obtain HRSA review and approval of any responses to the media or before putting any information related to performance under this contract out publicly.

9.1.3 Reporting

Contractors shall contribute to the development of internal and external reports as necessary for HRSA to meet statutory and regulatory requirements, including information such as data and analyses on organ donation and transplantation, policies and policy development, and system activities.

<u>9.2 Use of Plain Language Guidelines and Other Government Laws and Regulations for all Products</u>

The Contractor shall:

1. Follow the federal Plain Language Guidelines when developing products. The Plain Language Act of 2010 requires federal agencies to create communications that are clear and understandable to the public.

2. Produce content that follows federal plain language guidelines. All text content must aim for a Flesch-Kinkaid Reading Ease score of at least 60. HRSA's Office of Communications' liaisons use Readable to review, update, and score content. Contractor shall work with the Contracting Officer's Representative (COR) and program communications liaisons and use Readable to review, score and enhance the content.

3. Use PlainLanguage.gov's Checklist for Plain Language and HHS's Plain Writing Checklist as guidelines.

4. Ensure that all materials adhere to federal copyright laws including the citation of sources in endnotes or footnotes; obtaining written permission to reproduce, reprint, or adapt existing materials used in the creation of materials under this contract; and including credits for images, which include photographs, pictures, illustrations, tables, charts, figures, and graphs.

5. Ensure that all materials adhere to the Government Printing and Binding Regulations, including the prohibition on commercial advertising which says, "No Government publication or other Government printed matter, prepared or produced with either appropriated or nonappropriated funds or identified with an activity of the Government, shall contain any advertisement inserted by or for any private individual, firm, or corporation; or contain material which implies in any manner that the Government endorses or favors any specific commercial product, commodity, or service." -- (Title III--General Provisions, 13. Advertisements, Commercial.)

6. Ensure that all materials do not contain any non-federal logos (since logos are a form of institutional advertising); that materials do not contain contact information for non-federal organizations, except the website address for informational purposes; and that all materials do not contain any contact information for individuals.

7. Ensure that all materials do not contain the name of the contractor or subcontractors since this is also a form of advertising.

8. Ensure that all materials adhere to the prohibition against referring to lobbying in materials produced with appropriated funds. The prohibition against lobbying also includes grassroots lobbying, which is advocating for a change in legislation at the federal, state, or community level.

9.3 Key Personnel

The Contractor shall:

1. Provide qualified personnel to perform all requirements specified in this contract. The following positions are identified as Key Personnel:
   a) BPA Project Manager- the Program Manager (PM) who shall be responsible for all contractor work performed under this project. The PM shall be a single point of contact for the Contracting Officer and the Contracting Officer's Representative. It is anticipated that the PM shall be one of the senior level employees provided by the contractor for this work effort. The name of the PM, and the name of any alternate who shall act for the contractor in the absence of the PM, shall be provided to the Government as part of the contractor's proposal.

9.4 Data and Software Code Rights

In order to maintain adequate oversight of their software contracts, federal agencies are empowered to collect both data and custom source code developed in the performance of these contracts. These rights, granted, and in fact mandated by long-standing government-wide policy, ensure that agencies maintain the cost effectiveness, safety, and efficiency of the custom-developed software solutions they procure to serve the American people.

The Contractor shall:

1. Support Government adherence to M-16-21, the Federal Source Code Policy by providing Government-wide reuse rights for all custom source code that is developed under any BPA Call Order.

2. Grant to the Government unlimited rights to use, disclose, reproduce, and distribute all data delivered under this contract in accordance with FAR 52.227-14 and all other applicable FAR regulations.

3. Deliver both all data and all custom source code developed in the performance of any BPA Call Order. This includes delivery of custom-developed code, documentation, and other associated materials from the contractor and any subcontractors throughout the development process.

Task Area 10: Records Management Requirements (Reserved)

This subtask encompasses work and requirements that apply across the domain that will be specified at the task order level. See Appendix A.

Task Area 11: Security and Privacy Requirements (Reserved)

This subtask encompasses work and requirements that apply across the domain that will be specified at the task order level. See Appendix B.

Task Area 12: Section 508 Requirements (Reserved)

This subtask encompasses work and requirements that apply across the domain that will be specified at the task order level. See Appendix C.

Task Area 13: Other Requirements (Reserved)

This subtask encompasses work and requirements that are applicable to any information technology (IT) development or modernization work specified at the task order level. See Appendix D.

VI. Appendices

- Appendix A – Records Management
- Appendix B – Security and Privacy Requirements
- Appendix C – Section 508 Requirements
- Appendix D – Other Requirements