

Office of Management and Budget (OMB) Overview

*Materials shared with the Data Advisory Committee (DAC)
2024*

What is OMB?

- Office of Management and Budget (OMB) serves the President of the United States in overseeing the implementation of his or her vision across the Executive Branch.
- OMB carries out its mission through five main functions across executive departments and agencies:
 1. Budget development and execution;
 2. Management, including oversight of agency performance, procurement, financial management, and information technology;
 3. Coordination and review of all significant Federal regulations from executive agencies, privacy policy, information policy, and *review and assessment of information collection requests*; and
 4. Clearance and coordination of legislative and other materials, including agency testimony, legislative proposals, and other communications with Congress, and coordination of other Presidential actions.
 5. Clearance of Presidential Executive Orders and memoranda to agency heads prior to their issuance.

What is the Paperwork Reduction Act (PRA) ?

- To avoid overburdening the public with federally sponsored data collections, PRA of 1995 requires that U.S. federal government agencies receive OMB approval before collecting most types of information from the public.
- PRA is a law governing how federal agencies collect information from the public
- OMB oversees the information/data requests federal agencies make of the public
- OMB “Clearance” process requires:
 - Supporting statement: details on how the data collection fits with organization’s goals (clear rationale for the why, what, how, and who of the information collection)
 - Calculation of burden
 - What data will be collected
 - Two rounds of public comment on the Federal Register

Why is an OMB review required for OPTN data?

- Under the current Organ Procurement and Transplantation Network (OPTN) contract, the OPTN Contractor (UNOS) must collect all official OPTN data through OMB approved data collection forms under the PRA.
- Official OPTN data equates to all data collected by the OPTN Contractor (UNOS) pursuant to regulatory requirements (42 CFR 121.11) and to fulfill its obligations under contract with Health Resources and Services Administration (HRSA).

The OPTN manages two OMB packages

1. OMB Control Number: 0915-0157

- Information Collection Request (ICR) Title: **OPTN Data System**
- Data collection forms in OPTN Computer System (UNetSM)

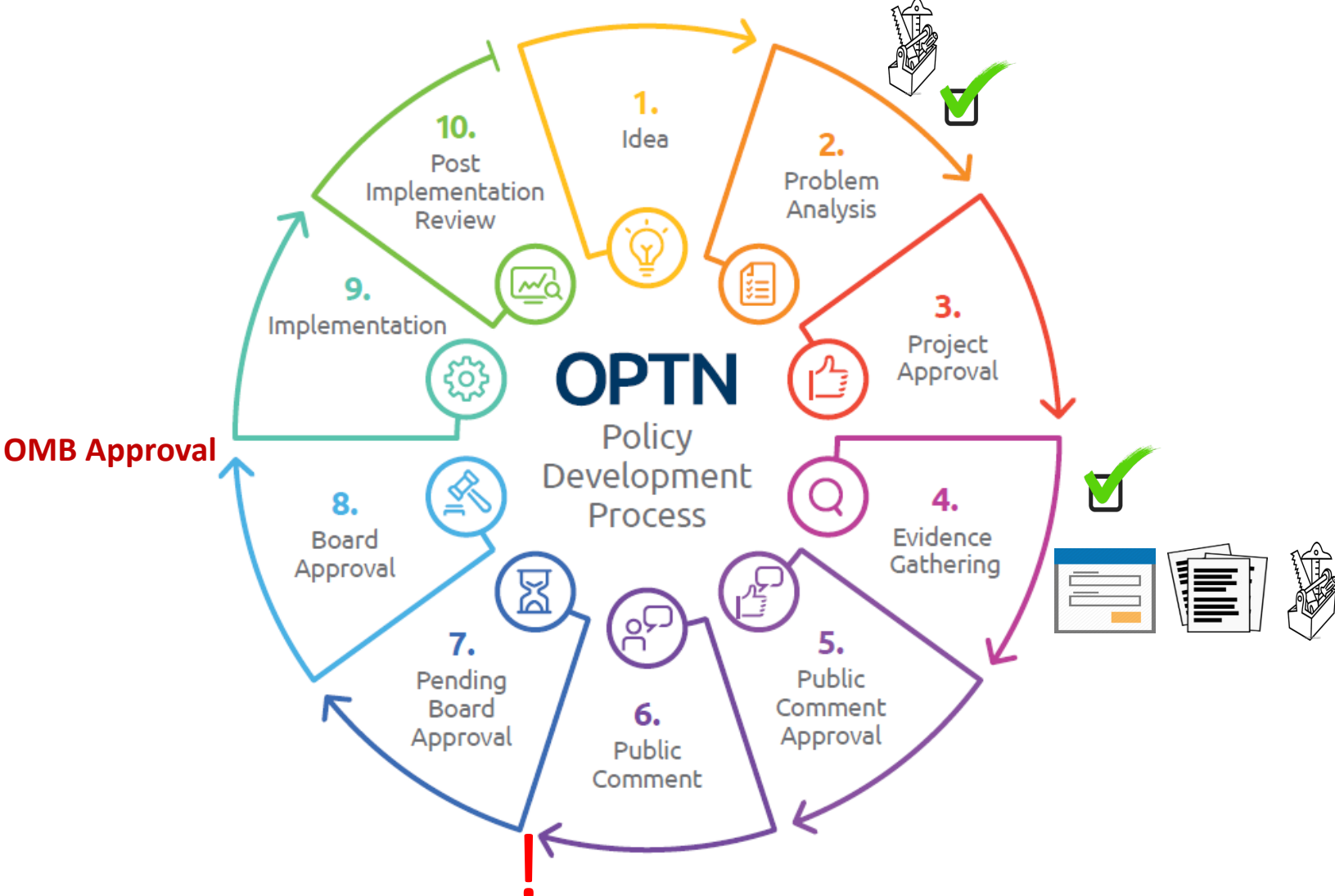
2. OMB Control Number: 0915-0184






- Information Collection Request (ICR) Title: **OPTN Application Form**
- Membership and transplant program forms

Applications included in the OMB packages

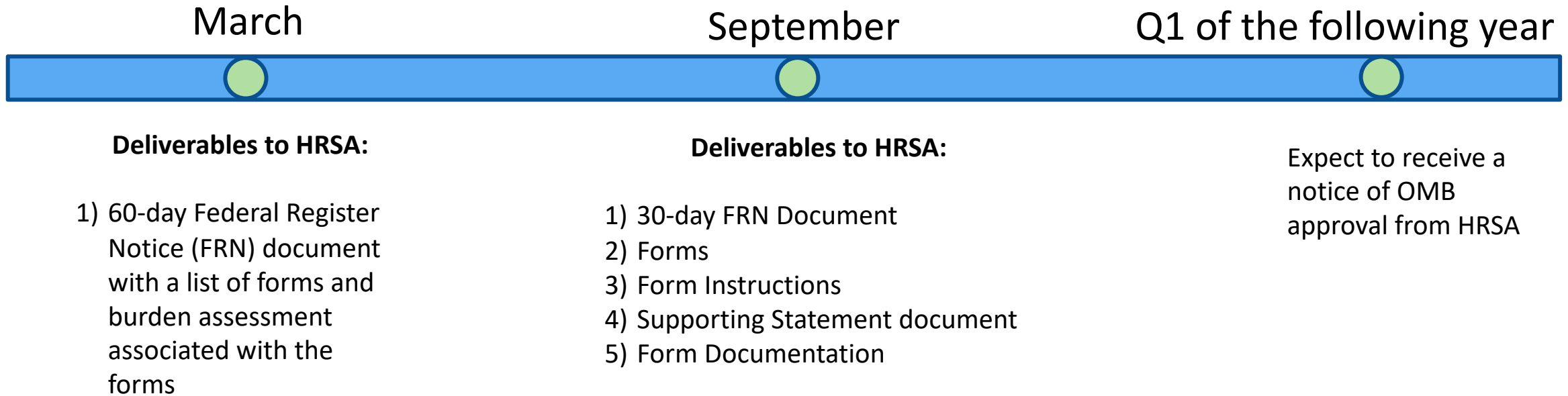
- OPTN Donor Data and Matching System (DonorNet[®])
- OPTN KPDPP (KPDSM)
- OPTN Data System (TIEDI[®])
- OPTN Organ Labeling, Packaging and Tracking System (TransNetSM)
- OPTN Waiting List (WaitlistSM)
 - Note: All data collection in the waiting list application will be submitted for OMB review and approval in 2024
- OPTN Patient Safety Portal
- OPTN Membership System

Implementation is dependent upon OMB approval



-  Required DAC check-ins
-  Tools
-  Data elements
-  Data definitions
-  Additional DAC check-in may be required

Typical Annual OMB Package Submission Timeline



Impacts to OPTN change management process

- OPTN data collection package is submitted annually for OMB review and contains all board approved projects (December Board and June Board)
- OMB approval process historically takes one year from submission to HRSA to OMB approval and involves two public comment cycles on the Federal Register
- To date, the OPTN has not received substantive feedback from OMB or the public on the data collection package revisions

Planned Improvement Opportunities

- Improve efficiency
 - Automate OMB package submission by maturing metadata management tooling and sharing with HRSA; ultimately sharing data dictionary with community.
 - Understand the OMB change management process in greater detail to find efficiencies
 - Adopt OMB consultation method for all data collection forms. Collect burden estimates directly from primary OPTN committees versus conducting surveys. Adoption will improve accuracy and reliability of estimates.
- Recommend HRSA adjust the OMB submission cycle to be aligned with each OPTN Board meeting (two cycles versus one each year)
- Determine with HRSA if there are alternative approaches to following OMB process allowing for major and minor data changes to be implemented timely

Appendix

OMB's definition of burden

The Paperwork Reduction Act defines burden as the time, effort, or financial resources expended by persons to generate, maintain, or provide information to or for a Federal agency, including the resources expended for— (A) reviewing instructions; (B) acquiring, installing, and utilizing technology and systems; (C) adjusting the existing ways to comply with any previously applicable instructions and requirements; (D) searching data sources; (E) completing and reviewing the collection of information; and (F) transmitting, or otherwise disclosing the information. In order to fulfill this mandate, administrative time for the respondents should be used for the burden estimate. Clinical decision making can also be used as part of the burden calculation.

OMB's definition - substantive and non-substantive

What is a substantive change:

“A substantive or material modification is any revision to the collection of information that adds or deletes questions, changes the scope of inquiry or the population actually or potentially subject to inquiry, revises the method of collection or the procedure for sample selection, reinterprets compliance directives or other policy guidance, significantly changes the uses of the information or otherwise meaningfully alters any aspect of the collection of information from that previously approved by OMB.”

What is a non-substantive change:

Examples of non-sub changes include rewording a question so that it is more understandable, changing the order of questions, re-formatting a form, title changes, etc. Basically, anything that doesn't alter the content of the tool in any way would be considered non-substantive.