2025 HHS EVALUATION PLAN

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About This Plan

The *FY 2025 HHS Evaluation Plan* details the Department of Health and Human Services' (HHS) efforts to answer the priority questions presented in the current HHS Evidence Building Plan. This plan provides both an overview of HHS evaluation activities planned for FY 2025 and detailed information for each new and continuing evaluation effort.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Assistant Secretary for Planning and Evaluation
Office of Science and Data Policy
Division of Evidence, Evaluation and Data Policy

200 Independence Avenue SW
Washington, D.C. 20201

ABOUT THE AUTHORS

Maura R. Reilly, PhD, MPH is Social Science Analyst in the Division of Evidence, Evaluation and Data Policy
Kristen Hudgins, PhD is a Senior Social Science Analyst in the Division of Evidence, Evaluation and Data Policy
Susan Jenkins, PhD is the HHS Evaluation Officer and Director, Division of Evidence, Evaluation and Data Policy

ACKNOWLEDGEMENTS

Special thanks to the HHS Evidence and Evaluation Council Division Evaluation Liaisons for their help in developing guidance for and coordinating Op/Staff Division submissions.

Letter from the HHS Evaluation Officer

The Foundations for Evidenced-Based Policymaking Act of 2018 (Evidence Act) provided an important opportunity to Federal Agencies to assess and improve, where needed, their evaluation and other evidence building activities. Since the passage of the Evidence Act, the US Department of Health and Human Services (HHS) has worked diligently to build on an existing culture of evidence that maintains principles of scientific integrity throughout the evaluation process, ensures adherence to the HHS Evaluation Policy, and upholds the standards delineated in the Office of Management and Budget's (OMB) Memorandum M-20-12.

Due to the size of HHS and the scope of its programs, policies, and regulations the development of this plan reflects a broad effort coordinated by the HHS Evaluation Officer (EO) and supported by the Office of the Assistant Secretary for Planning and Evaluation (ASPE). The EO works collaboratively with the evaluation leads in each Operating and Staff Division (Op/Staff Div) recognizing that they are best positioned to assess their evaluation needs and to determine which evaluations to highlight in the HHS Evaluation Plan.

Susan Jenkins, PhD

HHS Evaluation Officer

Director, Division of Evidence, Evaluation and Data Policy In the Office of Science and Data Policy in the Office of the Assistant Secretary for Planning and Evaluation (ASPE)

The FY 2025 HHS Evaluation Plan includes a range of evaluations that are planned to continue into or begin in FY 2025. While the forty-nine (49) evaluations featured in this plan do not represent all of the evaluations expected to be conducted by HHS, each evaluation contributes to HHS' ability to answer the priority questions presented in the current Evidence Building Plan, which tie directly to the current HHS Strategic Plan. In addition, they include 17 more evaluations than were included in the 2024 HHS Evaluation Plan. The range of data sources, methodological approaches, and dissemination plans reflect the diverse nature of the health and human services provided and populations served by HHS to address complex, multifaceted, and evolving health and human services issues.

In FY 2025 we will continue to work closely with the HHS Op/Staff Divs with a particular focus on supporting their efforts to develop their own Division-specific Evaluation Plans. HHS is proud of the work completed to date and the future work which will be produced through our ongoing effort to maintain a vibrant culture of evidence and provide exceptional service to the American people.

Introduction and Background

The Foundations for Evidence-Based Policymaking Act of 2018 (Evidence Act) is designed to improve decision-making for federal programs and policy development through a transparent, question-driven approach to evidence development and analysis.

The US Department of Health and Human Services (HHS) is a large, decentralized agency with 12 operating divisions, 16 staff divisions, and 10 regional offices whose programs and policies touch the lives of nearly all people living in the US and its territories. Evaluation provides essential information to help HHS understand how its programs and policies work, for whom, and under what circumstances. Evaluation also assists HHS in building evidence that informs budgetary, legislative, regulatory, strategic planning, program, and policy decisions.

Given the breadth of work supported by HHS, many evaluations and analyses are conducted each year. These efforts range in scope, scale, design, and methodology, but all aim to assess the effect of HHS programs and policies and identify strengths and opportunities for improvement. The evaluations presented in this plan include formative studies focused on program design and implementation as well as summative designs focused on measuring program outcomes and impacts. When taken together these evaluations work to address the priority evaluation questions set out in HHS' Evidence Building Plan by either building upon other evidence-building activities or laying the foundation for future evidence-building activities.

Understanding on-going evaluation, research, and analysis activities and coordinating those efforts across HHS is a significant undertaking. The Office of the Assistant Secretary for Planning and Evaluation (ASPE), through the HHS Evaluation Officer, plays a significant leadership role in studying and supporting HHS evaluation and evidence-building activities. ASPE coordinates the HHS evaluation community through regular convenings of the HHS Evidence and Evaluation Policy Council (the E&E Council), which coordinates activities to meet the requirements of the Evidence Act and builds capacity by sharing best practices and promising new approaches across HHS. Predating the Evidence Act, the E&E Council is made up of senior evaluation staff and subject matter experts from each HHS Division. Members of the E&E Council were instrumental in developing guidance for and coordinating submissions from Op/Staff Divs for this Evaluation Plan.

Commitment to Scientific Integrity

OMB's standards for program evaluations note that Federal evaluations must produce findings that Federal agencies and their stakeholders can confidently rely upon, while providing clear explanations of limitations in accordance with principles of scientific integrity. In addition to the program evaluation standards and practices issued by OMB and the subsequent HHS Evaluation Policy, the release of recent memoranda and guidance have provided HHS with additional support and direction for ensuring the scientific integrity of agency evaluations and evidence-building activities. The Presidential Memorandum, Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking, and OMB Memorandum M-21-27 Evidence-Based Policymaking: Learning Agendas and Annual Evaluation Plans require that scientific integrity principles be incorporated into agency evidence-building plans and annual

evaluation plans. The Presidential Memorandum emphasizes the role of scientific and technological information, data, and evidence for developing effective policies and delivering equitable programs. It affirms that evaluations are scientific activities which require the use of appropriate methods, are free from undue influence, employ processes that ensure integrity, quality, and fully incorporate diversity, equity, inclusion, and accessibility (DEIA). These recent requirements strengthen evaluation and evidence-building activities in HHS and inform the development and conduct of capacity building activities in accordance with the principles and foundations for scientific integrity.

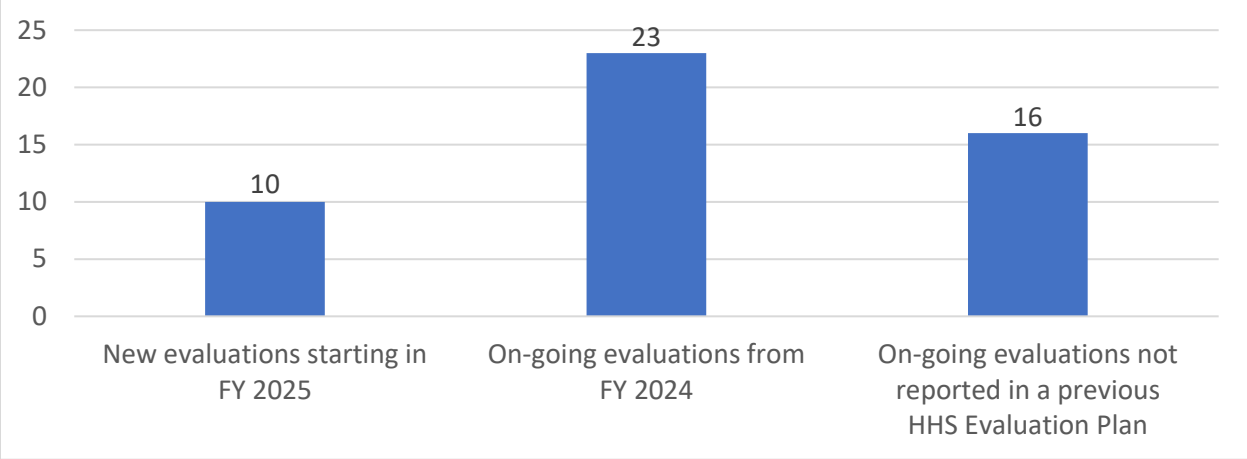
Plan Development

To develop this plan, ASPE asked HHS Operating and Staff Divisions (Op/Staff Divs) to share up to five significant[1] new evaluations scheduled to start in fiscal year (FY) 2025, indicate which evaluations described in the FY 2024 Evaluation Plan are expected to continue in FY 2025, and add relevant ongoing evaluations that were not included in a previous HHS Evaluation Plan.

Overview FY 2025 Evaluation Plan

The FY 2025 Evaluation plan lists a total of forty-nine (49) significant evaluations across ten (10) Op/Staff Divs. The evaluations include ten (10) new evaluations proposed to start in FY 2025, twenty-three (23) on-going evaluations described in the FY 2024 plan, and sixteen (16) additional ongoing evaluations not reported in a previous HHS evaluation plan (Figure 1). The latter group, on-going evaluations not reported in a previous HHS evaluation plan, is the result of a gap between the time when Op/Staff Divs provide information about planned evaluations and when final Op/Staff Div budgets are approved.

Figure 1: Total number of evaluations occurring in FY 2025 by implementation status. (n=49)



[1] For purposes of this plan, HHS defined *significant* as evaluations that "support answering questions identified in the HHS FY 2023-2026 Evidence-Building Plan. This definition was provided to Op/Staff Divs.in the data collection guidance documents. However, Divisions may have considered additional criteria in selecting the evaluations included in this plan.

In Figures 2-4 below, individual evaluations occurring in FY 2025 may be represented across multiple categories. Full descriptions of each evaluation, including methodological approaches, anticipated challenges, and mitigation strategies, intended use for evaluation findings, and dissemination plans can be found in the appendices at the end of this document. Appendix A contains information for new evaluation activities that Op/Staff Divs intend to start in FY 2025 and on-going evaluations that have not been reported in a previous evaluation plan. Appendix B contains information for evaluation activities continuing from FY 2024. All activities described in this plan are subject to availability of appropriations.

Building Evidence Related to Federal Learning Agendas

For FY 2025, ASPE asked Op/Staff Divs to report if any new or newly reported evaluations included questions related to one or more Federal learning agendas: Federal Evidence Agenda on LGBTQI+ Equity, President's Management Agenda, or the HHS Evidence-Building Plan.

Federal Evidence Agenda on LGBTQI+ Equity

The Federal Evidence Agenda on LGBTQI+ Equity (LGBTQI+ Evidence Agenda), released in January 2023, is a cross-Federal Learning Agenda created to address the concerns raised in Executive Order 14075 Advancing Equality for Lesbian, Gay, Bisexual, Transgender, and Intersex Individuals and is meant to serve as a roadmap for Federal agencies to continue to build evidence in order to advance equity for LGBTQI+ people. The LGBTQI+ Evidence Agenda is comprised of thirteen (13) priority questions and many more illustrative questions nested within each of those priority questions. HHS asked Op/Staff Divs if any of the evaluations that they were reporting focused on LGBTQI+ Evidence Agenda questions. The priority questions being addressed through these evaluations are:

- To what extent can the Federal Government protect and strengthen equitable access to high-quality and affordable healthcare for LGBTQI+ people across the lifespan?
- To what extent can the Federal Government safeguard and improve health conditions and outcomes for LGBTQI+ people?
- How can the Federal Government promote equitable outcomes for LGBTQI+ people in income, economic well-being, and the workplace?

These questions along with five other illustrative (or sub) questions within these priority question areas were part of Divisions' evaluative planning for FY 2025 and it is expected that this number will increase in the years to come. Further, there is overlap with many of these questions with HHS' own Strategic Plan FY 2022 – 2026 and Evidence-Building Plan areas – particularly around Strategic Goals 1, 2, 3, and 4.

Learning Agenda in Support of the President's Management Agenda

The President's Management Agenda (PMA Learning Agenda) defines Government-wide management priorities for all Federal agencies to improve Federal operations and performance. The PMA Learning Agenda consists of three priorities, Workforce, Service Delivery, and Equity with nine strategies for improving government performance across those areas. Building

evidence in support of the PMA Learning Agenda over a sustained, multi-year effort, requires engagement and collaboration from many stakeholders inside and outside of government. In keeping with this approach, HHS queried the Operating and Staff Divisions regarding their use of any of the PMA Learning Agenda questions in their own evaluation work. The Divisions have work ongoing in all three PMA priority areas and are focused on questions such as:

- What approaches build a strong, empowered, and diverse cohort across the Federal Government employee lifecycle?
- How can the federal government enhance the public's trust?
- What organizational tools and management structures advance equity?

Divisions were also focused on additional areas related to serving underserved communities, determining better data collection and analyses to understand service utilization in underserved communities, improving retention and reducing burnout within the Federal workforce and other salient questions facing us now. The PMA Learning Agenda provides many cross-cutting questions relevant to HHS' own Evidence-Building Plan and Strategic Plan FY 2022 – 2026 – particularly around Strategic Goal 4: Restore Trust and Accelerate Advancements in Science and Research for All and Strategic Goal 5: Advance Strategic Management to Build Trust, Transparency, and Accountability.

HHS Evidence-Building Plan

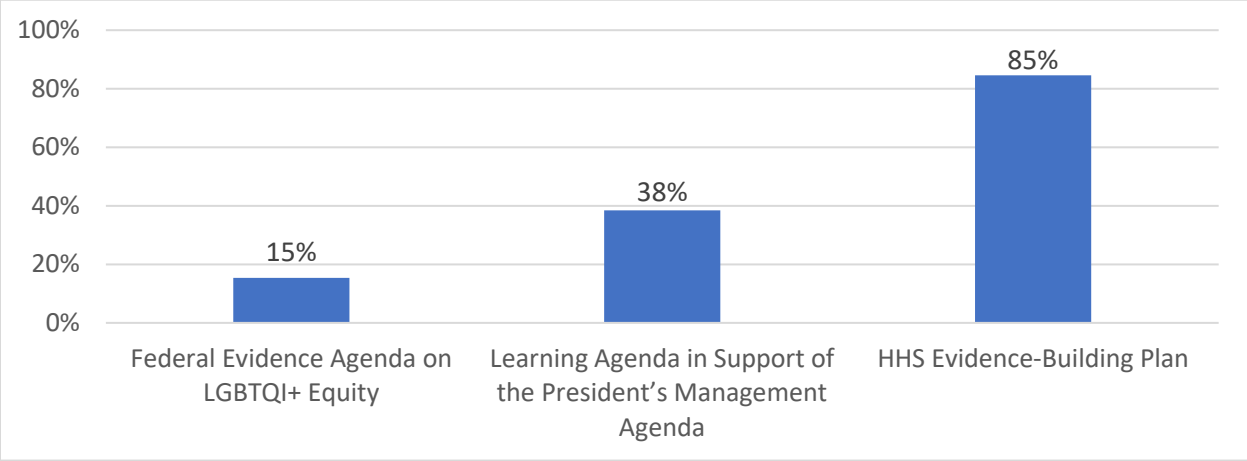
The HHS Evidence-Building Plan is a four-year plan running from FY 2023-2026 and is built around the HHS Strategic Plan Goals as determined by the Evidence Act and OMB guidance laid out in Memorandum M-19-23. There are twenty-three (23) questions in the HHS Evidence-Building Plan grouped by Strategic Goal. The priority questions most focused upon in the FY 2025 HHS Evaluation Plans were as follows:

- How do HHS policies and programs enhance promotion of healthy lifestyle behaviors to reduce occurrence and disparities in preventable injury, illness, and death?
- How does HHS improve the design, delivery, and outcomes of HHS programs by prioritizing science, evidence, and inclusion?
- Where does HHS need to further invest in the scientific workforce to maintain leadership in the development of innovations that broaden our understanding of diseases, healthcare, public health, and human services resulting in more effective interventions, treatments, and programs?
- Which HHS efforts are most effective for sustaining strong financial stewardship of HHS resources to foster prudent use of resources, accountability, and public trust?

Other priority questions related to reducing costs and improving the quality of service and expanding access to culturally competent care while addressing the social determinants of health. Tracking the HHS Evidence-Building Plan questions across evaluation plan years allows the Department to understand the questions that resonate throughout the HHS enterprise as well as to understand where we may still have knowledge gaps as we look forward to the next phase of evidence-building planning.

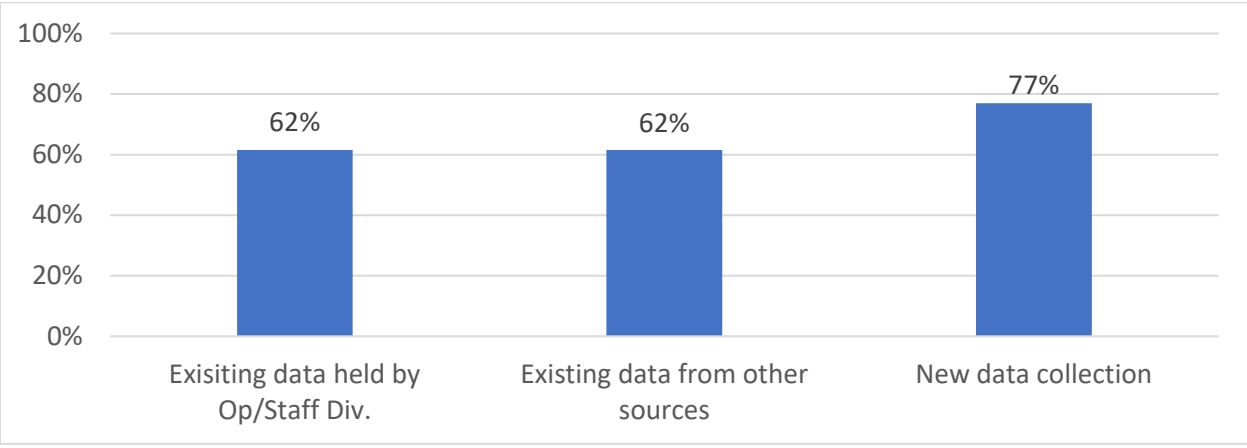
For FY 2025, six (6) Op/Staff Divs reported a total of twenty-six (26) new or newly reported evaluations expected to produce evidence related to one or more Federal learning agendas. The proportion of FY 2025 evaluations expected to produce evidence related to Federal learning agendas is shown in Figure 2.

Figure 2: Proportion of Op/Staff Div FY 2025 new and newly reported evaluations expected to produce evidence related to Federal Learning Agendas. (n=26)



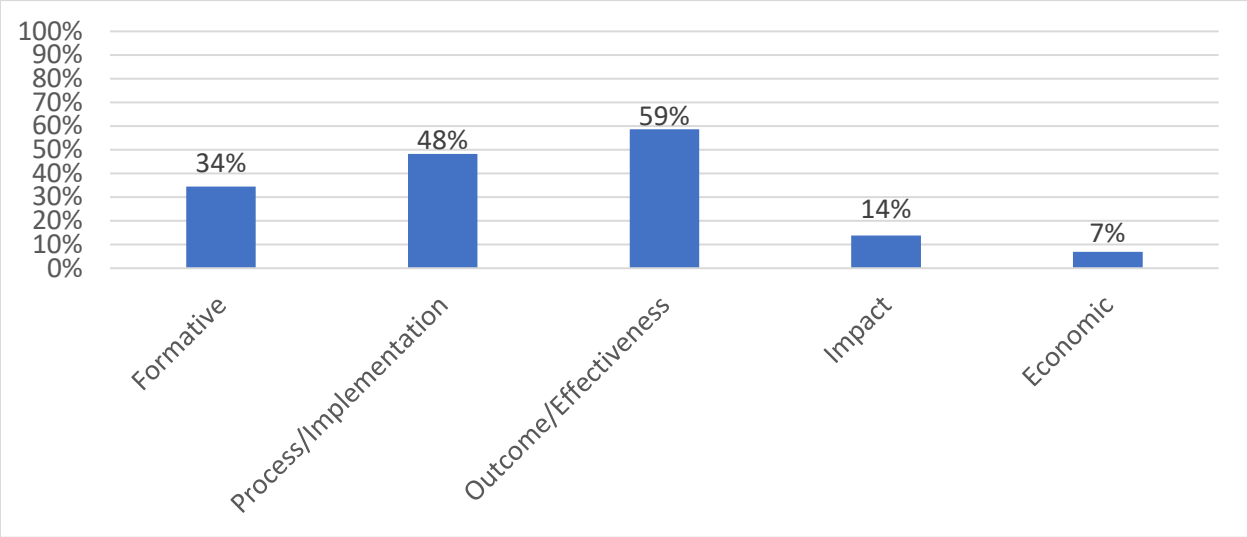
In FY 2025, data for new and newly reported evaluations will come from a variety of sources (Figure 3). Of the twenty-six (26) planned evaluations seventeen (17), or sixty-five percent (65%), will use data from two or more sources.

Figure 3: Proportion of FY 2025 new and newly reported evaluations by data source. (n=26)



New and newly reported evaluations scheduled for FY 2025 will represent a variety of evaluation activities (Figure 4). Of the twenty-six (26) planned evaluations fourteen (14), or fifty-four percent (54%), will include two or more types of evaluation activities.

Figure 4: Proportion of FY 2025 new and newly reported evaluations by evaluation type. (n=26)



New and Ongoing Evaluations in FY 2025 by Operating/Staff Division

This section lists all evaluations planned for FY 2025 by Op/Staff Div. This includes new evaluations that will start in FY 2025 and on-going evaluations from a previous fiscal year that will continue into FY 2025. All activities described listed below are subject to availability of appropriations.

Administration for Children and Families (ACF)

New evaluations in FY 2025:

- The Sexual Risk Avoidance Education National Evaluation 2.0 (SRAENE 2.0)
- Evaluations of Competency-Based Approaches to Support the Infant and Toddler Workforce

On-going evaluations from FY 2024:

- Supporting Evidence Building in Child Welfare
- Building Evidence on Employment Strategies for Low-Income Families
- Next Generation of Enhanced Employment Strategies (NextGen) Project

On-going evaluations not included in a previous HHS evaluation plan:

- Diaper Distribution Demonstration and Research Pilot (DDDRP) Evaluation

Administration for Community Living (ACL)

New evaluations in FY 2025:

- Community Care Hub Evaluation

On-going evaluations from FY 2024:

- Process and Outcome Evaluation of the National Paralysis Resource Center (NPRC)

On-going evaluations not included in a previous HHS evaluation plan: N/A

Centers for Disease Control and Prevention (CDC)

New evaluations in FY 2025:

- Transgender Women's HIV Prevention Interventions: Evaluating Adapted ChiCAS and TWIST
- Evaluation of the Implementation of PrEPmate: An evidence-based SMS (short message service/text-based) Pre-Exposure Prophylaxis (PrEP) intervention for young men who have sex with men (MSM) and Transgender women of color
- Evaluating the impact of integrating influenza vaccination into routine HIV care utilizing President's Emergency Plan for AIDS Relief (PEPFAR) implementing partners amongst patients at partner clinics
- Economic evaluations to strengthen the evidence base for influenza vaccination in Partnership for Influenza Vaccine Introduction (PIVI) partner countries and other settings
- Public Health Associate Program (PHAP) Host Site Supervisor Survey

On-going evaluations from FY 2024:

- Evaluation of the OT21-2103 National Initiative to Address COVID-19 Health Disparities Among Populations at High-Risk and Underserved, Including Racial and Ethnic Minority Populations and Rural Communities

On-going evaluations not included in a previous HHS evaluation plan:

- Evaluation of CDC's 2022 Clinical Guideline for Prescribing Opioids for Pain
- Evaluation of Virtual Reality (VR) Mine Rescue Training Platform
- Assessment of First Responder Well-being in Northwest Tribal Communities
- Evaluation and Translation of Promising Practices to Increase Equitable Access to Point-of-Care Testing During Public Health Emergencies
- Evaluation of Public and Private Laboratory Engagement for Effective Surge Testing During Future Public Health Emergencies

Centers for Medicare & Medicaid Services (CMS)

New evaluations in FY 2025: N/A

On-going evaluations from FY 2024:

- Maternal Opioid Misuse (MOM) Model Evaluation
- Integrated Care for Kids (InCK) Model Evaluation
- Network of Quality Improvement and Innovation Contractors (NQIIC) Independent Evaluation
- Evaluation of the Value-Based Insurance Design (VBID) Model
- Mixed-methods evaluation of the effectiveness of the CMS COVID-19 flexibilities and the development of recommendations to move beyond the pandemic to a resilient healthcare system
- CMS Pilot to Develop Targeted Oversight of Inappropriate Antipsychotic Prescribing Behavior in Nursing Homes

On-going evaluations not included in a previous HHS evaluation plan:

- Evaluation of the End-Stage Renal Disease (ESRD) Treatment Choices Model
- Evaluation of the Kidney Care Choices Model

Food and Drug Administration (FDA)

New evaluations in FY 2025:

- European Union (EU) Audit Sampling & Economic Fraud Program

On-going evaluations from FY 2024:

- Evaluation of the reach and utility of the Center for Tobacco Products (CTP) tobacco regulatory science research program

On-going evaluations not included in a previous HHS evaluation plan:

- Total Product Life Cycle Advisory Program (TAP) Pilot Assessment
- Independent Assessment of Medical Device User Fee Amendments (MDUFA) Workforce Metrics
- Fresh-Cut Leafy Green Processors Inspection Compliance Outcomes
- The Real Cost Campaign Outcomes Evaluation Study: Cohort 3
- Comprehensive, multi-method evaluations of statewide sales restrictions on flavored tobacco products

Health Resources & Services Administration (HRSA)

New evaluations in FY 2025: N/A

On-going evaluations from FY 2024:

- Evaluation of the Telehealth Technology Enabled Learning Program (TTELP)
- Provider Resiliency Evaluation
- Healthy Start (HS) Evaluation & Capacity Building Support
- Evaluation of the Rural Maternity and Obstetrics Management Strategies (RMOMS) Program
- Behavioral Health Workforce Supply

On-going evaluations not included in a previous HHS evaluation plan: N/A

Indian Health Service (IHS)

New evaluations in FY 2025: N/A

On-going evaluations from FY 2024:

- Trauma Informed Care (TIC): Policy manual & training development
- Indian Health Service (IHS) Evaluation Policy Roll-out Evaluation

On-going evaluations not included in a previous HHS evaluation plan: N/A

National Institutes of Health (NIH)

New evaluations in FY 2025:

- Program Evaluation of Administrative Supplement to Enhance Institutional Data Science Capacity

On-going evaluations from FY 2024:

- Evaluation of Oral Health in America: Challenges and Opportunities

On-going evaluations not included in a previous HHS evaluation plan:

- Evaluation of NIH Chief Officer for Scientific Workforce Diversity (COSWD) Office Programs
- Examining the Career Outcomes of Trainees and Scholars Supported by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and the National Center for Advancing Translational Sciences (NCATS) Using Third-Party Data
- Building Interdisciplinary Research Careers in Women's Health (BIRCWH) Program Evaluation 2025

Office of the National Coordinator for Health Information Technology (ONC)

New evaluations in FY 2025: N/A

On-going evaluations from FY 2024:

- Evaluation of the Trusted Exchange Framework and Common Agreement (TEFCA)

On-going evaluations not included in a previous HHS evaluation plan: N/A

Substance Abuse and Mental Health Services Administration (SAMHSA)

New evaluations in FY 2025: N/A

On-going evaluations from FY 2024:

- Internal Formative Evaluation of the Projects for Assistance in Transition from Homelessness (PATH)
- Evaluation of the Garrett Lee Smith (GLS) State/Tribal Youth Suicide Prevention and Early Intervention Program

On-going evaluations not included in a previous HHS evaluation plan: N/A

Significant Evaluations by HHS Evaluation Plan Priority Area

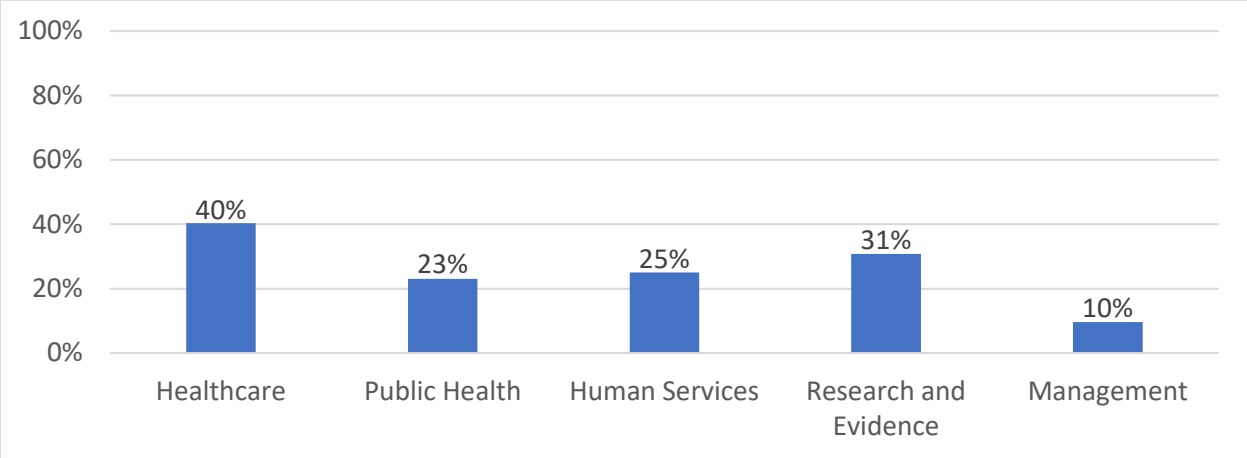
The FY 2025 Evaluation Plan priority areas are aligned with the goals and objectives of the HHS FY 2022-2026 Strategic Plan and the HHS FY 2023-2026 Evidence-Building Plan (Table 1). Together these plans coordinate and support the Op/Staff Divs in achieving key HHS priorities, especially those related to scientific research, evidence building, policy making, and capacity enhancements.

Table 1: Alignment of the Evaluation Plan Priority Areas with HHS Strategic Plan Goals

Evaluation Plan Priority Area	FY 2022-2026 HHS Strategic Goal
Healthcare	**Goal 1:** Protect and Strengthen Equitable Access to High Quality and Affordable Healthcare
Public Health	**Goal 2:** Safeguard and Improve National and Global Health Conditions and Outcomes
Human Services	**Goal 3:** Strengthen Social Well-being, Equity, and Economic Resilience
Research and Evidence	**Goal 4:** Restore Trust and Accelerate Advancements in Science and Research for All
Management	**Goal 5:** Advance Strategic Management to Build Trust, Transparency, and Accountability

The proportion of HHS Evaluation Plan priority areas addressed by new and on-going evaluations in FY 2025 is shown in Figure 5. Of the forty-nine (49) planned FY 2025 evaluations reported by Op/Staff Divs. sixteen (16), or thirty-three percent (33%), address two or more HHS Evaluation Plan priority areas.

Figure 5. Proportion of all FY 2025 evaluations by HHS Evaluation Plan priority area. (n=49)



The next section describes the types of actions being undertaken across HHS for each HHS Evaluation Plan priority area. This is followed by a list of the specific FY 2025 evaluations planned for each area by Op/Staff Div.

Priority Area 1: Healthcare

HHS is workings to protect and strengthen equitable access to high quality and affordable healthcare by reducing costs, increasing access to affordable health insurance, improving the quality of healthcare services, and ensuring access to safe medical devices and drugs. HHS is also expanding equitable access to comprehensive, community-based, and culturally competent healthcare services. HHS is driving the integration of behavioral health into primary care to strengthen and expand access to mental healthcare, substance use disorder treatment, and recovery services for individuals and families. HHS is working to bolster the health workforce and ensure the delivery of quality services and care.

Healthcare Evaluation Activities in FY 2025

Op/Staff Division	Evaluation Title
ACF	The Sexual Risk Avoidance Education National Evaluation 2.0 (SRAENE 2.0)
ACL	Process and Outcome Evaluation of the National Paralysis Resource Center (NPRC)
CDC	Assessment of First Responder Well-being in Northwest Tribal Communities
	Evaluation and Translation of Promising Practices to Increase Equitable Access to Point-of-Care Testing During Public Health Emergencies
	Evaluation of CDC's 2022 Clinical Guideline for Prescribing Opioids for Pain
	Evaluation of the Implementation of PrEPmate: An evidence-based SMS (short message service/text-based) Pre-Exposure Prophylaxis (PrEP) intervention for young men who have sex with men (MSM) and Transgender women of color
	Evaluation of Virtual Reality (VR) Mine Rescue Training Platform
CMS	CMS Pilot to Develop Targeted Oversight of Inappropriate Antipsychotic Prescribing Behavior in Nursing Homes
	Evaluation of the End-Stage Renal Disease (ESRD) Treatment Choices Model
	Evaluation of the Kidney Care Choices Model
	Evaluation of the Value-Based Insurance Design (VBID) Model
	Integrated Care for Kids (InCK) Model Evaluation
	Maternal Opioid Misuse (MOM) Model Evaluation
FDA	Independent Assessment of Medical Device User Fee Amendments (MDUFA) Workforce Metrics
	Total Product Life Cycle Advisory Program (TAP) Pilot Assessment
HRSA	Evaluation of the Rural Maternity and Obstetrics Management Strategies (RMOMS) Program
	Evaluation of the Telehealth Technology Enabled Learning Program (TTELP)
	Provider Resiliency Evaluation
IHS	Trauma Informed Care (TIC): Policy manual & training development
ONC	Evaluation of the Trusted Exchange Framework and Common Agreement (TEFCA)
SAMHSA	Internal Formative Evaluation of the Projects for Assistance in Transition from Homelessness (PATH)

Priority Area 2: Public Health

HHS is dedicated to safeguarding health and improving outcomes for everyone. HHS is improving the capacity of HHS agencies and grantees to predict, prevent, prepare for, respond to, and recover from emergencies, disasters, and threats, domestically and abroad. HHS protects individuals, families, and communities from infectious disease and prevents non-communicable disease through the development and equitable delivery of effective, innovative, readily available treatments, therapeutics, medical devices, and vaccines. HHS promotes healthy behaviors to reduce the occurrence of and disparities in preventable injury, illness, and death. HHS is also working to mitigate the impacts of environmental factors, including climate change, on health outcomes.

Public Health Evaluation Activities in FY 2025

Op/Staff Division	Evaluation Title
ACF	The Sexual Risk Avoidance Education National Evaluation 2.0 (SRAENE 2.0)
CDC	Economic evaluations to strengthen the evidence base for influenza vaccination in Partnership for Influenza Vaccine Introduction (PIVI) partner countries and other settings
	Evaluating the impact of integrating influenza vaccination into routine HIV care utilizing President's Emergency Plan for AIDS Relief (PEPFAR) implementing partners amongst patients at partner clinics
	Evaluation of Public and Private Laboratory Engagement for Effective Surge Testing During Future Public Health Emergencies
CMS	Mixed-methods evaluation of the effectiveness of the CMS COVID-19 flexibilities and the development of recommendations to move beyond the pandemic to a resilient healthcare system
FDA	Comprehensive, multi-method evaluations of statewide sales restrictions on flavored tobacco products
	European Union (EU) Audit Sampling & Economic Fraud Program
	Fresh-Cut Leafy Green Processors Inspection Compliance Outcomes
	The Real Cost Campaign Outcomes Evaluation Study: Cohort 3
HRSA	Behavioral Health Workforce Supply
NIH	Building Interdisciplinary Research Careers in Women's Health (BIRCWH) Program Evaluation 2025
SAMHSA	Evaluation of the Garrett Lee Smith (GLS) State/Tribal Youth Suicide Prevention and Early Intervention Program

Priority Area 3: Human Services

HHS is working to strengthen the economic and social well-being of Americans across the lifespan. HHS provides effective and innovative pathways leading to equitable economic success for all individuals and families. HHS is strengthening early childhood development programs and expanding opportunities to help children and youth thrive equitably within their families and communities. HHS is expanding access to high-quality services and resources for older adults and people with disabilities and their caregivers to support increased independence and quality of life. HHS is also increasing safeguards to empower families and communities to prevent and respond to neglect, abuse, and violence, while supporting those who have experienced trauma or violence.

Human Services Evaluation Activities in FY 2025

Op/Staff Division	Evaluation Title
ACF	Building Evidence on Employment Strategies for Low-Income Families
	Diaper Distribution Demonstration and Research Pilot (DDDRP) Evaluation
	Evaluations of Competency-Based Approaches to Support the Infant and Toddler Workforce
	Next Generation of Enhanced Employment Strategies (NextGen) Project
	Supporting Evidence Building in Child Welfare
ACL	Community Care Hub Evaluation
	Process and Outcome Evaluation of the National Paralysis Resource Center (NPRC)
CDC	Evaluation of CDC's 2022 Clinical Guideline for Prescribing Opioids for Pain
	Evaluation of Virtual Reality (VR) Mine Rescue Training Platform
	Transgender Women's HIV Prevention Interventions: Evaluating Adapted ChiCAS and TWIST
CMS	Integrated Care for Kids (InCK) Model Evaluation
	Maternal Opioid Misuse (MOM) Model Evaluation
HRSA	Healthy Start (HS) Evaluation & Capacity Building Support

Priority Area 4: Research and Evidence

HHS is dedicated to restoring trust and accelerating advancements in science and research. HHS has prioritized science, evidence, and inclusion to improve the design, delivery, and outcomes of HHS programs. HHS is investing in the research enterprise and the scientific workforce to maintain leadership in the development of innovations that broaden understanding of disease, healthcare, public health, and human services resulting in more effective interventions, treatments, and programs. Strengthening surveillance, epidemiology, and laboratory capacity to better understand and equitably address diseases and conditions is another major focus. HHS is also increasing evidence-based knowledge through improved data collection, use, and evaluation efforts to achieve better health outcomes, reduced health disparities, and improve social well-being, equity, and economic resilience.

Research and Evidence Evaluation Activities in FY 2025

Op/Staff Division	Evaluation Title
ACF	Supporting Evidence Building in Child Welfare
CDC	Assessment of First Responder Well-being in Northwest Tribal Communities
	Evaluation of Virtual Reality (VR) Mine Rescue Training Platform
	Public Health Associate Program (PHAP) Host Site Supervisor Survey
CMS	Network of Quality Improvement and Innovation Contractors (NQIIC) Independent Evaluation
FDA	Comprehensive, multi-method evaluations of statewide sales restrictions on flavored tobacco products
	Evaluation of the reach and utility of the Center for Tobacco Products (CTP) tobacco regulatory science research program
	Fresh-Cut Leafy Green Processors Inspection Compliance Outcomes
	The Real Cost Campaign Outcomes Evaluation Study: Cohort 3
HRSA	Behavioral Health Workforce Supply
IHS	Indian Health Service (IHS) Evaluation Policy Roll-out Evaluation
NIH	Building Interdisciplinary Research Careers in Women's Health (BIRCWH) Program Evaluation 2025
	Evaluation of NIH Chief Officer for Scientific Workforce Diversity (COSWD) Office Programs
	Evaluation of Oral Health in America: Challenges and Opportunities
	Examining the Career Outcomes of Trainees and Scholars Supported by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and the National Center for Advancing Translational Sciences (NCATS) Using Third-Party Data
	Program Evaluation of Administrative Supplement to Enhance Institutional Data Science Capacity

Priority Area 5: Management

HHS is dedicated to advancing strategic management across HHS to build trust, transparency, and accountability. A major focus of HHS is promoting effective enterprise governance to ensure programmatic goals are met equitably and transparently across all management practices. HHS sustains strong financial stewardship of resources to foster prudent use of resources, accountability, and public trust. HHS is working to uphold effective and innovative human capital resource management, resulting in an engaged, diverse workforce with the skills and competencies to accomplish the HHS mission. HHS is also ensuring the security of HHS facilities, technology, data, and information, while advancing environment-friendly practices.

Management Evaluation Activities in FY 2025

Op/Staff Division	Evaluation Title
CDC	Public Health Associate Program (PHAP) Host Site Supervisor Survey
CMS	Network of Quality Improvement and Innovation Contractors (NQIIC) Independent Evaluation
FDA	European Union (EU) Audit Sampling & Economic Fraud Program
	Fresh-Cut Leafy Green Processors Inspection Compliance Outcomes
NIH	Evaluation of NIH Chief Officer for Scientific Workforce Diversity (COSWD) Office Programs

Appendix A: HHS Evaluations Beginning in FY 2025 and On-Going Evaluations Not Previously Reported

Administration for Children and Families (ACF)

The Sexual Risk Avoidance Education National Evaluation 2.0 (SRAENE 2.0) (New in FY 2025)		
Which HHS Strategic Plan Goal(s) will this evaluation address?	☐	Strategic Goal 1: Healthcare
	☒	Strategic Goal 2: Public Health
	☐	Strategic Goal 3: Human Services
	☐	Strategic Goal 4: Research & Evidence
	☒	Strategic Goal 5: Management
Will this evaluation produce evidence related to the Federal Evidence Agenda on LGBTQI+ Equity?	No	
	If yes, please note which learning agenda questions are addressed.	
Will this evaluation produce evidence related to the Learning Agenda in Support of the President's Management Agenda?	No	
	If yes, please note which learning agenda questions are addressed.	
Will this evaluation produce evidence related to the HHS Evidence-Building Plan?	Yes	
	How do HHS policies and programs enhance promotion of healthy lifestyle behaviors to reduce occurrence and disparities in preventable injury, illness, and death?	
What are the evaluation questions guiding this evaluation?	• Which elements of Sexual Risk Avoidance Education (SRAE) programs are essential for obtaining positive youth outcomes? [Impact Study-Core Components] • What approaches are SRAE grant recipients utilizing to advance equity in access and outcomes? [Descriptive Study-Advancing Equity] • What are the implementation experiences of SRAE grant recipients serving youth in community settings? What are the experiences of the youth served by the programs? [Descriptive Study-Youth in Community Settings]	
Provide a brief description of the evaluation.	The Sexual Risk Avoidance Education (SRAE) program, authorized by Title V of the Social Security Act, supports the implementation of prevention services aiming to teach youth to avoid non-marital sexual activity, while promoting personal responsibility, self- regulation, goal setting, healthy decision-making, success sequencing for poverty prevention, a focus on the future, and the prevention of youth risk behaviors such as drug and alcohol usage. SRAENE 2.0 will produce findings on effective SRAE program components and address gaps in knowledge regarding the implementation experiences associated with SRAE program delivery to youth in community settings and the promotion of health equity. SRAENE 2.0 also aims to expand the evidence base on effective programming	

		by (1) supporting SRAE grant recipients' local evaluations and (2) conducting a federally led, multisite evaluation of select SRAE programs.	
Evaluation timeframe.		Start	Sep-23
		End	Sep-28
Data to be used	**Existing data held by the division**	No	
	Existing data from other sources	No	
	New data collection	Yes	
Evaluation Type(s)		☒	Formative
		☒	Process/implementation
		☒	Outcome/effectiveness
		☒	Impact
		☐	Economic
		☐	Other
		If other, describe below:	
Brief description of the evaluation design or approach.		Evaluation design plans are currently unknown. Data collection will start closer to FY25.	
Brief description of any anticipated challenges that may arise in the study or analysis and how you plan to address them.		Accruing a sample size sufficient for detecting impacts is a potential challenge. To mitigate this challenge, several strategies will be employed including ongoing to technical assistance for recruiting and retaining study participants, tokens of appreciation, and analytic methods that produce meaningful findings when sample size is constrained.	
Brief description of intended uses for evaluation findings.		▪ To add to the evidence-base of SRAE and similar teen pregnancy prevention programs. ▪ To identify areas where more support is needed to ensure any positive health outcomes related to SRAE programs are accessible to participating youth representing diverse backgrounds.	
Brief description of how results will be disseminated and to which audiences.		The dissemination plans are currently unknown.	
Estimated cost of the evaluation in FY25:		$4,000,000	
Estimated cost of the entire evaluation:		$14,000,000	

Evaluations of Competency-Based Approaches to Support the Infant and Toddler Workforce (New in FY 2025)		
Which HHS Strategic Plan Goal(s) will this evaluation address?	☐	Strategic Goal 1: Healthcare
	☐	Strategic Goal 2: Public Health
	☒	Strategic Goal 3: Human Services
	☐	Strategic Goal 4: Research & Evidence
	☐	Strategic Goal 5: Management
Will this evaluation produce evidence related to the Federal Evidence Agenda on LGBTQI+ Equity?	No	
	If yes, please note which learning agenda questions are addressed.	
Will this evaluation produce evidence related to the Learning Agenda in Support of the President's Management Agenda?	No	
	If yes, please note which learning agenda questions are addressed.	
Will this evaluation produce evidence related to the HHS Evidence-Building Plan?	Yes	
	What are the impacts of HHS programs and policies on strengthening early childhood development and expanding opportunities to help children and youth thrive equitably within their families and communities?	
What are the evaluation questions guiding this evaluation?	• What competency-based professional development approaches exist that target the infant and toddler workforce? Are existing approaches appropriate or feasible for implementation across types of settings (e.g., family childcare, center-based)? Are existing approaches appropriate for workforces of varying backgrounds and cultures? What is the evidence base for existing approaches? • What types of evaluation designs are appropriate for each approach and why? • How effective are the approaches in building the competencies of the infant and toddler workforce? For what populations and settings are they effective? • What supports can be provided to build evaluation capacity for developers and implementers of various approaches? • How can evaluation findings inform improvements as well as guide investments and decision-making?	
Provide a brief description of the evaluation.	The evidence-base for competency-based professional development approaches designed to support quality in infant and toddler care settings is extremely limited. Additional evaluation of existing approaches is critical to inform improvements as well as guide investments and decision-making. This evaluation is aimed at building the evidence base for competency-based professional development approaches that target the infant and toddler workforce, and ultimately to inform ACF's efforts to improve the quality of care for infants and toddlers. Candidate approaches may be ready for formative, process/implementation, or summative (i.e., impact/outcome) evaluation; they may still be in development or already be implemented; and they may or may	

		not have an existing evidence base. Evaluations may be conducted using existing data (e.g., administrative) or require the collection of new data.	
Evaluation timeframe.		Start	Nov-23
		End	Nov-28
Data to be used	**Existing data held by the division**	No	
	Existing data from other sources	Yes	
	New data collection	Yes	
Evaluation Type(s)		☒	Formative
		☒	Process/implementation
		☒	Outcome/effectiveness
		☒	Impact
		☐	Economic
		☐	Other
		If other, describe below:	
Brief description of the evaluation design or approach.		Evaluation designs will depend on the state of readiness for evaluation of approaches that are identified. Data collection will start close to FY25.	
Brief description of any anticipated challenges that may arise in the study or analysis and how you plan to address them.		Identifying approaches that are ready for evaluation is a potential challenge. There will be an initial landscaping effort to identify programs, and there will be opportunities to provide technical assistance to develop "readiness" for evaluation.	
Brief description of intended uses for evaluation findings.		▪ To build an evidence base around competency-based approaches. ▪ To inform decision-making by policymakers and practitioners.	
Brief description of how results will be disseminated and to which audiences.		The dissemination plans are currently unknown.	
Estimated cost of the evaluation in FY25:		$3,000,000	
Estimated cost of the entire evaluation:		$6,200,000	

Diaper Distribution Demonstration and Research Pilot (DDDRP) Evaluation (Not Previously Reported)			
Which HHS Strategic Plan Goal(s) will this evaluation address?		☐	Strategic Goal 1: Healthcare
		☐	Strategic Goal 2: Public Health
		☒	Strategic Goal 3: Human Services
		☐	Strategic Goal 4: Research & Evidence
		☐	Strategic Goal 5: Management
Will this evaluation produce evidence related to the Federal Evidence Agenda on LGBTQI+ Equity?	No		
	If yes, please note which learning agenda questions are addressed.		
Will this evaluation produce evidence related to the Learning Agenda in Support of the President's Management Agenda?	No		
	If yes, please note which learning agenda questions are addressed.		
Will this evaluation produce evidence related to the HHS Evidence-Building Plan?	Yes		
	If yes, please note which learning agenda questions are addressed.		
	Strategic Goal 3: Human Services: Strengthen Social Well-being, Equity, and Economic Resilience. Human Services Priority Questions: To what extent do HHS programs and policies provide effective and innovative pathways leading to equitable economic success for all individuals and families?		
What are the evaluation questions guiding this evaluation?	1) How is the DDDRP being implemented? 2) How are participants experiencing the DDDRP? 3) What are the opportunities for developing a rigorous impact assessment?		
Provide a brief description of the evaluation.	The DDDRP is the first-ever federal diaper distribution pilot. The evaluation will use a multiple case study approach to examine how the grant recipients organize and operate their program and service population. The evaluation will also examine the sites to draw broader conclusions about DDDRP's implementation and identify implications for a future impact study.		
Evaluation timeframe.		Start	Mar-23
		End	Mar-28
Data to be used	**Existing data held by the division**	Yes	

	Existing data from other sources	Yes	
	New data collection	Yes	
Evaluation Type(s)		☐	Formative
		☒	Process/implementation
		☒	Outcome/effectiveness
		☐	Impact
		☐	Economic
		☐	Other
		If other, describe below:	
Brief description of the evaluation design or approach.		To address the three overarching research questions, the evaluation includes three components: • Process evaluation to study grant recipient approaches, structures, activities, reach, and experience with ACF and technical assistance (TA) providers • Participant experience and outcome assessment to document caregiver characteristics, experiences as DDDRP participants, and changes in intended outcomes • Impact design assessment to inform development of a credible and reliable impact study design	
Brief description of any anticipated challenges that may arise in the study or analysis and how you plan to address them.		The evaluation includes three cohorts of grant recipients that were awarded in quick succession, represent diverse service delivery strategies, and include relatively short (two year) grant cycles. To address this, the research team is working closely with Office of Performance Research and Evaluation and Office of Community Services to minimize burden on grant recipients and prioritize research questions.	
Brief description of intended uses for evaluation findings.		The evaluation aims inform both program administration and future impact evaluation. As this is a new demonstration project, conducting an evaluation will provide crucial insights for the future of the program.	
Brief description of how results will be disseminated and to which audiences.		The evaluation will produce a final report summarizing across the components of the evaluation. In addition, it will produce several public-facing interim products (e.g., fact sheets, briefs, infographics) aimed at researchers, practitioners, and policymakers.	
Estimated cost of the evaluation in FY25:		Approximately $1 million is expected to be spent in FY25	
Estimated cost of the entire evaluation:		$3,131,955	

Administration for Community Living (ACL)

Community Care Hub Evaluation (New in FY 2025)		
Which HHS Strategic Plan Goal(s) will this evaluation address?	☐	Strategic Goal 1: Healthcare
	☐	Strategic Goal 2: Public Health
	☒	Strategic Goal 3: Human Services
	☐	Strategic Goal 4: Research & Evidence
	☐	Strategic Goal 5: Management
Will this evaluation produce evidence related to the Federal Evidence Agenda on LGBTQI+ Equity?	No	
	If yes, please note which learning agenda questions are addressed.	
Will this evaluation produce evidence related to the Learning Agenda in Support of the President's Management Agenda?	No	
	If yes, please note which learning agenda questions are addressed.	
Will this evaluation produce evidence related to the HHS Evidence-Building Plan?	Yes	
	If yes, please note which learning agenda questions are addressed.	
What are the evaluation questions guiding this evaluation?	Strategic Goal 3: Human Services: Strengthen Social Well-being, Equity, and Economic Resilience • What effective strategies or combinations of strategies expand access to high-quality services for older adults and people with disabilities, and their caregivers, to support increased independence and quality of life?	
Provide a brief description of the evaluation.	For decades, ACL and its federal partners have invested in infrastructure and systems change to enhance, streamline access to, and align social and healthcare services in communities for all populations and payers. Increasingly, community-based organizations (CBOs) are organizing into community provider networks, led by a Community Care Hub (CCH), to allow for a more efficient, scalable, and equitable approach to health care/CBO partnerships. The ACL CCH Grant Program aims to increase the capacity of participating CCHs to provide and coordinate social services to unmet social needs impacting patient health – addressing increased demand for these supports from health systems. The purpose of this evaluation is to assess the CCH Grant Program and its alignment with health outcomes, health care costs, and health services use.	
Evaluation timeframe.	Start	Oct-23
	End	Sep-28

Data to be used	**Existing data held by the division**	No	
	Existing data from other sources	Yes	
	New data collection	No	
Evaluation Type(s)		☐	Formative
		☐	Process/implementation
		☒	Outcome/effectiveness
		☐	Impact
		☐	Economic
		☐	Other
		If other, describe below:	
Brief description of the evaluation design or approach.		The purpose of this evaluation is to assess the CCH Grant Program and its alignment with health outcomes, health care costs, and health services use. The evaluator will work closely and collaboratively with ACL, a CCH Center of Excellence, and the grantees on the design, data collection, and implementation of the evaluation.	
Brief description of any anticipated challenges that may arise in the study or analysis and how you plan to address them.		A detailed list of potential challenges, as well as possible solutions, is one of the first deliverables for the evaluation contractor. Developing this thoughtful and comprehensive list, in collaboration with stakeholders, will be an involved process critical to the success of the evaluation.	
Brief description of intended uses for evaluation findings.		Findings will be used to inform program and policy decisions related to the CCHs, as well as to provide guidance, tools, and resources for aging, disability and healthcare-focused entities across the nation to enhance the development, implementation, and sustainability of CCHs.	
Brief description of how results will be disseminated and to which audiences.		Results will be systematically and strategically disseminated to a variety of audiences, such as policy makers, national aging, disability and healthcare-focused entities, etc. ACL will work with the contractor to develop a dissemination plan.	
Estimated cost of the evaluation in FY25:		$500,000	
Estimated cost of the entire evaluation:		$3,100,000	

Centers for Disease Control and Prevention (CDC)

Human Immunodeficiency Virus (HIV) – Transgender Women's HIV Prevention Interventions: Evaluating Adapted ChiCAS and TWIST (New in FY 2025)		
Which HHS Strategic Plan Goal(s) will this evaluation address?	☐	Strategic Goal 1: Healthcare
	☐	Strategic Goal 2: Public Health
	☒	Strategic Goal 3: Human Services
	☐	Strategic Goal 4: Research & Evidence
	☐	Strategic Goal 5: Management
Will this evaluation produce evidence related to the Federal Evidence Agenda on LGBTQI+ Equity?	Yes	
	If yes, please note which learning agenda questions are addressed.	
	To what extent can the Federal Government safeguard and improve health conditions and outcomes for LGBTQI+ people?	
Will this evaluation produce evidence related to the Learning Agenda in Support of the President's Management Agenda?	No	
	If yes, please note which learning agenda questions are addressed.	
Will this evaluation produce evidence related to the HHS Evidence-Building Plan?	Yes	
	If yes, please note which learning agenda questions are addressed.	
	Exploratory and preliminary quantitative and qualitative analysis to build evidence. To what extent do HHS programs provide effective and innovative pathways leading to equitable access to HIV prevention?	
What are the evaluation questions guiding this evaluation?	**Reach** 1. Did the Community Based Organizations (CBOs) enroll and retain the prioritized transgender populations in adapted ChiCAS (Chicas Creando Acceso a la Salud) and TWIST (Transgender Women Involved in Strategies for Transformation)? **Effectiveness** 2. Were HIV prevention outcomes improved after the interventions when compared to pre-intervention? **Adoption** 3. How quickly were CBOs able to adopt the interventions, and what successes, challenges, and adaptations occurred? **Implementation** 4. Were the interventions implemented with fidelity to the core elements? **Maintenance** 5. Did CBOs maintain delivery of the interventions throughout the funding period?	

Provide a brief description of the evaluation.		There are few CDC-supported HIV prevention interventions for transgender women in the Compendium of Evidenced-based Interventions. This is non-research program evaluation of two HIV prevention interventions for transgender women: CHICAS as adapted for black transgender women and TWIST. The intent is to evaluate whether CBOs can successfully implement these two interventions and achieve expected outcomes.	
Evaluation timeframe.		Start	Jan-25
		End	Jan-27
Data to be used	**Existing data held by the division**	No	
	Existing data from other sources	No	
	New data collection	Yes	
Evaluation Type(s)		☐	Formative
		☒	Process/implementation
		☒	Outcome/effectiveness
		☐	Impact
		☐	Economic
		☐	Other
		If other, describe below:	
Brief description of the evaluation design or approach.		Through a new Notice of Funding Opportunity (NOFO), CDC will fund four CBOs to deliver and evaluate adapted ChiCAS and four CBOs to deliver and evaluate TWIST for two years (FY25 and FY26 – the publication of these NOFOs is tentatively scheduled for August 2024 with notice of awards in April 2025). CBOs will conduct formative evaluation to ensure the interventions are feasible, appropriate, and acceptable to both CBOs and intervention participants, implementation evaluation to determine if the interventions are implemented with fidelity, and outcome monitoring using a baseline survey pre-intervention and three follow-up surveys post-intervention to compare post-intervention outcomes to baseline.	
Brief description of any anticipated challenges that may arise in the study or analysis and how you plan to address them.		None at this time.	

Brief description of intended uses for evaluation findings.	Results will be shared with participating CBOs for the immediate benefit of their program. Additionally, this work may inform CDC's program guidance for these interventions, including strategies to support adoption, recruitment, and maintenance of intervention delivery over time. Though evaluation findings are not generalizable, it will also benefit the broader field of HIV prevention by assessing the feasibility of implementing these interventions in real-world settings.
Brief description of how results will be disseminated and to which audiences.	Results will be shared with NOFO CBO recipients, leadership and partners in the Division of HIV prevention, and the broader field of HIV prevention.
Estimated cost of the evaluation in FY25:	$2,800,000
Estimated cost of the entire evaluation:	$5,600,000

Human Immunodeficiency Virus (HIV) – Evaluation of the Implementation of PrEPmate: An evidence-based SMS (short message service/text-based) Pre-Exposure Prophylaxis (PrEP) intervention for young men who have sex with men (MSM) and Transgender women of color (New in FY 2025)		
Which HHS Strategic Plan Goal(s) will this evaluation address?	☒	Strategic Goal 1: Healthcare
	☐	Strategic Goal 2: Public Health
	☐	Strategic Goal 3: Human Services
	☐	Strategic Goal 4: Research & Evidence
	☐	Strategic Goal 5: Management
Will this evaluation produce evidence related to the Federal Evidence Agenda on LGBTQI+ Equity?	Yes	
	If yes, please note which learning agenda questions are addressed.	
	1. To what extent can the Federal Government protect and strengthen equitable access to high-quality and affordable healthcare for LGBTQI+ people across the lifespan? • To what extent do federal programs and policies strengthen and expand access to mental and behavioral health services, primary care, and preventive services for LGBTQI+ people? 2. To what extent can the Federal Government safeguard and improve health conditions and outcomes for LGBTQI+ people? • How effective are federal programs and policies at protecting LGBTQI+ people from infectious disease and preventing non-communicable disease through development and equitable delivery of effective, innovative, and readily available treatments, therapeutics, medical devices, and vaccines? • How do federal policies and programs enhance promotion of healthy behaviors and wellness among LGBTQI+ people to reduce occurrence of and disparities in preventable injury, illness, and death? • To what extent do health outcomes for LGBTQI+ people vary by geographic region? • To what extent do health outcomes for LGBTQI+ people vary by demographic characteristics?	

Will this evaluation produce evidence related to the Learning Agenda in Support of the President's Management Agenda?	Yes	
	If yes, please note which learning agenda questions are addressed.	
	How can equity be advanced in the design, delivery, and evaluation of Federal services? Example questions: • What strategies effectively remove barriers to awareness of, access to, and delivery of Federal services, particularly for historically underserved individuals or populations? • What approaches to data collection and analysis could improve understanding about service utilization among underserved populations?	
Will this evaluation produce evidence related to the HHS Evidence-Building Plan?	Yes	
	If yes, please note which learning agenda questions are addressed.	
	• How and to what extent do HHS programs and policies ensure access to safe medical devices and drugs? • How do HHS programs and policies expand equitable access to comprehensive, community-based, innovative, and culturally competent healthcare services while addressing social determinants of health? • How effective are HHS programs and policies at integrating behavioral health services into the healthcare system? • How do HHS programs and policies bolster the primary and preventive healthcare workforce to ensure delivery of quality services and care?	
What are the evaluation questions guiding this evaluation?	• How is PrEPmate perceived, diffused, adopted, implemented, and maintained by staff of CBOs and clinics as well as clients/patients? (Data source: interviews) • What are the "real-world" complexities of implementation specifically of PrEPmate? (Data source: interviews) • What adaptations did the 12 agencies make to PrEPmate's adaptable features? (Data source; both interviews and downloads from PrEPmate dashboard) • What is the reach of the intervention in terms of number of clients/patients enrolled? (Data source: download from PrEPmate dashboard) • What proportion of PrEP clinic visits are met? (Data source: download from PrEPmate dashboard) • What is the proportion of daily PrEP dosage adherence? (Data source: download from PrEPmate dashboard)	
Provide a brief description of the evaluation.	PrEPmate is a short-message-service text based behavioral intervention for PrEP uptake and adherence that has been identified as evidence-based by CDC. This implementation evaluation of 12 adopting agencies of PrEPmate will inform CDC on strategies, challenges, and resources needed for national dissemination of a text-based intervention with potential for very wide application. This implementation evaluation will examine how the intervention is adopted by CBOs/Clinics and by African American and Latino men who have sex with men and transgender women of color. The 12 sites will be geographically distributed but 6 will be in the deep South where HIV incidence among racial, ethnic, and sexual minority persons remains the most severe.	
Evaluation timeframe.	Start	Oct-24
	End	Sep-28

Data to be used	**Existing data held by the division**	No	
	Existing data from other sources	Yes	
	New data collection	Yes	
Evaluation Type(s)		☐	Formative
		☒	Process/implementation
		☐	Outcome/effectiveness
		☐	Impact
		☐	Economic
		☐	Other
		If other, describe below:	
Brief description of the evaluation design or approach.		RE-AIM (Reach Effectiveness Adoption Implementation Maintenance) based evaluation design to look at Reach of PrEPmate to impacted persons. Efficacy of PrEPmate by adopting agencies. Barriers and challenges to PrEPmate adoption, implementation, and maintenance. Both qualitative interviews of clinicians and patients will be collected as well as quantitative data from PrEPmate dashboard on uptake and medication adherence.	
Brief description of any anticipated challenges that may arise in the study or analysis and how you plan to address them.		PrEPmate is a short message service text-based intervention so adopting agencies and their patients should be able to adopt and implement this evidence-based approach to PrEP uptake and adherence, however technical assistance will be provided to all 12 adopting agencies so as to build their capacity to adopt and implement a text-based approach to HIV prevention.	
Brief description of intended uses for evaluation findings.		Evaluation findings will inform CDC on future dissemination strategies and resources needed for broad national dissemination of a technology-based approach to HIV prevention.	
Brief description of how results will be disseminated and to which audiences.		• Series of peer reviewed papers on all qualitative and quantitative data on formative, process, and outcome stages. • Potential national dissemination via a NOFO to large numbers of clinics and CBOs providing HIV prevention services. Such a large dissemination project will require technical assistance to new adopters.	
Estimated cost of the evaluation in FY25:		$500,000	
Estimated cost of the entire evaluation:		$2,500,000 (over four years)	

National Center for Immunization and Respiratory Diseases (NCIRD) – Evaluating the impact of integrating influenza vaccination into routine HIV care utilizing President's Emergency Plan for AIDS Relief (PEPFAR) implementing partners amongst patients at partner clinics (New in FY 2025)			
Which HHS Strategic Plan Goal(s) will this evaluation address?		☐	Strategic Goal 1: Healthcare
		☒	Strategic Goal 2: Public Health
		☐	Strategic Goal 3: Human Services
		☐	Strategic Goal 4: Research & Evidence
		☐	Strategic Goal 5: Management
Will this evaluation produce evidence related to the Federal Evidence Agenda on LGBTQI+ Equity?		No	
		If yes, please note which learning agenda questions are addressed.	
Will this evaluation produce evidence related to the Learning Agenda in Support of the President's Management Agenda?		No	
		If yes, please note which learning agenda questions are addressed.	
Will this evaluation produce evidence related to the HHS Evidence-Building Plan?		No	
		If yes, please note which learning agenda questions are addressed.	
What are the evaluation questions guiding this evaluation?		Can PEPFAR (President's Emergency Plan for AIDS Relief) implementing partners be leveraged for routine influenza vaccination? What is the impact on influenza vaccination uptake when these partners are used for program implementation?	
Provide a brief description of the evaluation.		Utilizing existing infrastructure can be a cost-effective method for vaccine education and implementation. This project will evaluate the effectiveness and impact of utilizing PEPFAR implementing partners for routine influenza vaccination and will assess the impact on influenza vaccination uptake.	
Evaluation timeframe.		Start	Oct-24
		End	Sep-25
Data to be used	**Existing data held by the division**	Yes	
	Existing data from other sources	Yes	
	New data collection	Yes	
Evaluation Type(s)		☒	Formative

	☐	Process/implementation
	☐	Outcome/effectiveness
	☐	Impact
	☐	Economic
	☐	Other
	If other, describe below:	
Brief description of the evaluation design or approach.	Data on key performance metrics for vaccine uptake will be analyzed. Both quantitative and qualitative data will be analyzed using standardized methods to identify program successes and challenges to implementation.	
Brief description of any anticipated challenges that may arise in the study or analysis and how you plan to address them.	Consistent data collection across sites and consistent use of scanform technologies. Ensuring cultural appropriateness of information across sites. The project will leverage expertise and experience from other programs to gather best practices/lessons learned.	
Brief description of intended uses for evaluation findings.	This information will inform whether PEPFAR implementing platforms can be successfully utilized for influenza vaccination and will inform the potential use of this model for future strategies.	
Brief description of how results will be disseminated and to which audiences.	Results will be disseminated across CIOs, country partners, and implementing partners after obtaining appropriate clearance and approval.	
Estimated cost of the evaluation in FY25:	Not reported.	
Estimated cost of the entire evaluation:	Not reported.	

National Center for Immunization and Respiratory Diseases (NCIRD) – Economic evaluations to strengthen the evidence base for influenza vaccination in Partnership for Influenza Vaccine Introduction (PIVI) partner countries and other settings (New in FY 2025)		
Which HHS Strategic Plan Goal(s) will this evaluation address?	☐	Strategic Goal 1: Healthcare
	☒	Strategic Goal 2: Public Health
	☐	Strategic Goal 3: Human Services
	☐	Strategic Goal 4: Research & Evidence
	☐	Strategic Goal 5: Management

Will this evaluation produce evidence related to the Federal Evidence Agenda on LGBTQI+ Equity?		No	
		If yes, please note which learning agenda questions are addressed.	
Will this evaluation produce evidence related to the Learning Agenda in Support of the President's Management Agenda?		No	
		If yes, please note which learning agenda questions are addressed.	
Will this evaluation produce evidence related to the HHS Evidence-Building Plan?		No	
		If yes, please note which learning agenda questions are addressed.	
What are the evaluation questions guiding this evaluation?		What is the cost of influenza illness and what is cost of the influenza vaccine program? What is the cost-effectiveness of influenza vaccination?	
Provide a brief description of the evaluation.		This evaluation will assess the economic impacts of influenza disease burden as well as the cost of an influenza vaccine program to make an assessment of the cost-effectiveness of a vaccine program. This information will be used to inform the evidence-base for influenza vaccination in PIVI partner countries and other settings.	
Evaluation timeframe.		Start	Oct-24
		End	Sep-25
Data to be used	**Existing data held by the division**	Yes	
	Existing data from other sources	Yes	
	New data collection	Yes	
Evaluation Type(s)		☐	Formative
		☐	Process/implementation
		☐	Outcome/effectiveness
		☐	Impact
		☒	Economic
		☐	Other

	If other, describe below:
Brief description of the evaluation design or approach.	Both quantitative data will be analyzed using standardized methods to estimate disease burden, the cost of the influenza vaccine program and to estimate the cost-effectiveness of a vaccine program.
Brief description of any anticipated challenges that may arise in the study or analysis and how you plan to address them.	Completeness/availability of historical data on influenza disease burden may vary across countries. Completing public health priorities may arise, impacting availability of resources. We will leverage prior experience and existing partnerships to make efficient use of time/resources.
Brief description of intended uses for evaluation findings.	This information will be used to inform the economic evidence-base for influenza vaccination in PIVI partner countries and other settings and will also provide the evidence-base for national authorities to justify continued financial and programmatic support for influenza vaccination in their countries.
Brief description of how results will be disseminated and to which audiences.	Results will be disseminated across CIOs, country partners, and implementing partners after obtaining appropriate clearance and approval.
Estimated cost of the evaluation in FY25:	Not reported.
Estimated cost of the entire evaluation:	Not reported.

Public Health Associate Program (PHAP) Host Site Supervisor Survey (New in FY 2025)		
Which HHS Strategic Plan Goal(s) will this evaluation address?	☐	Strategic Goal 1: Healthcare
	☐	Strategic Goal 2: Public Health
	☐	Strategic Goal 3: Human Services
	☒	Strategic Goal 4: Research & Evidence
	☒	Strategic Goal 5: Management
Will this evaluation produce evidence related to the Federal Evidence Agenda on LGBTQI+ Equity?	No	
	If yes, please note which learning agenda questions are addressed.	
Will this evaluation produce evidence related to the Learning Agenda in Support of the President's Management Agenda?	Yes	
	If yes, please note which learning agenda questions are addressed.	
	What approaches build a strong, empowered, and diverse cohort across the Federal Government employee lifecycle?	

Will this evaluation produce evidence related to the HHS Evidence-Building Plan?		Yes	
		If yes, please note which learning agenda questions are addressed.	
		Strategic Goal 4: Research & Evidence: How does HHS improve the design, delivery, and outcomes of HHS programs by prioritizing science, evidence, and inclusion? **Strategic Goal 5: Management**: Which HHS investments are optimal to uphold effective and innovative human capital resource management resulting in an engaged, diverse workforce with the skills and competencies to accomplish the HHS mission?	
What are the evaluation questions guiding this evaluation?		1. How do PHAP associates contribute to State, Tribal, Local and Territory (STLT) agencies? 2. What effect does PHAP have on the STLT workforce? 3. What impact do PHAP associates have on STLT-implemented interventions and programs?	
Provide a brief description of the evaluation.		The Public Health Associate Program (PHAP) is a service-learning program designed to train and provide experiential learning to early career professionals who contribute to the public health workforce. They complete their two-year program at a host site (a STLT agency or NGO); the host sites design associate assignments to meet agencies' unique needs while also providing on-the-job experience that prepare associates for future careers in public health. To evaluate this component of PHAP, the PHAP Evaluation Team implements a PHAP Host Site Supervisor Survey. The PHAP Host Site Supervisor Survey gathers information on host site supervisors' perceptions of PHAP's value to their agencies and their suggestions to improve the program. *NOTE: this evaluation is conducted every-other-year; the next administration of this evaluation is scheduled for FY25.*	
Evaluation timeframe.		Start	May-25
		End	Jul-25
Data to be used	**Existing data held by the division**	Yes	
	Existing data from other sources	No	
	New data collection	Yes	
Evaluation Type(s)		☐	Formative
		☒	Process/implementation
		☒	Outcome/effectiveness
		☐	Impact
		☐	Economic
		☐	Other

	If other, describe below:
Brief description of the evaluation design or approach.	The approach for the PHAP Host Site Supervisor Survey is a mixed-methods design. Electronically administered surveys will contain both quantitative and qualitative questions. Analyses will include descriptive and advanced statistical analyses for quantitative items and grounded theory for qualitative items.
Brief description of any anticipated challenges that may arise in the study or analysis and how you plan to address them.	The primary anticipated challenge is ensuring that the distribution list for PHAP host site supervisors is up-to-date. With high turnover rates at STLTs and NGOs, PHAP host site supervisor lists can change regularly, making it challenging to certify that the list of participants is accurate at the time of survey dissemination. This challenge will be addressed by working with PHAP leadership to make sure that the evaluation team as the most current list of PHAP host site supervisors when it is time to distribute the survey.
Brief description of intended uses for evaluation findings.	This survey is instrumental in helping PHAP staff learn about the host site supervisor perspective. These findings inform where program improvements may be warranted, as well as giving PHAP leadership information on how these host site stakeholders view the quality, impact, and value of the program. These findings also demonstrate to PHAP leadership how their associates are actively contributing to field work and the overall public health workforce.
Brief description of how results will be disseminated and to which audiences.	Results are given to PHAP leadership, as well as division leadership, in the form of reports and presentations. Results may also be published in peer-reviewed journals and/or non-scientific publications in grey literature.
Estimated cost of the evaluation in FY25:	10% of GS-13 equivalent's time
Estimated cost of the entire evaluation:	10% of GS-13 equivalent's time

Evaluation of CDC's 2022 Clinical Guideline for Prescribing Opioids for Pain[2] (Not Previously Reported)		
Which HHS Strategic Plan Goal(s) will this evaluation address?	☒	Strategic Goal 1: Healthcare
	☐	Strategic Goal 2: Public Health
	☒	Strategic Goal 3: Human Services
	☐	Strategic Goal 4: Research & Evidence
	☐	Strategic Goal 5: Management
Will this evaluation produce evidence related to the Federal Evidence Agenda on LGBTQI+ Equity?	No	
	If yes, please note which learning agenda questions are addressed.	

[2] This evaluation will conclude before FY 2025. It is included here because this evaluation was not captured in the FY 2024 Evaluation Plan.

Will this evaluation produce evidence related to the Learning Agenda in Support of the President's Management Agenda?		No	
		If yes, please note which learning agenda questions are addressed.	
Will this evaluation produce evidence related to the HHS Evidence-Building Plan?		Yes	
		If yes, please note which learning agenda questions are addressed.	
		Protect and Strengthen Equitable Access to High Quality and Affordable Healthcare Strengthen Social Well-being, Equity, and Economic Resilience	
What are the evaluation questions guiding this evaluation?		1. How did CDC disseminate the Guideline to providers, health systems, medical boards, professional associations, or payers? 2. How did CDC communicate guideline content to the public and stakeholders through tools and resources? 3. What were successes and challenges of the Guideline's dissemination and communication? 4. How have prescribing metrics changed since the implementation of the 2022 CDC Guideline.	
Provide a brief description of the evaluation.		CDC is in the process of starting a rigorous multiyear evaluation of the implementation and uptake of the 2022 Clinical Practice Guideline. CDC is interested in evaluating the Clinical Practice Guideline uptake across a multitude of partners and settings to ensure that patients are receiving safe, evidence-based care for pain management. A comprehensive evaluation to track Clinical Practice Guideline implementation, uptake, and outcomes will allow CDC to understand impact and to work carefully to ensure that Americans have access to safer, effective ways of managing their pain.	
Evaluation timeframe.		Start	Aug-23
		End	Jul-24
Data to be used	**Existing data held by the division**	Yes	
	Existing data from other sources	Yes	
	New data collection	Yes	
<u>Evaluation Type(s)</u>		☐	Formative
		☒	Process/implementation
		☒	Outcome/effectiveness
		☐	Impact
		☐	Economic
		☐	Other
		If other, describe below:	

Brief description of the evaluation design or approach.	Mixed-method, quasi-experimental design. Proposed evaluation is based on the Practical, Robust Implementation and Sustainability Model (PRISM) which expands on the outcome measures of RE-AIM (reach, effectiveness, adoption, implementation, and maintenance) to address key contextual factors, including the intervention, recipients, implementation and sustainability infrastructure, and external environment of the implementation setting.
Brief description of any anticipated challenges that may arise in the study or analysis and how you plan to address them.	Potential for low response rates on national survey – proposed staff have extensive experience fielding surveys and with strategies to encourage a higher response rate.
Brief description of intended uses for evaluation findings.	A comprehensive evaluation to track Clinical Practice Guideline implementation, uptake, and outcomes will allow CDC to understand impact and to work carefully to ensure that Americans have access to safer, effective ways of managing their pain.
Brief description of how results will be disseminated and to which audiences.	The findings of these analyses will be synthesized in evaluation update reports and at potentially a journal manuscript.
Estimated cost of the evaluation in FY25:	1,000,000
Estimated cost of the entire evaluation:	1,000,000 (2-year contract with two 12-month option years)

Evaluation of Virtual Reality (VR) Mine Rescue Training Platform (Not Previously Reported)		
Which HHS Strategic Plan Goal(s) will this evaluation address?	☐	Strategic Goal 1: Healthcare
	☐	Strategic Goal 2: Public Health
	☐	Strategic Goal 3: Human Services
	☒	Strategic Goal 4: Research & Evidence
	☐	Strategic Goal 5: Management
Will this evaluation produce evidence related to the Federal Evidence Agenda on LGBTQI+ Equity?	No	
	If yes, please note which learning agenda questions are addressed.	
Will this evaluation produce evidence related to the Learning Agenda in Support of the President's Management Agenda?	No	
	If yes, please note which learning agenda questions are addressed.	

Will this evaluation produce evidence related to the HHS Evidence-Building Plan?		Yes	
		If yes, please note which learning agenda questions are addressed.	
		How does HHS improve the design, delivery, and outcomes of HHS programs by prioritizing science, evidence, and inclusion? (SG4)	
What are the evaluation questions guiding this evaluation?		Is the National Institute for Occupational Safety and Health'a (NIOSH) VR Mine Rescue Training Platform (VR-MRT) an effective training tool for preparing mine rescue teams to respond in the event of an emergency? What, if any adaptations could be made to this tool to improve adoption and implementation?	
Provide a brief description of the evaluation.		Recent research suggest that a large portion of mine rescue team members do not feel fully prepared to respond in in the event of an emergency. Traditional mine rescue training lacks the context, fidelity, and structure needed to fully prepare mine rescue team members to respond in the event of an emergency. It predominantly relies on competitive drills in above-ground facilities or open fields that have undetermined 'real world' application, are low fidelity, and have limited documented evidence for effectiveness. Using the RE-AIM (Reach Effectiveness Adoption Implementation Maintenance) framework (https://re-aim.org/), this project will focus on evaluating the Effectiveness, Adoption, and Implementation of NIOSH's VR-MRT as a training tool for mine rescue teams. The evaluation will include effectiveness experiments (i.e., comparing VR-MRT to traditional training), longitudinal implementation interviews and observations, and organizational readiness surveys. Researchers plan to work with collegiate mine rescue teams, mining companies, training centers, and government facilities.	
Evaluation timeframe.		Start	Oct-23
		End	Sep-27
Data to be used	**Existing data held by the division**	No	
	Existing data from other sources	No	
	New data collection	Yes	
Evaluation Type(s)		☐	Formative
		☒	Process/implementation
		☒	Outcome/effectiveness
		☐	Impact
		☐	Economic
		☐	Other
		If other, describe below:	

Brief description of the evaluation design or approach.	The primary effort of this project is to evaluate the effectiveness, adoption, and implementation of NIOSH's VR VR-MRT. College mine rescue teams and their associated institutions will be the target population for the effectiveness study with the Beta version of VR-MRT. This effort will be started first to ensure the students have controlled exposure to VR-MRT. Industry training sites (e.g., mine rescue facilities, training centers) are the main population for the for adoption and implementation study. For parity, universities that participated in the effectiveness study will also be recruited. Several rounds of surveys (including organizational readiness), interviews, and observations will be conducted as NIOSH researchers work with recruited implementation sites to integrate VR-MRT into their existing mine rescue training programs (e.g., train the trainer). The same Beta version of VR-MRT will be used. Lastly, NIOSH researchers will also recruit general industry participants (e.g., mine sites, mine rescue teams, international partners) interested in independently trying VR-MRT to complete the organizational readiness survey at various time points as they test or implement VR-MRT on their own.
Brief description of any anticipated challenges that may arise in the study or analysis and how you plan to address them.	The IRB and OMB approval processes, in addition to software testing and recruitment challenges could impact the project's data collection schedule. This is currently scheduled to occur in FY24.
Brief description of intended uses for evaluation findings.	Using the evaluation results NIOSH will modify VR-MRT and release it as a stand-alone software package that other mine rescue teams, mines, and training centers can adopt and implement to augment their current training. Researchers will also explore future VR-related opportunities for health and safety applications employing the lessons learned from the evaluation effort.
Brief description of how results will be disseminated and to which audiences.	Since the project primarily focuses on the evaluation of a mine rescue training tool, the target audience is both users and decision makers. Researchers are interested in interfacing with all levels that may play a role in the adoption, implementation, use, and maintenance of the system. This includes mine rescue team members, trainers, training developers, safety and health professionals, information technology specialists, supervisors, and leaders. NIOSH researchers will be actively collaborating with these interested parties in several ways: evaluation activities, VR-MRT demonstrations, and application exploration.
Estimated cost of the evaluation in FY25:	$70,000
Estimated cost of the entire evaluation:	$280,000

Assessment of First Responder Well-being in Northwest Tribal Communities (Not Previously Reported)		
Which HHS Strategic Plan Goal(s) will this evaluation address?	☒	Strategic Goal 1: Healthcare
	☐	Strategic Goal 2: Public Health
	☐	Strategic Goal 3: Human Services
	☒	Strategic Goal 4: Research & Evidence
	☐	Strategic Goal 5: Management

Will this evaluation produce evidence related to the Federal Evidence Agenda on LGBTQI+ Equity?		No	
		If yes, please note which learning agenda questions are addressed.	
Will this evaluation produce evidence related to the Learning Agenda in Support of the President's Management Agenda?		Yes	
		If yes, please note which learning agenda questions are addressed.	
		How can the Federal Government advance equity and support underserved communities?	
Will this evaluation produce evidence related to the HHS Evidence-Building Plan?		Yes	
		If yes, please note which learning agenda questions are addressed.	
		• How do HHS programs and policies bolster the primary and preventive healthcare workforce to ensure delivery of quality services and care? (SG 1) • What improvements are needed to HHS programs and policies for data collection, use, and evaluation to increase evidence-based knowledge that leads to better health outcomes, reduced health disparities, and improved social well-being, equity, and economic resilience? (SG 4)	
What are the evaluation questions guiding this evaluation?		What are the risks and protective factors affecting American Indian/Alaska Native (AI/AN) first responders' mental health and well-being at the individual, organizational, and community level?	
Provide a brief description of the evaluation.		The purpose of this project is to gain a greater understanding of the risks and protective factors that affect the well-being of AI/AN first responders in the Indian Health Service (IHS) Portland Area. The AI/AN population as a whole face a disproportionate burden of illness and lower life expectancy than the total U.S. population. AI/AN health disparities are in large part the result of structural racism and racial and ethnic stereotyping that has hindered health care and progress in AI/AN communities. Although there have been studies to describe overarching health disparities in the AI/AN population, very little research has examined occupational safety and health (OSH) among AI/AN workers. Within the worker population, AI/AN first responders are a significantly understudied and underserved population.	
Evaluation timeframe.		Start	Oct-23
		End	Sep-27
Data to be used	**Existing data held by the division**	No	
	Existing data from other sources	No	
	New data collection	Yes	

Evaluation Type(s)	☒	Formative
	☐	Process/implementation
	☐	Outcome/effectiveness
	☐	Impact
	☐	Economic
	☒	Other
	If other, describe below:	
	Needs Assessment, Foundational Fact Finding	
Brief description of the evaluation design or approach.	The primary goals of the project are to identify factors affecting AI/AN first responders' mental health and well-being at the individual, organizational, and community level. These goals will be accomplished through the following specific aims: 1) administering a two-part questionnaire consisting of the NIOSH Worker Well-being Questionnaire (WellBQ) and a set of partner-informed supplemental questions to 120 AI/AN first responders in the IHS Portland Area to characterize workplace risk factors, protective factors, and mental health outcomes; 2) conducting 6 to 10 focus groups with AI/AN first responders from a subset of communities in the IHS Portland Area to better understand tribal, community, organizational, and individual level factors that foster or hinder well-being; and 3) integrating and analyzing quantitative and qualitative data using a mixed methods approach.	
Brief description of any anticipated challenges that may arise in the study or analysis and how you plan to address them.	The IRB and OMB approval process may impact the project's data collection. This project is a collaboration with the Northwest Portland Area Indian Health (NPAIHB), a tribal advisory organization serving 43 federally recognized tribes in Oregon, Washington, and Idaho. NPAIHB houses the Northwest Tribal Epidemiology Center, which is one of the twelve IHS Tribal Epidemiology Centers, and it hosts the Portland Area IHS Institutional Review Board (IRB), which oversees protection of AI/AN human subjects in research occurring in the IHS Portland Area.	
Brief description of intended uses for evaluation findings.	This project will reveal previously unknown information that will help guide tailored tribal first responder well-being initiatives. It is anticipated that tribes and tribal-serving organizations will use the project's outputs to better understand individual, organizational, and community level factors that impact the well-being of tribal first responders in the IHS Portland Area. Participating organizations will use project findings to inform a future intervention study for AI/AN first responders in this IHS area and inform further exploratory research in other IHS areas.	
Brief description of how results will be disseminated and to which audiences.	The findings of this project will be disseminated to partner organizations to use to develop resources devoted to AI/AN first responder mental health. Expected outputs include presentations, peer-reviewed publications, trade publications, and lay publications.	
Estimated cost of the evaluation in FY25:	$50,000	
Estimated cost of the entire evaluation:	$200,000	

Office of Laboratory Science and Safety – Evaluation and Translation of Promising Practices to Increase Equitable Access to Point-of-Care Testing During Public Health Emergencies (Not Previously Reported)		
Which HHS Strategic Plan Goal(s) will this evaluation address?	☒	Strategic Goal 1: Healthcare
	☐	Strategic Goal 2: Public Health
	☐	Strategic Goal 3: Human Services
	☐	Strategic Goal 4: Research & Evidence
	☐	Strategic Goal 5: Management
Will this evaluation produce evidence related to the Federal Evidence Agenda on LGBTQI+ Equity?	No	
	If yes, please note which learning agenda questions are addressed.	
Will this evaluation produce evidence related to the Learning Agenda in Support of the President's Management Agenda?	Yes	
	If yes, please note which learning agenda questions are addressed.	
	How can the Federal Government advance equity and support underserved communities?	
Will this evaluation produce evidence related to the HHS Evidence-Building Plan?	Yes	
	If yes, please note which learning agenda questions are addressed.	
	How do HHS programs and policies expand equitable access to comprehensive, community-based, innovative, and culturally competent healthcare services while addressing social determinants of health?	
What are the evaluation questions guiding this evaluation?	1. What approaches (i.e., strategies, interventions, policies, partnerships, coalitions, and/or practices) to increase access to point of care (POC) testing during public health emergencies (PHEs) or outbreaks have been evaluated in the literature over the past 5 years? 2. What is the availability of evidence that evaluates approaches implemented to increase access to POC testing during PHEs or outbreaks? 3. What factors facilitated access to POC testing for different population groups? 4. What barriers impeded access to POC testing for different population groups? 5. What are the facilitators, barriers, and strategies to overcome barriers implemented by selected entities (up to 9) to increase access to POC testing for different population groups that were disproportionately affected during PHEs or outbreaks?	

Provide a brief description of the evaluation.		This multi-step evaluation and translation project led by the Division of Laboratory Systems (DLS) aims to identify promising practices in increasing access to POC testing among different settings or population groups during PHEs or outbreaks. For phase 1 of the project is to conduct a scoping review within the last 5 years to identify the most effective and/or promising practice strategies or approaches associated with increased equitable access to POC testing for different population groups during public health emergencies. For phase 2, a ten-item survey will be developed and disseminated to 2,000 U.S. adults with a sample of minority segments including Black, Hispanic, Asian, LGBTQ+, and people with disability. Findings from phases 1 & 2 will be used to select up to 9 organizations or coalitions or testing providers for further evaluation and translation into an actionable toolkit or resources that State, Tribal, Local, and Territorial (STLT) health departments (HDs) and Public Health Laboratories (PHLs) can use to improve equitable access to POC testing in particular for underserved and socially vulnerable communities.	
Evaluation timeframe.		Start	Nov-22
		End	Sep-26
Data to be used	**Existing data held by the division**	Yes	
	Existing data from other sources	Yes	
	New data collection	Yes	
Evaluation Type(s)		☒	Formative
		☒	Process/implementation
		☒	Outcome/effectiveness
		☐	Impact
		☐	Economic
		☐	Other
		If other, describe below:	
Brief description of the evaluation design or approach.		This is a multi-step evaluation and translation project using a mixed-methods, case study design consisting of a formative, process, and outcome evaluation. The scoping review and survey serve as a formative evaluation to inform the design and selection of case studies (up to 9 entities) that have successfully implemented promising practices or approaches to identify facilitators, barriers, and strategies to overcome barriers related to providing access to POC testing for disproportionately affected populations during PHEs or outbreaks. The outcome	

	evaluation will assess the relevance, effectiveness, and feasibility of identified promising practices for further translation or broader implementation during future public health events.
Brief description of any anticipated challenges that may arise in the study or analysis and how you plan to address them.	We anticipate limitations in the literature for effective or promising practices in increasing equitable access to POC testing during PHEs. To address this, we will explore options to gather feedback from representatives of the affected communities, subject matter experts in the field, STLT health departments, clinical and public health laboratories, and other key partners on the potential promising strategies or approaches for further evaluation.
Brief description of intended uses for evaluation findings.	The findings from this multi-step evaluation and translation project will be used to develop an actionable toolkit or resources that are easily accessible to STLT HDs, PHLs, community-based organizations, and affected communities. If there are relevant public health events (outbreaks or emergencies) after the toolkit or resources are developed, we will conduct a pilot study to assess the effectiveness of the strategies included in the toolkit to improve equitable access to POC testing for different population groups who are disproportionately affected.
Brief description of how results will be disseminated and to which audiences.	Evaluation results will be shared with project collaborators, implementing partners, and other relevant audiences through presentations, evaluation briefs, and an evaluation report. We will promote and evaluate the developed resources and toolkit via multiple channels of communication to reach and tailor for different audiences.
Estimated cost of the evaluation in FY25:	$500,000.00
Estimated cost of the entire evaluation:	$900,000.00

Office of Laboratory Science and Safety – Evaluation of Public and Private Laboratory Engagement for Effective Surge Testing During Future Public Health Emergencies (Not Previously Reported)		
Which HHS Strategic Plan Goal(s) will this evaluation address?	☐	Strategic Goal 1: Healthcare
	☒	Strategic Goal 2: Public Health
	☐	Strategic Goal 3: Human Services
	☐	Strategic Goal 4: Research & Evidence
	☐	Strategic Goal 5: Management
Will this evaluation produce evidence related to the Federal Evidence Agenda on LGBTQI+ Equity?	No	
	If yes, please note which learning agenda questions are addressed.	

Will this evaluation produce evidence related to the Learning Agenda in Support of the President's Management Agenda?	Yes	
	If yes, please note which learning agenda questions are addressed.	
	How can the Federal Government advance equity and support underserved communities?	
Will this evaluation produce evidence related to the HHS Evidence-Building Plan?	Yes	
	If yes, please note which learning agenda questions are addressed.	
	What improvements are needed to HHS capabilities to predict, prepare for, respond to, and recover from public health emergencies and threats in the nation and across the globe?	
What are the evaluation questions guiding this evaluation?	1. What opportunities exist for engagement between public and private partners for surge testing during public health emergencies? 2. What role could academic labs play for surge testing during public health emergencies? 3. What funding or mechanisms exist to support partnerships for emergency response between public and private sectors? 4. How can contracts or agreements can be established between partners in advance of a public health emergency?	
Provide a brief description of the evaluation.	This effort builds upon previous work to improve critical relationships between the federal government and key laboratory partners from public health, clinical, and commercial laboratory sectors to achieve widespread national capacity for diagnostic, screening, and surveillance. In order to inform the development of a roadmap for public and private laboratory engagement to support surge testing during public health emergencies, this project assesses capabilities, capacities, and willingness of commercial and clinical laboratories to provide surge testing, assesses challenges that commercial and clinical labs encountered for testing during the COVID-19 pandemic, and identifies opportunities for engagement between public and private laboratories for surge testing during public health emergencies. The CDC understands the capability and capacity of public health laboratories but was unaware of these in clinical and commercial laboratories. Results from this evaluation will help with future public health emergency response by guiding the development and execution of formal agreements with partners through MOUs or contracts as appropriate.	
Evaluation timeframe.	Start	Sep-23
	End	Sep-25

Data to be used	**Existing data held by the division**	Yes	
	Existing data from other sources	Yes	
	New data collection	No	
Evaluation Type(s)		☒	Formative
		☒	Process/implementation
		☐	Outcome/effectiveness
		☐	Impact
		☐	Economic
		☐	Other
		If other, describe below:	
Brief description of the evaluation design or approach.		This formative evaluation will use a mixed methods design. It includes analysis of survey data from over 1200 laboratories to assess the capabilities, capacities, and willingness of clinical laboratories to provide surge testing and interviews with experts and partners about how to best engage, and review lessons learned and other action plans from previous emergency responses. Analysis of data from all sources will be guided by our evaluation questions and will be used to inform the development of a roadmap for partnering with private sector laboratories and other partners.	
Brief description of any anticipated challenges that may arise in the study or analysis and how you plan to address them.		We anticipate that a roadmap of this magnitude will be difficult to be fully comprehensive in such a short window. However, we plan to leverage all available data, including existing experiences and collation of known lessons learned and action reports from previous public health emergencies to help elucidate proper pathways to improving laboratory testing needs for future emergency responses.	
Brief description of intended uses for evaluation findings.		The evaluation findings will be helpful towards the development of a roadmap or blueprint for public and private engagement for future public health emergencies requiring laboratory testing and surge support. This work will specifically pre-position the agency (CDC) for rapidly, efficiently, and effectively respond to public health emergencies.	
Brief description of how results will be disseminated and to which audiences.		Results from this evaluation will be shared throughout the agency (CDC) as well as with other partners identified through this evaluation. More specifically, key partners will have pre-established MOUs or agreements in place in advance of future public health emergencies.	
Estimated cost of the evaluation in FY25:		$500,000	
Estimated cost of the entire evaluation:		$1,000,000	

Centers for Medicare & Medicaid Services (CMS)

Evaluation of the End Stage Renal Disease (ESRD) Treatment Choices (ETC) Model (Not Previously Reported)		
Which HHS Strategic Plan Goal(s) will this evaluation address?	☒	Strategic Goal 1: Healthcare
	☐	Strategic Goal 2: Public Health
	☐	Strategic Goal 3: Human Services
	☐	Strategic Goal 4: Research & Evidence
	☐	Strategic Goal 5: Management
Will this evaluation produce evidence related to the Federal Evidence Agenda on LGBTQI+ Equity?	No	
	If yes, please note which learning agenda questions are addressed.	
Will this evaluation produce evidence related to the Learning Agenda in Support of the President's Management Agenda?	No	
	If yes, please note which learning agenda questions are addressed.	
Will this evaluation produce evidence related to the HHS Evidence-Building Plan?	Yes	
	If yes, please note which learning agenda questions are addressed.	
	To what extent do HHS programs and policies reduce costs and improve quality of healthcare services?	
What are the evaluation questions guiding this evaluation?	The ETC model tests the hypothesis that payment adjustments can increase the use of home dialysis and/or transplant waitlisting (which includes living donor transplantation) and if these investments decrease spending and/or increase quality of care. The payments are meant to increase alternatives to in-center dialysis. This can lead to greater patient education about alternatives and improving health equity. Generally speaking, research questions fall into three categories: (1) who is in the model and how was it implemented (2) what are the impacts of the model (spending, utilization, and quality), and (3) did the model have differing outcomes across subgroups in the examination of health equity, where applicable and appropriate.	
Provide a brief description of the evaluation.	The mixed-methods evaluation draws on a variety of data sources to test if the payment changes noted above (1) change home dialysis trends, (2) improve quality of care and/or (3) change or improve the beneficiary experience. In addition, the evaluation will examine how the model was implemented. Primary dialysis/ESRD outcomes include home dialysis (peritoneal and home hemodialysis), nocturnal dialysis, home dialysis training, transplant waitlisting and transplantation. Primary spending outcomes include Medicare Parts A, B, and D spending, both totals and by service line. Quality and utilization outcomes include ED visits hospitalizations, readmissions, peritonitis, and vascular infection rates. Beneficiary experience will be measured using home dialysis surveys as	

		well as the ICH CAHPS survey (to get a complete picture of the dialysis experience for those that have not moved to home dialysis), beneficiary key informant interviews, and care partner interviews. Participant experience is being captured through qualitative interviews. Analyses of subpopulations (e.g., by race/ethnicity, LIS) will examine, where applicable and appropriate, if outcomes differ across groups.	
Evaluation timeframe.		Start	Feb-22
		End	Aug-28
Data to be used	**Existing data held by the division**	Yes	
	Existing data from other sources	Yes	
	New data collection	Yes	
Evaluation Type(s)		☐	Formative
		☐	Process/implementation
		☐	Outcome/effectiveness
		☒	Impact
		☐	Economic
		☐	Other
		If other, describe below:	
Brief description of the evaluation design or approach.		The mixed-methods evaluation uses a variety of data sources and methods. Quantitatively, difference-in-difference methods are the preferred analytic approach. The comparison group is comprised of the Hospital Referral Regions (HRRs) not selected to be a part of the model. Trend analyses are performed for analyses where comparison group data are unavailable. Qualitatively, we are collecting data via key-informant interviews and focus groups with model participants and providers.	
Brief description of any anticipated challenges that may arise in the study or analysis and how you plan to address them.		Home dialysis trends have been increasing over the past several years predating the announcement of the ETC Model (2019) and the COVID-19 PHE, that likely accelerated this trend. The evaluation accounts for this in the Difference-in-Difference design which, to be valid, must have parallel trends in the treatment in comparison groups in the pre-ETC period. The evaluation has tested for these trends in home dialysis between the two groups for 2017-2019, the pre-ETC period, and we are confident that the HRRs not included in the model are a valid comparison	

	group. The evaluation leaves out 2020 in the pre-ETC period due to the movement towards home-based health care options because of the PHE and because the HRRs to be included in ETC were announced in September 2020. A statistically significant effect would denote that the ETC model is substantially outperforming (or underperforming) in increasing (or decreasing) the rate of home dialysis relative to the comparison group. A not statistically significant effect would mean that the model is not increasing its rates any faster/slower relative to the comparison group. The evaluation controls for the presence of KCC in its regression methods as is standard statistical practice to account for possible confounders.
Brief description of intended uses for evaluation findings.	If the goals of this model are met, scaling the model could be pursued to reach the entire Medicare population with ESRD. Short of scaling the model, the evaluation will illustrate how a mandatory model was implemented, how it affected or changed the beneficiary experience of care for those dialyzing at home or in-center, if such an approach differed across subgroups, and/or if the model lowered spending, increased home dialysis and transplantation, and/or improved quality. Such findings are helpful in discussion new models and how to improve upon them. For example, the CEC model's evaluation findings were used to help design the KCC model (see below for more detail). In addition, the ETC evaluation accounts for a possible interactive (quantitative) effect with the KCC model. Qualitatively, the evaluation will collect primary data to understand how the mandatory ETC model was implemented and affected impacted home dialysis considering the implementation of the contemporaneous voluntary KCC model that has similar goals.
Brief description of how results will be disseminated and to which audiences.	Annual reports are posed to the CMMI (Center for Medicare & Medicaid Innovation) website: https://innovation.cms.gov/innovation-models/esrd-treatment-choices-model.
Estimated cost of the evaluation in FY25:	$6,179,998
Estimated cost of the entire evaluation:	$12,875,563

Evaluation of the Kidney Care Choices (KCC) Model (Not Previously Reported)		
Which HHS Strategic Plan Goal(s) will this evaluation address?	☒	Strategic Goal 1: Healthcare
	☐	Strategic Goal 2: Public Health
	☐	Strategic Goal 3: Human Services
	☐	Strategic Goal 4: Research & Evidence
	☐	Strategic Goal 5: Management
Will this evaluation produce evidence related to the Federal Evidence Agenda on LGBTQI+ Equity?	No	
	If yes, please note which learning agenda questions are addressed.	

Will this evaluation produce evidence related to the Learning Agenda in Support of the President's Management Agenda?		No	
		If yes, please note which learning agenda questions are addressed.	
Will this evaluation produce evidence related to the HHS Evidence-Building Plan?		Yes	
		If yes, please note which learning agenda questions are addressed.	
		To what extent do HHS programs and policies reduce costs and improve quality of healthcare services?	
What are the evaluation questions guiding this evaluation?		The KCC model tests the hypothesis if outcomes can improve and/or costs through care coordination and payment incentives for CKD, ESRD, and Transplant beneficiaries. The mixed-methods evaluation draws on a variety of data sources to examine if the KCC payment structure can (1) increase home dialysis rates, delay the onset of ESRD and the start of dialysis, and/or alter transplant rates, (2) lower Medicare spending (3) change or improve quality of care, and/or (4) change or improve the beneficiary experience. In addition, the evaluation will examine how the model was implemented through qualitative methods.	
Provide a brief description of the evaluation.		Primary dialysis/ESRD outcomes include home dialysis (peritoneal and home hemodialysis), in-center dialysis, home dialysis training, transplant waitlisting and transplantation. Primary spending outcomes include Medicare Parts A, B, and D spending, both total and broken into service lines. Quality and utilization outcomes include ED visits, hospitalizations, readmissions, optimal ESRD starts, and delayed onset of ESRD. Beneficiary experience will be measured using home dialysis surveys as well as the ICH CAHPS survey (to get a complete picture of the dialysis experience for those that have not moved to home dialysis), beneficiary key informant interviews, and care partner interviews. Analyses of subpopulations (e.g. by race/ethnicity) will examine if outcomes differ across groups, as applicable and appropriate. Participant experience is being captured through qualitative interviews and surveys.	
Evaluation timeframe.		Start	Feb-22
		End	Aug-28
Data to be used	**Existing data held by the division**	Yes	
	Existing data from other sources	Yes	
	New data collection	Yes	

Evaluation Type(s)	☐	Formative
	☐	Process/implementation
	☐	Outcome/effectiveness
	☒	Impact
	☐	Economic
	☐	Other
	If other, describe below:	
Brief description of the evaluation design or approach.	The mixed-methods evaluation uses a variety of data sources and methods. Quantitatively, difference-in-difference methods are the preferred analytic approach where model participant performance is compared to a matched comparison group. The comparison group is comprised of matched nephrology practices that are selected using propensity score methods. Trend analyses are performed for analyses where comparison group data are unavailable. Qualitatively, we are collecting data via key-informant interviews and focus groups with model participants and providers.	
Brief description of any anticipated challenges that may arise in the study or analysis and how you plan to address them.	N/A	
Brief description of intended uses for evaluation findings.	If the goals of this model are met, expansion could be pursued to reach the entire Medicare population with CKD or ESRD. Short of scaling the model, the evaluation will illustrate how the model was implemented, how it affected or changed the beneficiary experience of care for those dialyzing at home or in-center, if such an approach differed across subgroups, and/or if the model lowered spending and/or improved quality. Such findings are helpful in discussion new models and how to improve upon them. In CEC, KCC's predecessor, we found through qualitative data collection from awardees that an ACO-like model for those with CKD (and not just for ESRD like CEC) could be used to improve care and possibly delay the onset of ESRD and provide incentives to optimal starts to dialysis. These lessons learned were incorporated into KCC.	
Brief description of how results will be disseminated and to which audiences.	Annual reports are posed to the CMMI (Center for Medicare & Medicaid Innovation) website: https://innovation.cms.gov/innovation-models/kidney-care-choices-kcc-model.	
Estimated cost of the evaluation in FY25:	N/A	
Estimated cost of the entire evaluation:	$24,120,931	

Food and Drug Administration (FDA)

European Union (EU) Audit Sampling & Economic Fraud Program (New in FY 2025)		
Which HHS Strategic Plan Goal(s) will this evaluation address?	☐	Strategic Goal 1: Healthcare
	☒	Strategic Goal 2: Public Health
	☐	Strategic Goal 3: Human Services
	☐	Strategic Goal 4: Research & Evidence
	☒	Strategic Goal 5: Management
Will this evaluation produce evidence related to the Federal Evidence Agenda on LGBTQI+ Equity?	No	
	If yes, please note which learning agenda questions are addressed.	
Will this evaluation produce evidence related to the Learning Agenda in Support of the President's Management Agenda?	Yes	
	If yes, please note which learning agenda questions are addressed.	
	• How can the federal government enhance the public's trust? • What approaches deliver an excellent customer experience with the Federal Government?	
Will this evaluation produce evidence related to the HHS Evidence-Building Plan?	Yes	
	If yes, please note which learning agenda questions are addressed.	
	• How do HHS policies and programs enhance promotion of healthy lifestyle behaviors to reduce occurrence and disparities in preventable injury, illness, and death? • What improvements to HHS programs and policies can promote effective enterprise governance to ensure programmatic goals are met equitably and transparently across all management practices? • Which HHS efforts are most effective for sustaining strong financial stewardship of HHS resources to foster prudent use of resources, accountability, and public trust?	
What are the evaluation questions guiding this evaluation?	TBD	
Provide a brief description of the evaluation.	FDA partners requested/needed by EU health agencies to perform sampling work as needed/requested. This evaluation will determine the outcomes associated with this program and how it interacts with other FDA programs. The evaluation will investigate ways FDA could use the outputs of this program with other FDA programs. The evaluation will analyze the FDA resource needs to complete EU requests and an ROI comparing how to utilize work performed here with other program needs.	
Evaluation timeframe.	Start	Oct-24
	End	Sep-25

You Data to be used	**Existing data held by the division**	Yes	
	Existing data from other sources	No	
	New data collection	No	
Evaluation Type(s)		☐	Formative
		☐	Process/implementation
		☒	Outcome/effectiveness
		☐	Impact
		☒	Economic
		☐	Other
		If other, describe below:	
Brief description of the evaluation design or approach.		This evaluation will investigate the process EU uses to make requests, interviewing people that participate in the project, including creation of associated assignments. Data would be gathered related to EU requests and then reviewed for the volume of requested work, outputs, and outcomes to determine the effect on public health.	
Brief description of any anticipated challenges that may arise in the study or analysis and how you plan to address them.		FDA currently operates this program with EU under an agreement and changes found during this process could be politically tied. FDA also participates in a foreign systems recognition program that recognizes the results of the public health results of other countries, which are important to continue.	
Brief description of intended uses for evaluation findings.		Findings will determine the level of resource demands and needs, which will provide FDA and understanding to negotiate future sampling requests from the EU. Findings will also provide senior leadership with an understanding of the inputs and outputs of this program.	
Brief description of how results will be disseminated and to which audiences.		Results will be shared with senior leadership within Center for Food Safety and Applied Nutrition (CFSAN) through a written evaluation report posted on CFSAN's evaluation SharePoint site. Findings will also be shared within the human food program, which is currently being structured. Briefings will be provided to senior leadership, as required.	
Estimated cost of the evaluation in FY25:		N/A, evaluation will be conducted within FDA without the need for outside resources or costs.	
Estimated cost of the entire evaluation:		N/A, evaluation will be conducted within FDA without the need for outside resources or costs.	

Total Product Life Cycle Advisory Program (TAP) Pilot Assessment (Not Previously Reported)			
Which HHS Strategic Plan Goal(s) will this evaluation address?		☒	Strategic Goal 1: Healthcare
		☐	Strategic Goal 2: Public Health
		☐	Strategic Goal 3: Human Services
		☐	Strategic Goal 4: Research & Evidence
		☐	Strategic Goal 5: Management
Will this evaluation produce evidence related to the Federal Evidence Agenda on LGBTQI+ Equity?		No	
		If yes, please note which learning agenda questions are addressed.	
Will this evaluation produce evidence related to the Learning Agenda in Support of the President's Management Agenda?		No	
		If yes, please note which learning agenda questions are addressed.	
Will this evaluation produce evidence related to the HHS Evidence-Building Plan?		No	
		If yes, please note which learning agenda questions are addressed.	
What are the evaluation questions guiding this evaluation?		To what extent does the Total Product Life Cycle Advisory Program (TAP) lead to more rapid development as well as more rapid and widespread patient access to safe, effective, high-quality medical devices of public health importance?	
Provide a brief description of the evaluation.		The TAP Pilot is intended to demonstrate the feasibility and benefits of process improvements to FDA's early interactions with participants and FDA's facilitation of interactions between participants and stakeholders that support the vision for TAP. The assessment will include a participant survey and quantitative and qualitative success metrics. An overall assessment of the outcomes of the Pilot and opportunities for improvement will be identified.	
Evaluation timeframe.		Start	Oct-23
		End	Jan-26
Data to be used	**Existing data held by the division**	No	
	Existing data from other sources	No	
	New data collection	Yes	

Evaluation Type(s)	☒	Formative
	☐	Process/implementation
	☐	Outcome/effectiveness
	☐	Impact
	☐	Economic
	☐	Other
	If other, describe below:	
Brief description of the evaluation design or approach.	FDA will be using an independent third-party contractor for this assessment. The contractor will submit a final evaluation design and approach as one of their first deliverables.	
Brief description of any anticipated challenges that may arise in the study or analysis and how you plan to address them.	TBD	
Brief description of intended uses for evaluation findings.	The findings will be used to inform improvement efforts. Additionally, the findings will be used to inform further negotiations with the regulated medical device industry.	
Brief description of how results will be disseminated and to which audiences.	Results will be posted on FDA's website.	
Estimated cost of the evaluation in FY25:	TBD	
Estimated cost of the entire evaluation:	TBD	

Independent Assessment of Medical Device User Fee Amendments (MDUFA) Workforce Metrics (Not Previously Reported)		
Which HHS Strategic Plan Goal(s) will this evaluation address?	☒	Strategic Goal 1: Healthcare
	☐	Strategic Goal 2: Public Health
	☐	Strategic Goal 3: Human Services
	☐	Strategic Goal 4: Research & Evidence
	☐	Strategic Goal 5: Management
Will this evaluation produce evidence related to the Federal Evidence Agenda on LGBTQI+ Equity?	No	
	If yes, please note which learning agenda questions are addressed.	

Will this evaluation produce evidence related to the Learning Agenda in Support of the President's Management Agenda?		No	
		If yes, please note which learning agenda questions are addressed.	
Will this evaluation produce evidence related to the HHS Evidence-Building Plan?		No	
		If yes, please note which learning agenda questions are addressed.	
What are the evaluation questions guiding this evaluation?		What are the best methodologies and data/metrics for representing a public sector workforce?	
Provide a brief description of the evaluation.		FDA will retain a qualified, independent contractor with expertise in assessing public sector workforce data analysis and reporting to conduct an assessment of current methodologies and data/metrics available to represent the MDUFA workforce. This will include assessment of positions (filled/vacant) and MDUFA process FTEs, including the subset funded by user fees, for each applicable FDA Center and Office.	
Evaluation timeframe.		Start	Oct-23
		End	Mar-25
Data to be used	**Existing data held by the division**	Yes	
	Existing data from other sources	Yes	
	New data collection	No	
Evaluation Type(s)		☒	Formative
		☐	Process/implementation
		☐	Outcome/effectiveness
		☐	Impact
		☐	Economic
		☐	Other
		If other, describe below:	

Brief description of the evaluation design or approach.	FDA will be using an independent third-party contractor for this assessment. The contractor will submit a final evaluation design and approach as one of their first deliverables.
Brief description of any anticipated challenges that may arise in the study or analysis and how you plan to address them.	TBD
Brief description of intended uses for evaluation findings.	The findings will be used to inform improvement efforts. Additionally, the findings will be used to inform further negotiations with the regulated medical device industry.
Brief description of how results will be disseminated and to which audiences.	Results will be posted on FDA's website.
Estimated cost of the evaluation in FY25:	TBD
Estimated cost of the entire evaluation:	TBD

Fresh-Cut Leafy Green Processors Inspection Compliance Outcomes (Not Previously Reported)		
Which HHS Strategic Plan Goal(s) will this evaluation address?	☐	Strategic Goal 1: Healthcare
	☒	Strategic Goal 2: Public Health
	☐	Strategic Goal 3: Human Services
	☒	Strategic Goal 4: Research & Evidence
	☒	Strategic Goal 5: Management
Will this evaluation produce evidence related to the Federal Evidence Agenda on LGBTQI+ Equity?	No	
	If yes, please note which learning agenda questions are addressed.	
Will this evaluation produce evidence related to the Learning Agenda in Support of the President's Management Agenda?	Yes	
	If yes, please note which learning agenda questions are addressed.	
	• How can the federal government enhance the public's trust?	

Will this evaluation produce evidence related to the HHS Evidence-Building Plan?		Yes	
		If yes, please note which learning agenda questions are addressed.	
		• How do HHS policies and programs enhance promotion of healthy lifestyle behaviors to reduce occurrence and disparities in preventable injury, illness, and death? • How does HHS improve the design, delivery, and outcomes of HHS programs by prioritizing science, evidence, and inclusion? • Which HHS efforts are most effective for sustaining strong financial stewardship of HHS resources to foster prudent use of resources, accountability, and public trust?	
What are the evaluation questions guiding this evaluation?		What is the compliance rate of processors in the leafy-green produce industry? Are there gaps in the inspection process for assessing this industry's compliance with supply chain regulations (21 CFR 117, subpart G)? At what rate are violations identified in this industry for full and limited scope inspections?	
Provide a brief description of the evaluation.		Over the past decade, fresh-cut leafy green processors have been involved in many of FDA's food-related recalls and outbreaks. However, roughly 24% of FDA's inspections have been full scope preventive control (PC) inspections that require a review of a firm's compliance with this part of the FSMA regulations. An evaluation will determine if the industry is either in compliance or if the inspection process needs to be modified to better address this part of the industry.	
Evaluation timeframe.		Start	Jan-24
		End	Feb-25
Data to be used	**Existing data held by the division**	Yes	
	Existing data from other sources	No	
	New data collection	No	
Evaluation Type(s)		☒	Formative
		☒	Process/implementation
		☒	Outcome/effectiveness
		☐	Impact
		☐	Economic
		☐	Other
		If other, describe below:	

Brief description of the evaluation design or approach.	Review outputs of inspection results from leafy-green processors, both foreign and domestic. Interview investigators and program monitors for current inspection processes and compliance activities. Review the completion of inspection protocol (IP) data for consistency and accuracy of data entry.
Brief description of any anticipated challenges that may arise in the study or analysis and how you plan to address them.	IP data is cumbersome to query, requiring special access to data tables. Evaluation team is currently working on gaining the training and approval to gain access to these tables. IP data is also not organized for easy query, with simple, identifiable field names. Previous crosswalk has been performed for some of these data tables to IP questionnaire used by the field.
Brief description of intended uses for evaluation findings.	Findings will provide recommendations for ways to improve FDA's inspection process with cut leafy-green processors. These improvements will result in better understanding of current compliance rates of this industry and thereby reduce illness rates in consumer populations.
Brief description of how results will be disseminated and to which audiences.	Results will be shared with senior leadership within CFSAN through a written evaluation report posted on CFSAN's evaluation SharePoint site. Findings will also be shared within the human food program, which is currently being structured. Briefings will be provided to senior leadership, as required.
Estimated cost of the evaluation in FY25:	N/A, evaluation will be conducted within FDA without the need for outside resources or costs.
Estimated cost of the entire evaluation:	N/A, evaluation will be conducted within FDA without the need for outside resources or costs.

The Real Cost Campaign Outcomes Evaluation Study: Cohort 3 (Not Previously Reported)		
Which HHS Strategic Plan Goal(s) will this evaluation address? .	☐	Strategic Goal 1: Healthcare
	☒	Strategic Goal 2: Public Health
	☐	Strategic Goal 3: Human Services
	☒	Strategic Goal 4: Research & Evidence
	☐	Strategic Goal 5: Management
Will this evaluation produce evidence related to the Federal Evidence Agenda on LGBTQI+ Equity?	Yes	
	If yes, please note which learning agenda questions are addressed.	
	To what extent can the Federal Government safeguard and improve health conditions and outcomes for LGBTQI+ people?	
Will this evaluation produce evidence related to the Learning Agenda in Support of the President's Management Agenda?	No	
	If yes, please note which learning agenda questions are addressed.	

<table>
<tr><td colspan="2" rowspan="3">Will this evaluation produce evidence related to the HHS Evidence-Building Plan?</td><td colspan="2">Yes</td></tr>
<tr><td colspan="2">If yes, please note which learning agenda questions are addressed.</td></tr>
<tr><td colspan="2">How do HHS policies and programs enhance promotion of healthy lifestyle behaviors to reduce occurrence and disparities in preventable injury, illness, and death?</td></tr>
<tr><td colspan="2">What are the evaluation questions guiding this evaluation?</td><td colspan="2">• To what extent are U.S. youth exposed to Center for Tobacco Product's (CTP) "The Real Cost" tobacco prevention campaign?
• How is exposure to "The Real Cost" associated with changes in precursors of tobacco use behavior (e.g., health and addiction risk perceptions, intentions to use tobacco)?</td></tr>
<tr><td colspan="2">Provide a brief description of the evaluation.</td><td colspan="2">CTP launched the national "The Real Cost" mass media campaign in 2014 with the goal of preventing teen tobacco use. This evaluation will be used to inform FDA, policy makers in the United States, prevention practitioners, and researchers about: (a) the extent of teen exposure to campaign messages, and (b) the extent to which this exposure is associated with changes in intended outcomes such as tobacco risk perceptions and use intentions. While not exhaustive, the list below illustrates a range of purposes and uses for this evaluation:
• Provide critical data on the reach of the campaign among teens in the United States; particularly estimates of the proportion of the population that was exposed to the campaign.
• Understand the impact of the campaign on psychosocial predictors and precursors of tobacco use behavior, such as:
o Health and addiction risk perceptions
o Perceived loss of control or threat to freedom expected from tobacco use
o Anticipated guilt, shame, and regret from tobacco use
o Intention and willingness to use tobacco
o Intention to quit and/or reduce daily consumption</td></tr>
<tr><td colspan="2" rowspan="2">Evaluation timeframe.</td><td>Start</td><td>Jul-23</td></tr>
<tr><td>End</td><td>Jul-25</td></tr>
<tr><td rowspan="3">Data to be used</td><td>Existing data held by the division</td><td colspan="2">No</td></tr>
<tr><td>Existing data from other sources</td><td colspan="2">No</td></tr>
<tr><td>New data collection</td><td colspan="2">Yes</td></tr>
</table>

Evaluation Type(s)	☐	Formative
	☐	Process/implementation
	☒	Outcome/effectiveness
	☐	Impact
	☐	Economic
	☐	Other
	If other, describe below:	
Brief description of the evaluation design or approach.	A longitudinal sample of U.S. youth (ages 11-17 at baseline) will be recruited through address-based sampling. Teen participants will complete an online survey approximately every six month for two years. Survey topics include awareness of "The Real Cost" campaign and tobacco-related perceptions, beliefs, intentions, and use. Additional samples of teens who identify as LGBTQ+ or who experience psychological distress will be recruited through social media advertising in order to increase the statistical power to study the campaign among these populations who are at higher risk for tobacco use.	
Brief description of any anticipated challenges that may arise in the study or analysis and how you plan to address them.	Given the longitudinal design of this evaluation, sample attrition and resulting loss of statistical power is a possible challenge. To address this, the evaluation design includes the recruitment of a replenishment sample at the second follow-up wave.	
Brief description of intended uses for evaluation findings.	Evaluation findings will be used to inform the development and implementation of "The Real Cost" campaign. Additionally, findings will contribute to the broader tobacco control field by providing insights into effective health communication strategies to prevent tobacco use.	
Brief description of how results will be disseminated and to which audiences.	Results of this evaluation will be disseminated through presentations to FDA/CTP leadership, as well as through academic conference presentations and peer-reviewed journal publications.	
Estimated cost of the evaluation in FY25:	$1,840,020	
Estimated cost of the entire evaluation:	$7,494,509	

Comprehensive, multi-method evaluations of statewide sales restrictions on flavored tobacco products (Not Previously Reported)		
Which HHS Strategic Plan Goal(s) will this evaluation address?	☐	Strategic Goal 1: Healthcare
	☒	Strategic Goal 2: Public Health
	☐	Strategic Goal 3: Human Services
	☒	Strategic Goal 4: Research & Evidence
	☐	Strategic Goal 5: Management
Will this evaluation produce evidence related to the Federal Evidence Agenda on LGBTQI+ Equity?	No	
	If yes, please note which learning agenda questions are addressed.	
Will this evaluation produce evidence related to the Learning Agenda in Support of the President's Management Agenda?	No	
	If yes, please note which learning agenda questions are addressed.	
Will this evaluation produce evidence related to the HHS Evidence-Building Plan?	Yes	
	If yes, please note which learning agenda questions are addressed.	
	How do HHS policies and programs enhance promotion of healthy lifestyle behaviors to reduce occurrence and disparities in preventable injury, illness, and death?	
What are the evaluation questions guiding this evaluation?	• Were the statewide/district-wide sales restrictions on flavored tobacco products implemented as intended? • How were the statewide/district-wide sales restrictions on flavored tobacco products monitored and enforced? • To what extent were retailers in compliance with the statewide/district-wide sales restrictions on flavored tobacco products? • To what extent did marketing, availability and sales of tobacco products change following implementation of the statewide/district-wide sales restrictions on flavored tobacco products?	
Provide a brief description of the evaluation.	We are conducting two comprehensive, multi-method evaluations of statewide sales restrictions on flavored tobacco products. The Family Smoking Prevention and Tobacco Control Act (FSPTCA) grants the FDA authority to issue product standards and conduct pre-market review to protect and promote population health. Under the FSPTCA, states and localities maintain their authority to restrict the time, place, and manner of tobacco sales, thereby providing the FDA with unique opportunities to learn from their experiences. We use findings from the evaluation studies to inform tobacco regulatory science base and Center for Tobacco Products regulatory decision-making.	

Evaluation timeframe.		Start	Jul-23
		End	Jul-25
Data to be used	**Existing data held by the division**	No	
	Existing data from other sources	Yes	
	New data collection	Yes	
Evaluation Type(s)		☐	Formative
		☒	Process/implementation
		☒	Outcome/effectiveness
		☐	Impact
		☐	Economic
		☐	Other
		If other, describe below:	
Brief description of the evaluation design or approach.		Using the CDC Framework for Program Evaluation, we will conduct two comprehensive, multi-method evaluations of statewide sales restrictions on flavored tobacco products. These evaluations will assess the influence of two statewide sales restrictions on flavored tobacco products on availability of tobacco products; sales of tobacco products; and tobacco product use behaviors among youth and adults.	
Brief description of any anticipated challenges that may arise in the study or analysis and how you plan to address them.		Regarding the tobacco product availability and sales analyses, it is important to note that Nielsen retail scanner data have coverage limitations (e.g., no estimated sales provided for tobacco specific stores or online stores); we will seek out other complementary data sources (e.g., population-based surveys) to use as well.	
Brief description of intended uses for evaluation findings.		To inform the regulatory science base and regulatory actions including product standards, product application review, compliance and enforcement strategies, and monitoring and surveillance.	
Brief description of how results will be disseminated and to which audiences.		We intend to disseminate findings via published papers in scientific journals and presentations to public health and industry stakeholders.	
Estimated cost of the evaluation in FY25:		$800,000	
Estimated cost of the entire evaluation:		$1,600,000	

National Institutes of Health (NIH)

Program Evaluation of Administrative Supplement to Enhance Institutional Data Science Capacity (New in FY 2025)		
Which HHS Strategic Plan Goal(s) will this evaluation address?	☐	Strategic Goal 1: Healthcare
	☐	Strategic Goal 2: Public Health
	☐	Strategic Goal 3: Human Services
	☒	Strategic Goal 4: Research & Evidence
	☐	Strategic Goal 5: Management
Will this evaluation produce evidence related to the Federal Evidence Agenda on LGBTQI+ Equity?	No	
	If yes, please note which learning agenda questions are addressed.	
Will this evaluation produce evidence related to the Learning Agenda in Support of the President's Management Agenda?	Yes	
	If yes, please note which learning agenda questions are addressed.	
	What organizational tools and management structures advance equity?	
Will this evaluation produce evidence related to the HHS Evidence-Building Plan?	Yes	
	If yes, please note which learning agenda questions are addressed.	
	• How does HHS improve the design, delivery, and outcomes of HHS programs by prioritizing science, evidence, and inclusion? • What improvements would most strengthen surveillance, epidemiology, and laboratory capacity to understand and equitably address diseases and conditions?	
What are the evaluation questions guiding this evaluation?	1. How many projects addressed human capacity? Infrastructure enhancement? Partnership building? 2. In each of the three categories, what are the primary activities and associated outcomes? 3. What are the target populations affected by the outcomes of the program activities? 4. What areas of data science were addressed by the program activities? 5. How has the program enhanced data and digital capabilities of the participating institutions? 6. What are the areas for improvement?	
Provide a brief description of the evaluation.	The focus of the evaluation is a program that supports efforts to build institutional capacity in areas of data science in institutions serving medically underserved communities and underrepresented students, as described in the Notice of NIH's Interest in Diversity (NOT-OD-20-031). This Notice of Special Interest aligns with the NIH Data Science Strategic Plan to ensure that data science advances in biomedical and health research can benefit all populations. Funded projects must address at least one of the three objectives: to grow human capital with data science competencies; to develop or expand infrastructure to support data science research, training and	

		education; and to build data science partnerships. The evaluation will help to assess program effectiveness in addressing the three objectives and identifying areas for improvement, thereby guiding future program direction.	
Evaluation timeframe.		Start	Oct-24
		End	Sep-25
Data to be used	**Existing data held by the division**	Yes	
	Existing data from other sources	Yes	
	New data collection	Yes	
Evaluation Type(s)		☐	Formative
		☐	Process/implementation
		☒	Outcome/effectiveness
		☐	Impact
		☐	Economic
		☐	Other
		If other, describe below:	
Brief description of the evaluation design or approach.		The evaluation approach will include identification of relevant and measurable metrics, data collection and analysis, and generation of an evaluation report. Logic models will be used to develop evaluation metrics. Data will be collected through the Research Performance Program Report (RPPR) and surveys administered to the investigators of the supplement awards.	
Brief description of any anticipated challenges that may arise in the study or analysis and how you plan to address them.		Anticipated challenges may include inconsistent data reporting, difficulty in identifying common metrics across diverse projects, and lack of dedicated staff time toward evaluation. Inconsistent data reporting can be alleviated by frequent and consistent communication with the investigators on the relevant metrics. Engaging the investigators in meaningful dialogue on the impact and effectiveness of their projects will help to identify common metrics as well as unique ones that need to be accounted for. Lack of dedicated staff time may be alleviated by the funding availability for contractor support.	

Brief description of intended uses for evaluation findings.	Evaluation findings will be used to help NIH assess how well the program achieved its goals and demonstrate the impact of the program. The findings will identify best practices and areas of improvement, which in turn will help determine future program directions. Evaluation findings will also help extramural investigators improve their projects and identify possibilities of collaboration.
Brief description of how results will be disseminated and to which audiences.	The evaluation report will be shared with relevant NIH staff and leadership. Portions of the evaluation results will also be shared with the stakeholders in the extramural community through presentations and program meetings. The results may also be shared via blogs or white papers.
Estimated cost of the evaluation in FY25:	$30,000
Estimated cost of the entire evaluation:	$60,000

Evaluation of NIH Chief Officer for Scientific Workforce Diversity (COSWD) Office Programs (Not Previously Reported)		
Which HHS Strategic Plan Goal(s) will this evaluation address?	☐	Strategic Goal 1: Healthcare
	☐	Strategic Goal 2: Public Health
	☐	Strategic Goal 3: Human Services
	☒	Strategic Goal 4: Research & Evidence
	☒	Strategic Goal 5: Management
Will this evaluation produce evidence related to the Federal Evidence Agenda on LGBTQI+ Equity?	Yes	
	If yes, please note which learning agenda questions are addressed.	
	How can the Federal Government promote equitable outcomes for LGBTQI+ people in income, economic well-being, and the workplace?	
Will this evaluation produce evidence related to the Learning Agenda in Support of the President's Management Agenda?	Yes	
	If yes, please note which learning agenda questions are addressed.	
	• What strategies improve retention, engagement, inclusion, belonging, and wellbeing among Federal employees, while reducing burnout and attrition? • What approaches build a strong, empowered, and diverse cohort across the Federal Government employee lifecycle?	
Will this evaluation produce evidence related to the HHS Evidence-Building Plan?	Yes	
	If yes, please note which learning agenda questions are addressed.	
	• How does HHS improve the design, delivery, and outcomes of HHS programs by prioritizing science, evidence, and inclusion?	

	• Which HHS investments in the research enterprise are most effective for maintaining leadership in the development of innovations that broaden our understanding of diseases, healthcare, public health, and human services resulting in more effective interventions, treatments, and programs? • Where does HHS need to further invest in the scientific workforce to maintain leadership in the development of innovations that broaden our understanding of diseases, healthcare, public health, and human services resulting in more effective interventions, treatments, and programs? • What improvements are needed to HHS programs and policies for data collection, use, and evaluation to increase evidence-based knowledge that leads to better health outcomes, reduced health disparities, and improved social well-being, equity, and economic resilience? • Which HHS investments are optimal to uphold effective and innovative human capital resource management resulting in an engaged, diverse workforce with the skills and competencies to accomplish the HHS mission?
What are the evaluation questions guiding this evaluation?	1. To what extent does the 21st Century Scholars Program (21CSP) lead to greater consideration of Diversity, Equity, Inclusion and Accessibility (DEIA) principles in NIH Notices of Funding Opportunity? 2. To what extent is the 21CSP associated with greater diversity amongst scientists funded by awards from NIH-funded institutions? 3. To what extent does the 21CSP enhance related job skills, career opportunities, and overall career trajectories for NIH extramural staff participants? 4. To what extent does the Scientific Workforce Diversity Seminar Series (SWDSS) improve the reach of COSWD to external and internal audiences? 5. What data and metrics are needed to assess the reach of, effectiveness of, and engagement with the SWDSS webinars? 6. To what extent has the DEIA Mentorship administrative supplement program facilitated the research and impact of investigators who are committed to DEIA? 7. To what extent has the COSWD-supported Diversity Supplement awards enhanced the ability for mentees to apply for and receive research funding? 8. What activities and research do the DEIA Mentorship administrative supplement program and COSWD-supported Diversity Supplement awards facilitate? *NOTE: Given the breadth and nascent stage of this evaluation effort, the listed questions are merely representative and do not embody the entirety or final set of questions that will guide the evaluation.*
Provide a brief description of the evaluation.	The COSWD Office uses data-driven, evidence-based approaches in leading NIH's effort to diversify the national scientific workforce. COSWD aims to build, disseminate, and act on evidence to catalyze cultures of inclusive excellence and enable NIH and NIH-funded institutions to benefit from a full range of talent in science. The COSWD Office will perform an implementation and outcome evaluation on three primary COSWD programs: 1) The 21st Century Scholars Program (21CSP), 2) The Scientific Workforce Diversity Seminar Series (SWDSS), and 3) DEIA Mentorship Supplements and Diversity Supplements. The evaluation will assess the short-, medium-, and long-term outcomes associated with each program and the impact of program activities on several factors,

		including but not limited to, submission of grant applications to NIH, improving the reach of the COSWD and use of the shared knowledge, and diversity of the scientific workforce. The evaluation purpose is to determine the alignment of each program to the goals stated in the 2022-2026 COSWD Strategic Plan and the overall mission of the COSWD Office and provide recommendations for additional data collection and metrics that can be developed and utilized for additional evaluative efforts.	
Evaluation timeframe.		Start	Oct-23
		End	Sep-25
Data to be used	**Existing data held by the division**	Yes	
	Existing data from other sources	No	
	New data collection	Yes	
Evaluation Type(s)		☐	Formative
		☒	Process/implementation
		☒	Outcome/effectiveness
		☐	Impact
		☐	Economic
		☐	Other
		If other, describe below:	
Brief description of the evaluation design or approach.		A mixed methods approach will be used to assess the implementation and short-, medium-, and long-term outcomes of the three COSWD programs. Surveys and interviews will be used to collect data from past and current program participants and administrators. Program documents will be reviewed to collect qualitative data on program activities. Additional quantitative data from existing databases, repositories, and web metrics will also be analyzed to answer the evaluation questions.	
Brief description of any anticipated challenges that may arise in the study or analysis and how you plan to address them.		Certain data the COSWD plans to collect, such as survey responses from SWDSS participants and DEIA-related activities in other NIH Institutes and Centers (ICs), may have low response rates. To address this challenge, the purpose for the data collection will be clearly delineated for potential respondents including plans for sharing the results on completion of the evaluation in order to increase buy-in. Additionally, multiple sources of data (e.g.,	

	existing data bases, existing repositories, webpages, etc.) will be explored to collect a comprehensive dataset in order to sufficiently address the evaluation questions.
Brief description of intended uses for evaluation findings.	Findings from the evaluation will provide evidence for the integration of these or similarly based programs with activities from other ICs. Additionally, they will provide data which can be utilized for activities and outcomes reports related to progress on the 2022-2026 COSWD Strategic Plan.
Brief description of how results will be disseminated and to which audiences.	Results from the evaluation will be disseminated via written report for internal NIH use. A summarized graphic presentation or brief will be developed for dissemination to audiences external to NIH.
Estimated cost of the evaluation in FY25:	$300,000
Estimated cost of the entire evaluation:	$300,000

Examining the Career Outcomes of Trainees and Scholars Supported by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and the National Center for Advancing Translational Sciences (NCATS) Using Third-Party Data (Not Previously Reported)		
Which HHS Strategic Plan Goal(s) will this evaluation address?	☐	Strategic Goal 1: Healthcare
	☐	Strategic Goal 2: Public Health
	☐	Strategic Goal 3: Human Services
	☒	Strategic Goal 4: Research & Evidence
	☐	Strategic Goal 5: Management
Will this evaluation produce evidence related to the Federal Evidence Agenda on LGBTQI+ Equity?	No	
	If yes, please note which learning agenda questions are addressed.	
Will this evaluation produce evidence related to the Learning Agenda in Support of the President's Management Agenda?	No	
	If yes, please note which learning agenda questions are addressed.	
Will this evaluation produce evidence related to the HHS Evidence-Building Plan?	Yes	
	If yes, please note which learning agenda questions are addressed.	
	• Where does HHS need to further invest in the scientific workforce to maintain leadership in the development of innovations that broaden our understanding of diseases, healthcare, public health, and human services resulting in more effective interventions, treatments, and programs?	
What are the evaluation questions guiding this evaluation?	What are the career outcomes of NIDDK and NCATS Trainees and Scholars when they do not apply for subsequent NIH support?	

Provide a brief description of the evaluation.		A consistent operational roadblock NIH Institutes and Centers (ICs) encounter when assessing training and educational programs is identifying career outcomes of those supported through institutional training and career development awards when they do not apply for follow-on NIH funding. Assessments often require expending extensive resources in manually curating career outcomes data through online searches, which often limits how often such assessments can be performed. Conducting surveys of past scholars, trainees, and participants have also been done but are prone to non-response bias. NCATS and NIDDK are collaborating to examine sources of secondary data for examining career outcomes of trainees and scholars. Specifically, NIDDK and NCATS are conducting a pilot of having a third-party vendor, Stepping Blocks (SB), perform data linkages of trainees and scholars using data they harvest from publicly available sources. The Institute for Research on Innovation and Science (IRIS) at the University of Michigan has reported success having SB link their data to administrative records across numerous universities in a secure, reproducible way. If the data received from SB is a valid source for conducting assessments of career outcomes of NIDDK and NCATS trainees, the two ICs plan to request regular installments of this data for future evaluations and share their findings with other ICs that may benefit from using these data.
Evaluation timeframe.		Start	Jul-22
		End	Dec-25
Data to be used	**Existing data held by the division**	Yes	
	Existing data from other sources	Yes	
	New data collection	No	
Evaluation Type(s)		☐	Formative
		☐	Process/implementation
		☒	Outcome/effectiveness
		☐	Impact
		☐	Economic
		☐	Other
		If other, describe below:	
Brief description of the evaluation design or approach.		The third-party vendor will be performing a match of NIDDK- and NCATS-supported trainees using personal identifiers, grants data, and training appointments data to their career outcomes data, which is based on publicly	

	available information. An assessment of match quality will be performed against the NIH-linked Association of American Medical Colleges faculty roster file. Among those who did not apply for NIH grant funding, NIDDK and NCATS plan to ascertain whether these trainees and scholars entered positions in the government or private sector.
Brief description of any anticipated challenges that may arise in the study or analysis and how you plan to address them.	One challenge the SB team has encountered is linking "information poor" records—that is, where the individual's only NIH touchpoint was their training or scholar appointment. It may not be possible to match these individuals. An assessment that examines correlates of poor match quality is planned and is considered standard practice.
Brief description of intended uses for evaluation findings.	The challenge most ICs encounter is how to expand definitions of success in training and career development programs to include those who enter positions in the government or private sector, and how to demonstrate to IC Leadership that programs are still successful even if scholars and trainees do not apply for follow-on NIH funding. For example, the ultimate goal of NCATS to provide "more treatments to all people more quickly" cannot be achieved with a workforce that only focuses on investigator-initiated research grants. An analysis that focuses solely on NIH grant funding would not be consistent with meeting this goal.
Brief description of how results will be disseminated and to which audiences.	NIDDK and NCATS plan to share findings with other ICs (through various NIH committees and communities), through peer reviewed publications, and through IC-level dissemination to extramural communities (e.g., blogs).
Estimated cost of the evaluation in FY25:	$40,000
Estimated cost of the entire evaluation:	$80,000 (*Note: The initial contract was only for one year. However, the Level 2/Public Trust clearance process took about 9 months to complete, so another year has been added to the contract.*)

Building Interdisciplinary Research Careers in Women's Health (BIRCWH) Program Evaluation 2025 (Not Previously Reported)		
Which HHS Strategic Plan Goal(s) will this evaluation address?	☐	Strategic Goal 1: Healthcare
	☒	Strategic Goal 2: Public Health
	☐	Strategic Goal 3: Human Services
	☒	Strategic Goal 4: Research & Evidence
	☐	Strategic Goal 5: Management
Will this evaluation produce evidence related to the Federal Evidence Agenda on LGBTQI+ Equity?	No	
	If yes, please note which learning agenda questions are addressed.	

Will this evaluation produce evidence related to the Learning Agenda in Support of the President's Management Agenda?		Yes	
		If yes, please note which learning agenda questions are addressed.	
		What organizational tools and management structures advance equity?	
Will this evaluation produce evidence related to the HHS Evidence-Building Plan?		Yes	
		If yes, please note which learning agenda questions are addressed.	
		• How effective are HHS programs and policies at protecting individuals, families, and communities from infectious diseases and preventing non-communicable diseases through development and equitable delivery of effective, innovative, readily available, treatments, therapeutics, medical devices, and vaccines? • Which HHS investments in the research enterprise are most effective for maintaining leadership in the development of innovations that broaden our understanding of diseases, healthcare, public health, and human services resulting in more effective interventions, treatments, and programs? • Where does HHS need to further invest in the scientific workforce to maintain leadership in the development of innovations that broaden our understanding of diseases, healthcare, public health, and human services resulting in more effective interventions, treatments, and programs?	
What are the evaluation questions guiding this evaluation?		1. Was the BIRCWH program able to build a cadre of scientists pursuing women's health research? 2. What are the other program outcomes of the BIRCWH program? 3. What do BIRCWH scholars, principal investigators, and program alumni see as the most valuable aspect of the program?	
Provide a brief description of the evaluation.		The BIRCWH program is a junior faculty career development program that was established in 2000. The NIH Office of Research on Women's Health needs to inform the Advisory Committee on Research on Women's Health of the BIRCWH program's contributions to women's health research workforce, in preparation for the program's 25th anniversary. The evaluation will also inform improvements of program-related Notices of Funding Opportunity and program implementation.	
Evaluation timeframe.		Start	Mar-24
		End	Mar-25
Data to be used	**Existing data held by the division**	Yes	
	Existing data from other sources	Yes	
	New data collection	Yes	

Evaluation Type(s)	☒	Formative
	☒	Process/implementation
	☒	Outcome/effectiveness
	☐	Impact
	☐	Economic
	☐	Other
	If other, describe below:	
Brief description of the evaluation design or approach.	This evaluation will use a post-intervention only, mixed-methods quasi-experimental design. The comparison group will be other researchers that were supported by NIH on individual or institutional research career development (K) awards. The quantitative matching will be done among the pool of other researchers that were supported on individual or institutional K awards to ensure they are like BIRCWH Scholars based on observed and measured quantitative criteria. While NIH has the sampling frame for the comparison population, the exact study population for the comparison group to be used in the evaluation has not yet been determined. Primary data collection will include surveys and qualitative data collection (in-depth semi-structured interviews and focus groups) of BIRCWH program alumni and BIRCWH scholars. The mixed methods approach will start with quantitative surveys; the evaluation team will design and implement more in-depth qualitative data collection based on the results of the quantitative surveys.	
Brief description of any anticipated challenges that may arise in the study or analysis and how you plan to address them.	The primary challenges for the study and analysis are defining a comparison group and non-response to surveys. The study team will seek access to necessary datasets and define methods for quantitively matching the comparison group as a first step in the evaluation. Survey respondents will receive two follow-up notifications if they have not completed the survey and results will be weighted for nonresponse.	
Brief description of intended uses for evaluation findings.	The results will provide an assessment of the BIRCWH program's contributions to the women's health research workforce to inform guidance from and decisions by the Advisory Committee. The evaluation will also provide evidence on the implementation of career development programs to inform activities of the BIRCWH program and other programs intending to increase or improve the women's health research workforce.	
Brief description of how results will be disseminated and to which audiences.	Results will be presented to the Advisory Committee, NIH staff, and at the BIRCWH Annual meeting. Publication in a peer-reviewed journal(s) will also be considered.	
Estimated cost of the evaluation in FY25:	TBD—will provide when available	
Estimated cost of the entire evaluation:	TBD—will provide when available	

Appendix B: Previous HHS Evaluations Continuing into FY 2025

Administration for Children and Families (ACF)

Supporting Evidence Building in Child Welfare

Priority Area: Human Services; Research and Evidence

Priority Question: What are the effects of HHS programs and policies on strengthening early childhood development and expanding opportunities to help children and youth thrive equitably within their families and communities? How does HHS improve the design, delivery, and outcomes of HHS programs by prioritizing science, evidence, and inclusion?

Description: This project aims to increase the number of evidence-supported interventions for the child welfare population, by conducting rigorous evaluations and supporting the field in moving toward rigorous evaluations.

Time Period for the Activity (start and estimated end dates): 2016 - 2025

Existing Data Sources Held by the Division: N/A

Existing Data from Other Sources: Administrative data from state and/or local public child welfare agencies, service providers, and other agencies

New Data Collection: New information collections related to the evaluation of the Family Unification Program have been reviewed and approved by the OMB Office of Information and Regulatory Affairs under OMB #0970-0514, #0970-0575, and #0970-0577. Related materials are available at the RegInfo.gov pages for the Evaluation of the Family Unification Program (FUP), the Evaluation of Project Connect, and the Evaluation of LifeSet, respectively.

Study Design or Approach: For each studied intervention, the project is conducting an impact study and an implementation study.

Anticipated Challenges and Mitigation Strategies: Challenges include mismatch of annual funding vis-à-vis long-term evaluation timelines; and an earlier challenge was finding sites willing and able to participate in evaluations. Examples of barriers to site participation include small service populations and unwillingness to conduct a randomized control trial, even when there is excess demand. As a result, our engagement with intervention developers, child welfare administrators, and other interested individuals and groups to secure buy-in and determine the feasibility of rigorous impact evaluations took longer than anticipated, leading to delayed starts for the three evaluations. As a result, all three evaluations are proceeding more slowly than planned. All three evaluations have been trimmed to accommodate the shorter timeframes. For example, the implementation studies will involve fewer site visits than planned. The evaluation of LifeSet will not be able to assess the impact of program participation on outcomes, although baseline data collection and a strong implementation study will provide the foundation for future analyses should the opportunity arise at a later point.

Dissemination plan: ACF will produce comprehensive research reports, such as this one produced in November 2019: https://www.acf.hhs.gov/opre/research/project/supporting-evidence-building-in-child-welfare. ACF will also produce shorter documents aimed at policy and practitioner audiences. ACF

will disseminate results through posting reports on the Internet; writing academic journal articles; using social media to alert potential audiences of the availability of results; presenting results at research, policy, and practitioner conferences; and briefing policymakers and program officials. ACF will use these findings include informing federal, state, and local policymaking. ACF will archive data for secondary use.

Building Evidence on Employment Strategies for Low-Income Families

Priority Area: Human Services

Priority Question: To what extent do HHS programs and policies provide effective and innovative pathways leading to equitable economic success for all individuals and families?

Description: This project is rigorously evaluating promising programs serving recipients of the Temporary Assistance for Needy Families (TANF) program or other families with low incomes in order to strengthen ACF's understanding of evidence-supported programs that are effective in improving employment and economic security. The project will prioritize evaluations of programs that are state-initiated and programs that serve adults whose employment prospects have been affected by opioid use disorder, other substance use disorders, or mental health conditions. In addition, in concert with the Office of Planning, Research, and Evaluation's (OPRE) Next Generation of Enhanced Employment Strategies Project, the project has partnered with the Social Security Administration to evaluate employment-related interventions targeting individuals with current or foreseeable disabilities who have limited work history and have not yet applied for Supplemental Security Income (SSI).

Time Period for the Activity (start and estimated end dates): 2017 - 2028

Existing Data Sources Held by the Division: National Directory of New Hires (NDNH)

Existing Data from Other Sources: State and local administrative data, such as TANF data, and local program management information system data

New Data Collection: New information collections related to this project have been reviewed and approved by the OMB Office of Information and Regulatory Affairs under OMB #0970-0537. Related materials are available at the Building Evidence on Employment Strategies for Low-Income Families (BEES) Project page on RegInfo.gov.

Study Design or Approach: The project will conduct experimental impact studies, descriptive evaluations, cost analyses, and case studies.

Anticipated Challenges and Mitigation Strategies: Challenges include availability and quality of administrative data and adequacy of outcome measures. The COVID-19 pandemic has presented challenges to study enrollment (as several sites paused operations during the pandemic) and intervention fidelity (as it prompted changes to the type and mode of services in many sites). To address these challenges, ACF is providing technical assistance to the participating sites, such as developing strategies to boost recruitment and adapt service provision to a virtual setting and extending enrollment periods to support sites in meeting target sample sizes.

Dissemination plan: ACF will produce comprehensive research reports as well as shorter documents aimed at policy and practitioner audiences. ACF will disseminate results through posting reports on the

Internet; using social media to alert potential audiences of the availability of results; presenting results at research, policy, and practitioner conferences; briefing policymakers and program officials; and submitting the findings for review by the ACF-sponsored Pathways to Work Evidence Clearinghouse. Briefs, Newsletters, and Reports on this project can be found online at: https://www.acf.hhs.gov/opre/project/building-evidence-employment-strategies-project-bees. Uses for these findings include informing federal, state, and local policymaking as well as state and local selection and design of services to help individuals with low incomes find jobs and advance in the labor market. ACF will archive data for secondary use.

Next Generation of Enhanced Employment Strategies (NextGen) Project

Priority Area: Human Services

Priority Question: To what extent do HHS programs and policies provide effective and innovative pathways leading to equitable economic success for all individuals and families?

Description: This project is completing rigorous evaluations of innovative employment interventions to build the evidence base on effective interventions for people with low incomes and complex challenges to employment such as physical and mental health conditions, criminal justice system involvement, or limited formal work skills and experience. In addition, in concert with OPRE's Building Evidence on Employment Strategies for Low-Income Families Project, the project has partnered with the Social Security Administration to evaluate employment-related interventions targeting individuals with current or foreseeable disabilities who have limited work history and have not yet applied for Supplemental Security Income (SSI). Descriptive, cost, and experimental impact studies are being conducted of the programs participating in the project. The project includes the analysis, reporting, and dissemination of findings.

Time Period for the Activity (start and estimated end dates): 2018- 2028

Existing Data Sources Held by the Division: National Directory of New Hires (NDNH)

Existing Data from Other Sources: State and local administrative data, such as Temporary Assistance for Needy Families (TANF) data, and local program management information system data.

New Data Collection: New information collections related to this project have been reviewed and approved by the OMB Office of Information and Regulatory Affairs under OMB #0970-0545. Related materials are available at the OPRE Evaluation: Next Generation of Enhanced Employment Strategies Project [Impact, Descriptive, and Cost Studies] page on RegInfo.gov.

Study Design or Approach: The project is conducting experimental impact studies, descriptive evaluations, and cost analyses.

Anticipated Challenges and Mitigation Strategies: The COVID-19 pandemic has presented challenges to study enrollment (as several sites paused operations during the pandemic) and intervention fidelity (as it prompted changes to the type and mode of services in many sites). ACF is providing technical assistance to the participating sites, such as developing strategies to boost recruitment and adapt service provision to a virtual setting and extending enrollment periods to support sites in meeting target sample sizes.

Dissemination plan: ACF is producing comprehensive research reports as well as shorter documents aimed at policy and practitioner audiences, which can be found online at: https://www.acf.hhs.gov/opre/project/next-generation-enhanced-employment-strategies-project-2018-2023. ACF will disseminate results through posting reports on the Internet; using social media to alert potential audiences of the availability of results; presenting results at research, policy, and practitioner conferences; briefing policymakers and program officials; and submitting the findings for review by the ACF-sponsored Pathways to Work Evidence Clearinghouse. Uses for these findings include informing federal, state, and local policymaking as well as state and local selection and design of services to help individuals with low incomes find jobs and advance in the labor market. ACF will archive data for secondary use.

Administration for Community Living (ACL)

Process and Outcome Evaluation of the National Paralysis Resource Center (NPRC)

Priority Area: Healthcare; Human Services

Priority Questions: How do HHS programs and policies expand equitable access to comprehensive, community-based, innovative, and culturally competent health care services while recognizing social determinants of health? What effective strategies or combinations of strategies expand access to high-quality services for older adults and people with disabilities, and their caregivers, to support increased independence and quality of life?

Description: The purpose of this work is to systematically obtain information on the activities and the effectiveness of the NPRC to document and improve its activities. This evaluation of the NPRC will determine the extent to which it is meeting the goals of improving the health and quality of life of individuals living with paralysis of all ages, their families, and their support system by raising awareness of and facilitating access to a broad range of services relevant to individuals with paralysis. The study is reviewing how the NPRC is providing services, how the services are being targeted to different communities, the barriers and facilitators to implementing varied programs and their activities among several other factors. Other areas of interest among people living with paralysis are increased confidence and independence, stronger support networks, and increased opportunities to be valued participants in all aspects of community living.

Time Period for the Activity (estimated start and end dates): FY 2022-2027

Existing Data Sources Held by the Division: Grant applications and reports (administrative data)

Existing Data from Other Sources: None

New Data Collection: Interviews and surveys of a sample of key stakeholders and service recipients.

Study Design or Approach: Data for the process evaluation will be collected primarily through reviews and administrative records and interviews with NPRC staff and partners (including grantees and subcontractors). This secondary data collection will provide information about the inputs, activities and outputs of the NPRC to provide information about the quality, structure, and efficiency of NPRC services. Data for the outcome evaluation will be collected through surveying and interviewing a sample of those

served by the NPRC. This primary data collection will provide information about the effect of the NPRC services on individuals living with paralysis of all ages, their families, and their support system.

Anticipated Challenges and Mitigation Strategies: None

Dissemination plan: The evaluation will use a multi-method approach to gather data, that when combined, will produce an accurate assessment of the value of the NPRC highlighting approaches that are working well and identifying areas for improvement. The data will be disseminated through the ACL website, webinars, conference presentations, and peer reviewed journal articles.

Centers for Disease Control and Prevention (CDC)

Evaluation of the OT21-2103 National Initiative to Address COVID-19 Health Disparities Among Populations at High-Risk and Underserved, Including Racial and Ethnic Minority Populations and Rural Communities

Priority area: Healthcare; Human Services

Priority questions: To what extent do recipients improve capacity and services to address COVID-19 health disparities and advance health equity among populations, including racial and ethnic groups and rural populations?

Description: This evaluation consists of multiple studies and is a complementary and coordinated approach to the evaluation inclusive of performance measures analyses. The purposes are to demonstrate accountability for grant funds, understand the effect of the grant on health department capacity and support, and learn which practices contribute to mitigating/reducing COVID-19 health disparities.

Time period of the activity: March 1, 2021 – June 30, 2025

Existing Data Sources Held by the Division: Recipient work plans, performance measures and progress reports

Existing Data from Other Sources: COVID-19 surveillance, behavior and policy data; NACCHO National Profile of Local Health Departments and ASTHO Profile of State and Territorial Public Health data

New data collection: Evaluation study data (e.g., surveys, interviews)

Study design or approach: Specific methods will be outlined in each evaluation study. Whenever possible, evaluation studies will leverage administrative and surveillance data on key outcomes of interest. Evaluation studies will collect additional information from recipients on a limited basis as needed through interviews, focus groups, and surveys. Methods will be determined through a collaborative vetting process with internal interested parties, select group of recipients participating in the Evaluation Recipient Collaborative, and feasibility assessments. For example, a survey will gather data on grant contributions to and sustainability of health department and jurisdiction capacity to address health disparities and advance health equity.

Anticipated challenges and mitigation strategies: Challenges are a short period of performance, the need to aggregate data across multiple sources to understand effect and remaining flexible in the face

of evolving pandemic needs. We designed the reporting system and evaluation so that multiple studies and data points can be triangulated to understand the contribution of the grant.

Dissemination plan for results: Findings from the evaluation will be disseminated to key audiences using a variety of communication channels.

- Primary audiences: Grant recipients, policy organizations (APHA & NACDD), national partner organizations (ASTHO, NACCHO, and NNPHI) involved in the provision of technical assistance and conduct of evaluation studies, CDC CIOs, federal agencies and congress, and other audiences that support cross-agency coordination around COVID-19, social determinants of health, data modernization, and other related CDC initiatives.
- Dissemination channels: Webinars, recipient and national partner meetings, CDC internet, COVID-19 Health Equity Resource Library, and journal publications.
- Possible uses: Dissemination will support increased understanding of what works within U.S. public health jurisdictions and how CDC can support these changes across the U.S. public health system.

Centers for Medicare & Medicaid Services (CMS)

Maternal Opioid Misuse (MOM) Model Evaluation

Priority Area: Healthcare; Human Services

Priority Question: To what extent do HHS programs and policies strengthen and expand access to mental health and substance use disorder treatment and recovery services for individuals and families? What are the impacts of HHS programs and policies on strengthening early childhood development and expanding opportunities to help children and youth thrive equitably within their families and communities?

Description: The MOM Model addresses fragmentation in the care of pregnant and postpartum Medicaid beneficiaries with opioid use disorder (OUD) through state-driven transformation of the delivery system surrounding this vulnerable population. By supporting the coordination of clinical care and the integration of other services critical for health, wellbeing, and recovery, the MOM Model has the potential to improve quality of care and reduce costs for mothers and infants.

Time Period for the Activity (estimated start and end dates): January 2020 - March 2027

Existing Data Sources Held by the Division: T-MSIS data, data collected through program deliverables and implementation and monitoring.

Existing Data from Other Sources: State Vital records data provided (birth and death certificates).

New Data Collection: Health and social needs data collected through individual screening and/or patient health records. Qualitative case study data (e.g. interviews).

Study Design or Approach: Integrated, mixed-methods approach involving analysis of T-MSIS data, state vital records data, beneficiary-level program data, program documentation, interviews and focus groups with program and program affiliated staff/providers, and participant-led qualitative methods to assess beneficiary experience.

Anticipated Challenges and Mitigation Strategies:

- Each state is implementing a different version of the program
- Providing complete/accurate data from care sites is challenging for awardees.
- Data sharing across providers and across service sectors is challenging.
- Engaging and retaining beneficiaries is challenging.
- Beneficiaries fear engagement will lead to CPS involvement/child removal.
- Maintaining clinical and lay provider staff can be challenging, especially in the post-COVID environment.
- Social service infrastructure is limited.
- Transportation and childcare resources are inadequate to meet model participants' needs.
- Stigma across health, social service, and personal networks interferes with care engagement and success.
- Behavioral health infrastructure is inadequate.
- Enrollment in the model is below projections.

Dissemination plan: The evaluation aims to demonstrate whether providing evidence-based, comprehensive services for this population helps achieve better care and health outcomes and lower spending such that other state Medicaid programs might implement similar models. The second annual report can be found here: https://innovation.cms.gov/data-and-reports/2023/mom-scnd-ann-eval-rpt.

Integrated Care for Kids (InCK) Model Evaluation

Priority Area: Healthcare; Human Services

Priority Questions: To what extent do HHS programs and policies reduce costs and improve quality and safety of healthcare services? What are the impacts of HHS programs and policies on strengthening early childhood development and expanding opportunities to help children and youth thrive equitably within their families and communities?

Description: The Integrated Care for Kids (InCK) Model is a child-centered local service delivery and state payment model that aims to reduce expenditures and improve the quality of care for children under 21 years of age covered by Medicaid through prevention, early identification, and treatment of behavioral and physical health needs. Some programs also include pregnant beneficiaries age 21 and over and Children's Health Insurance Program (CHIP) beneficiaries. The model aims to integrate clinical care and health-related social services.

Time Period for the Activity (estimated start and end dates): August 2020 - August 2029

Existing Data Sources Held by the Division: T-MSIS data

Existing Data from Other Sources: Child service data from states such as WIC, SNAP, child welfare, education, TANF; Housing data from HUD

New Data Collection: Qualitative interviews, focus groups, and participant-led qualitative activities, model service-level stratification process data and results.

Study Design or Approach: Integrated, mixed-methods approach involving analysis of T-MSIS data, state-based social service data, beneficiary-level program data, program documentation, interviews and focus groups with program and program affiliated staff/providers, and participant-led qualitative methods to assess beneficiary experience.

Anticipated Challenges and Mitigation Strategies:

- Data sharing across providers and across service sectors is challenging.
- Engaging and screening beneficiaries can be challenging.
- Social service infrastructure is limited.
- Specialist services and appropriate behavioral health providers can be hard to access everywhere, with rural areas having more acute shortages

Dissemination plan: The evaluation hopes to understand whether integrated care models and APMs to support them improve health and reduce costs to Medicaid and could be expanded across states in accordance with the requirements of section 1115A of the Social Security Act. The pre-implementation report can be found online at: https://innovation.cms.gov/data-and-reports/2022/inck-model-pre-imp-first-eval-rpt.

Network of Quality Improvement and Innovation Contractors (NQIIC) Independent Evaluation

Priority Area: Research and Evidence; Management

Priority Question: How does HHS improve the design, delivery, and outcomes of HHS programs by prioritizing science, evidence, and inclusion? What improvements to HHS programs and policies can promote effective enterprise governance to ensure programmatic goals are met equitably and transparently across all management practices?

Description: The Quality Improvement Organizations (QIO) and other quality improvement contractors are required to provide evidence-based, data-driven technical assistance to health care facilities to improve quality and meet pre-defined outcomes related to:

- Opioid use and misuse;
- Patient safety;
- Chronic disease management
- Care coordination;
- Responding to public health emergencies and COVID-19 and infection control;
- Immunization;
- Training

CMS's evaluation strategy aims to understand:

- Which aspects of QIOs interventions are effective with the greatest estimated return on investment (ROI)
- Variance in performance across QIOs and interventions;
- Providers' satisfaction with the quality improvement interventions.

This information will inform current work and future Quality Improvement Program planning to shape program based on potential for maximum effectiveness and influence, addition focusing resources on high impact, high value activities.

Time Period for the Activity (estimated start and end dates): September 25, 2020-September 24, 2025

Existing Data Sources Held by the Division: Major quantitative data sources include: Medicare fee-for-service claims; Nursing Home Minimum Data set; Provider/Physician Performance (Hospital Compare, Nursing Home Compare); Medicare Current Beneficiary Survey (MCBS); Quality and Safety Review System.

Existing Data from Other Sources: National Healthcare Safety Network (NHSN)

New Data Collection: CMS began tracking completion of nursing home staff training on infection control through its Quality and Safety Education Portal as part of this statement of work. QIOs complete standardized data collection to describe encounters and trainings with nursing home providers, especially vaccination-related supports provided to nursing homes. The QIOs also document which nursing homes they work with have emergency preparedness plans and COVID-19 infection control policies and plans. Data on QIO encounters with hospitals and community coalitions are also noted by the QIOs. Survey data are also collected from hospitals, nursing homes, and outpatient clinicians to better understand provider perception of QIO program services.

Study Design or Approach: This is a 5-year mixed methods evaluation using both qualitative and quantitative methods such as multivariate-adjusted comparative interrupted time series analysis. An Independent Evaluation Contractor, Booz Allen Hamilton, with highly credentialed statisticians and health services researchers conducts the work under the direction of CMS. Although the evaluation is independent, the specific research questions are defined and the work is monitored by Ph.D.-trained researchers and clinicians at CMS who use their program knowledge to assure the contractors investigate the right populations, interventions, and outcomes.

Anticipated Challenges and Mitigation Strategies: The targeted response approach of using different strategies depending on the needs of different nursing homes, makes evaluating what processes work difficult; different processes may work in different facilities with no discernable patterns. OMB approval times for provider surveys longer than those posted on its website.

Dissemination plan:

Annual Reports to Congress, peer reviewed manuscripts, and internal program documents are all components of the dissemination plan. The IEC submitted a manuscript to the Journal of Evaluation and Program Planning in January estimating impacts of QIN-QIO care coordination work from the 11th SOW. A manuscript estimating QIO program impacts on COVID-19 will be submitted for peer review in July 2023.

Evaluation of the Value-Based Insurance Design (VBID) Model

Priority Area: Healthcare

Priority Question: To what extent do HHS programs and policies reduce costs and improve quality of healthcare services for the Medicare population?

Description: The VBID Model allows participating Medicare Advantage organizations (MAOs) to further target benefit design to enrollees based on chronic condition and/or socioeconomic characteristics and/or incentivize the use of Part D prescription drug benefits through rewards and incentives. MAOs may also offer the Medicare hospice benefit to their enrollees as part of the VBID Model. Additionally, the VBID model requires that all participating MAOs engage their enrollees through structured and timely wellness and health care planning, including advanced care planning.

Time Period for the Activity (estimated start and end dates): Sept. 2020 – Feb. 2028

Existing Data Sources Held by the Division: Part D Event, MA encounter, Claims, HCC, Bid Pricing Tool, HEDIS, HOS.

Existing Data from Other Sources: CAHPS, Participating plan reported data.

New Data Collection: Semi-structured interviews with participating and non-participating plans, in-network and out-of-network hospices, other VBID providers, and beneficiaries, Reusable Framework monitoring data (submitted by VBID plans)

Study Design or Approach: Our evaluation of the VBID model test takes a mixed-methods approach by integrating primary qualitative data with secondary quantitative data to assess the model test's effects on key outcomes. This approach allows us to observe, from multiple angles, the experiences of MAOs, beneficiaries, and providers with the model test and develop a more complete picture of the potential benefits and drawbacks of VBID in the Medicare population. MAOs that offer VBID through the model test are required to submit information on beneficiary participation to CMMI's Reusable Framework reporting system. We use these data to calculate the number of VBID-eligible beneficiaries in participating POs, the share of VBID-eligible beneficiaries who participated in the model test (versus opting out or not completing participation requirements), and changes over time in participation rates. We use difference-in-differences regression models to estimate whether MAOs that participated in VBID and their eligible beneficiaries experienced changes in outcomes relative to a matched comparison group. Our analyses estimate how MAOs' participation in the VBID model test affected outcomes. For most analyses, we pool all VBID-participating MAOs and beneficiaries (and their matched comparators) into a single regression. As a result, the "treatment" effect is generally exposure to any VBID intervention implemented by a participating MAO, rather than exposure to a specific VBID design. The hospice component will be evaluated separately. Finally, we characterize the experience of beneficiaries, providers, and MAOs with VBID through a series of semi-structured telephone interviews.

Anticipated Challenges and Mitigation Strategies: The evaluation relies on encounter data submitted by MAOs. While quality of these data has improved in recent years, the ongoing time lag (approximately 24-month runout period) delays answering key questions related to utilization. While the hospice component will be separately evaluated, the other flexibilities embodied in VBID are evaluated collectively even though there is variation in how they are used by participating MAOs. Thus, our evaluation of the VBID "proper" (non-hospice) model components speaks to access to the overall suite of flexibilities rather than the impact of any single one or subset of mechanisms.

Dissemination plan: https://innovation.cms.gov/innovation-models/vbid - Evaluation resources can be found at the bottom of the page.

- 2022: First report focusing on 2020 and 2021 implementation and enrollment is now posted here: https://innovation.cms.gov/data-and-reports/2022/vbid-1st-report-2022.
- 2023: Second report focusing on beneficiary experiences and utilization, health outcomes, and quality
- 2025: Third report focusing on Wellness and Healthcare Planning
- 2026: Fourth report focusing on hospice component
- 2027: Fifth report focusing on individual component impacts
- 2028: Sixth report focusing on generalizability Potential expansion of socioeconomic/Low Income Subsidy (LIS) targeting flexibility and inclusion of hospice in Medicare Advantage benefits package

Mixed-methods evaluation of the effectiveness of the CMS COVID-19 flexibilities and the development of recommendations to move beyond the pandemic to a resilient healthcare system

Priority Area: Public health

Priority Question: How effective are HHS programs and policies at protecting individuals, families, and communities from infectious disease and preventing non-communicable disease through development and equitable delivery of effective, innovative, readily available, treatments, therapeutics, medical devices, and vaccines.

Description: The COVID 19 public health emergency (PHE) was unprecedented resulting in CMS processing over 250,000 individual 1135 waiver requests from states, associations and provider communities and issuing 160 blanket waivers. As with any public health emergency, flexibilities issued in response to the COVID-19 PHE that are appropriate only as an emergency measure will generally terminate at the end of the PHE. Some flexibilities will continue for a period after the end of the PHE. This implementation evaluation project will provide information on the utilization, implementation and effectiveness of the flexibilities and recommendations to ensure that CMS and the healthcare system is resilient and holistically prepared for addressing another major event.

Time Period for the Activity (estimated start and end dates): Evaluation is underway with an expected completion date in the summer of 2024.

Existing Data Sources Held by the Division: TBD

Existing Data from Other Sources: Literature review.

New Data Collection: Qualitative interviews with healthcare providers and experts in the field with knowledge of outcomes observed during PHE. Quantitative analysis will focus on understanding provider response during the PHE (e.g., quality of care) based on available data and to identify providers for interview.

Study Design or Approach: Mixed-methods evaluation of the effectiveness of CMS flexibilities in response to the 2020 COVID-19 Public Health Emergency (PHE) to inform potential future policy and program decisions to support a resilient healthcare system. A review of the emerging literature from credible sources will be conducted. Qualitative analysis will also be conducted to include interviews with healthcare providers and experts in the field with knowledge of outcomes observed during PHE. Quantitative analysis will focus on understanding provider response during the PHE (e.g., quality of care) based on available data and to identify providers for interview.

Anticipated Challenges and Mitigation Strategies: None.

Dissemination plan: Results will be included in a Report to Congress

CMS Pilot to Develop Targeted Oversight of Inappropriate Antipsychotic Prescribing Behavior in Nursing Homes

Priority Area: Healthcare

Priority Question: To what extent do HHS programs and policies reduce costs and improve quality of healthcare services for individuals in long-term care settings?

Description: The pilot used data from six different authoritative sources in addition to detailed medical record reviews and facility-level data validation audits to substantiate the clinical appropriateness of antipsychotic use in accordance with standards of care as well as compliance with existing regulations.

Time Period for the Activity (estimated start and end dates): 2022-2023

Existing Data Sources Held by the Division: Data sources include:

- Minimum Data Set (MDS) — source of data on residents in the nursing home, including diagnoses;
- Medicare Part A, B, and D claims — Part A and B claims provide information on diagnoses before residents entered the nursing home, Part D claims provide information on medications/drugs before and after nursing home entry;
- Nursing Home Compare — source of data on star ratings and bed size;
- Beneficiary Information in the Cloud (BIC) — source of data on program enrollment status (FFS, MA);
- Master Data Management (MDM) — source of additional data on facility names

Existing Data from Other Sources: None

New Data Collection: None

Study Design or Approach: Analysis occurs at the resident and facility level. This pilot examined data before and after residents' nursing home entry to examine whether diagnoses appearing in the nursing home can be substantiated from pre-existing Medicare claims; unsubstantiated diagnoses may warrant further investigation and are then aggregated by facility to detect patterns of antipsychotic use, also incorporating survey and enforcement data as appropriate. The proposed analytical data, pattern and sequence for this activity are consistent with systematic evaluation approaches. In this case, it aims at problem-solving and identifying possible root causes.

Anticipated Challenges and Mitigation Strategies: None

Dissemination plan: The findings from these reviews facilitated further action by CMS and other federal partners, including the HHS Office of the Inspector General and the Department of Justice, and the pilot was designed to test new referral pathways from the Beneficiary and Family Centered Care-Quality Improvement Organizations reviews.

Eighty-six of the highest priority cases were reviewed, and of these 21 selected nursing homes underwent additional referral action:

- Fifteen (15) of the nursing homes were referred to the Quality Innovation Network-Quality Improvement Organizations (QIN-QIOs) for a Quality Improvement Initiative; and
- Six (6) were referred to the BFCC-QIO Sanctions process, as the degree of violation was more significant.

Food and Drug Administration (FDA)

Evaluation of the reach and utility of the Center for Tobacco Product (CTP) tobacco regulatory science research program

Priority area: Research and Evidence

Priority questions: Which HHS investments in the research enterprise are most effective for maintaining leadership in the development of innovations that broaden our understanding of disease, healthcare, public health, and human services resulting in more effective interventions, treatments, and programs?

Description: Ongoing external evaluation to measure the effectiveness of the results and utility of the CTP-funded tobacco regulatory science research program with annual evaluation reports.

Time period of the activity: Annual report is delivered to CTP from contractor in September

Existing Data Sources Held by the Division: Administrative data on: research projects; publications generated from research projects

Existing Data from Other Sources: Altmetric, iCite, PubMed, Web of Science, FDA Docket Management System

New data collection: None

Study design or approach: Mixed-methods (quantitative and qualitative); Descriptive analyses of focus of research projects and generated publications (e.g., disease, tobacco product, population); Examination of scientific influence on the tobacco regulatory science field by citation analysis (e.g., raw citation counts, Relative Citation Ratio); Examination of contribution of CTP-funded research to regulatory policy and practice by citation analysis of select CTP regulatory documents.

Anticipated challenges and mitigation strategies: Challenges in assessing the reach of internal or unpublished research on CTP's tobacco regulatory activities; these challenges are key challenges inherent to the evaluation of research. Doing pilot work to develop mitigation strategies.

Dissemination plan for results: Findings from annual reports are used to identify research gap areas, make informed decisions on priority research areas and how best to address those areas, and to continue the growth of the CTP-funded Tobacco Regulatory Science program. Goal is ensuring CTP supports tobacco regulatory science research that is most impactful to CTP's mission. Plan to disseminate key results in presentations to stakeholders and in scientific journals.

Update for FY23: Interim results using data through FY22 indicate CTP-funded publications are informing CTP regulations, including 301 unique CTP-funded publications referenced across 29 CTP regulatory documents analyzed for this year's report. Regulatory documents include various CTP guidances, product standards, regulatory impact analyses (RIAs), and select Technical Project Lead (TPL) reviews for Premarket Tobacco Product Applications (PMTAs) and Modified Risk Tobacco Product Applications (MRTPAs).

Health Resources & Services Administration (HRSA)

Evaluation of the Telehealth Technology Enabled Learning Program (TTELP)

Priority Area: Healthcare

Priority Question: How do HHS programs and policies bolster the primary and preventive healthcare workforce to ensure delivery of quality services and care?

Description: This project will assess the implementation of Telehealth Technology Enabled Learning Program (TTELP) and examine the extent to which providers are able to participate in evidence-based training and support to help them treat patients with complex conditions in their communities. The project also will assess the TTELP's ability to facilitate learning community models of professional education and support that are adaptable to organizations that serve rural and underserved populations.

Time Period for the Activity (estimated start and end dates): September 2021 – September 2026

Existing Data Sources Held by the Division: None

Existing Data from Other Sources: None

New Data Collection: Provider level data from grantees

Study Design or Approach: HRSA will collect quantitative data about grantees using either an online survey tool or an Excel-based tool and use a descriptive analysis to report frequencies and percentages of data elements.

Anticipated Challenges and Mitigation Strategies: The TTELP grantees have varying levels of organizational data and evaluation capacity based on their level of experience. Reporting on some of the data elements may be challenging for resource-limited grantees.

Dissemination plan: HRSA will disseminate results through publicly available reports and articles, webinars/presentations, and other data visualization/information sharing tools as proposed by the evaluator and approved by HRSA Office of Communications. HRSA will use this information to inform future similar programs.

Provider Resiliency Evaluation

Priority Area: Healthcare

Priority Question: How do HHS programs and policies bolster the primary and preventive healthcare workforce to ensure delivery of quality services and care?

Description: This evaluation will determine the effectiveness and reach of the Bureau of Health Workforce's health workforce resiliency training programs for health care and public safety workforce. The evaluation will focus on health care workforce remaining in or leaving medically underserved communities and primary care settings and factors associated with each.

Time Period for the Activity (estimated start and end dates): October 2022 – October 2026

Existing Data Sources Held by the Division: Annual Performance Reports, non-competing Progress Reports

Existing Data from Other Sources: National-level workforce benchmark data such as the Area Health Resources File, American Medical Association Masterfile or other sources deemed useful by HRSA and the contractor

New Data Collection: Surveys of both grantees and participants

Study Design or Approach: HRSA and the contractor will determine the final evaluation design. The anticipated mixed methods outcome evaluation will use both quantitative administrative and survey data as well as interviews and other qualitative data to determine overall effectiveness of the Bureau of Health Workforce's workforce resiliency programs. The evaluation will examine the extent to which health care providers remain in their settings and profession, along with factors influencing those decisions, including the effectiveness of the resiliency programs.

Anticipated Challenges and Mitigation Strategies: The primary challenge will be response rates to surveys from participants as well as recruiting a suitable comparison group. The contractor must have a plan to address adequate response rates to surveys and interviews.

Dissemination plan: HRSA will disseminate results through summary outcome documents posted to the HRSA website, and through three published professional papers containing aspects of the results of this four-year study.

Healthy Start (HS) Evaluation & Capacity Building Support

Priority Area: Human Services

Priority Question: What are the impacts of HHS programs and policies on strengthening early childhood development and expanding opportunities to help children and youth thrive equitably within their families and communities?

Description: This effort is a four-year national evaluation of the HS program applying implementation, utilization, outcome, and transformative evaluation approaches to determine the effectiveness of the program. The social ecological model is used as the framework to assess characteristics, behaviors, and activities at the individual level (e.g., use of program services), the organizational level (e.g., HS initiatives), the community level (e.g., HS Community Action Networks), and the larger social-structural level (e.g., policies, systems, structural environment). Results of the evaluation will be used to inform decision-making and develop recommendations to improve implementation of the HS program.

Time Period for the Activity (estimated start and end dates): September 2021 - September 2025

Existing Data Sources Held by the Division:

Healthy Start Monitoring & Evaluation Data System (HSMED) - Reporting system for participant-level data received on a monthly basis - Based on information provided in the Healthy Start Data Collection Forms (Background Form, Prenatal Form, Parent/Child Form) - Contains demographic, participant behavior, healthcare utilization, access, and perinatal outcomes data Discretionary Grant Information System (DGIS) - Collects grantee-level data on annual basis - Addresses MCHB-wide and HS program-specific performance measures

Existing Data from Other Sources: Vital records data from at least one state will be used for the same year in which data from the Healthy Start participants is collected

New Data Collection: Quantitative and qualitative data collected from Healthy Start grantees and their stakeholders via web-based surveys, semi-structured interviews, and site visit assessments

Study Design or Approach: The evaluation will use a mixed methods approach: for much of the implementation and utilization evaluation, HSMED data, DGIS data, and the Program Staff Survey will be analyzed to provide descriptive statistics and determine associations. Grantee reports, stakeholder interviews, and network analysis will inform the implementation and transformative evaluation components. The outcome evaluation will measure the effect of HS on participant health outcomes using dosage analysis.

Anticipated Challenges and Mitigation Strategies: The HS grantees have varying levels of organizational data and evaluation capacity based on level of experience with the program and other factors. An organizational assessment was conducted that identified challenges in collecting and submitted required data, time and effort required, staff experience, and variations in data systems. The evaluation design includes a risk mitigation plan to address these challenges that includes technical assistance provided by the evaluation contractor and the HS TA & Support Center.

Dissemination plan: The evaluation design includes an outreach and dissemination component involving a variety of approaches based on the target audience for specific products. The results will be disseminated via the creation of written materials, reports, and possible publications, and presenting evaluation findings in webinars and in-person, to both internal and external stakeholders. The findings may be used to inform quality improvement efforts within the program, program policy, and future national (or local) evaluations of the program. Information about the Healthy Start Program can be found online at: https://healthystartepic.org/healthy-start/program-overview/.

Evaluation of the Rural Maternity and Obstetrics Management Strategies (RMOMS) Program

Priority Area: Healthcare

Priority Question: To what extent do HHS programs and policies reduce costs and improve quality of healthcare services?

Description: This project will document the implementation of two RMOMS program cohorts (FY 2019 and FY 2021) and assess how many women and infants the RMOMS program served, examine the extent to which services were delivered, and examine factors that help explain the volume and types of services used. It will also assess the RMOMS program's effect on the program goals and objectives over time and examine factors associated with improved various patient outcomes.

Time Period for the Activity (estimated start and end dates): September 2021 - August 2025

Existing Data Sources Held by the Division: None

Existing Data from Other Sources: National vital statistics data, peer-reviewed publications about rural and maternal health topics, and publicly available data on health disparities in the awardee service areas

New Data Collection: Patient level data from grantee

Study Design or Approach: The RMOMS evaluation uses a mixed methods approach. The study design combines qualitative data from interviews and progress reports with de-identified patient-level data on clinical and support services to understand model implementation and the resulting impact on service

utilization, health behaviors, and health outcomes for each awardee as well as the RMOMS program overall.

Anticipated Challenges and Mitigation Strategies: Patient level, primary data collection can be a challenge for resource-limited rural providers. Contractor will provide TA on data collection and share best practices.

Dissemination plan: Results will be disseminated through publicly available reports, webinars/presentations, and other data visualization/information sharing tools as proposed by the contractor and approved by HRSA Office of Communications. Information will be used to inform future RMOMS programming specifically as well as to inform improvements to maternal health outcomes in rural communities more broadly.

Behavioral Health Workforce Supply

[From 2023]

Priority Area: Healthcare

Priority Question: How do HHS programs and policies bolster the primary and preventive healthcare workforce to ensure delivery of quality services and care?

Research Question: How many new behavioral health providers and paraprofessionals graduated from the program and are currently practicing? To what extent are the new graduates practicing in primary care and underserved settings?

Description: Evaluation of BHW's behavioral health workforce expansion programs in terms of cumulative outputs and outcomes. Reduction in forecast national-level shortages of specific behavioral health occupations will be demonstrated.

Time Period for the Activity (estimated start and end dates): Ongoing annually

Existing Data Sources Held by the Division: program performance metrics, NCHWA projection reports, Area Health Resources Files

Existing Data from Other Sources: None

New Data Collection: Annual collection of performance metrics. Study Design or Approach: Primary analysis of performance data includes a cumulative count of total new graduates in each of the behavioral health occupations trained across the Bureau's behavioral health expansion programs. Additionally, for key occupations that also have NCHWA projections available, a percent reduction in the forecast FTE shortage will be calculated, assuming that each new graduate will be employed full-time in their trained occupation.

Anticipated Challenges and Mitigation Strategies: The only challenge is receiving complete and accurate performance data each year for these programs in a timely fashion. While most grantees report on-time, employment data is not always complete. Project officers remind grantees to report all data and of the importance this data has to continued funding of the program.

Dissemination plan: Results will be disseminated via a brief evaluation summary document posted on HRSA's website as well as highlights included in HRSA's Congressional Justification.

Indian Health Service (IHS)

Implementation of Trauma Informed Care (TIC) in Federal Healthcare Settings – Policy manual & training development

Priority Area: Healthcare

Priority Question: How can HHS programs and policies expand equitable access to comprehensive, community-based, innovative, and culturally competent healthcare services while addressing social determinants of health? How effective are HHS programs and policies at integrating trauma informed concepts into health services in the healthcare system? To what extent do HHS programs and policies strengthen and expand access to Department priorities including mental health and substance use disorder treatment and recovery services for individuals and families?

Description: In response to IHS Manual Part 3, Chapter 37: Trauma Informed Care (TIC): IHS is developing and evaluating the effect of a new mandatory one-hour TIC training for the agency at large.

Time Period for the Activity (estimated start and end dates): October 2023 – September 2024

Existing Data Sources Held by the Division: Current IHS TIC activities and existing IHS policy guidance

Existing Data from Other Sources: Current TIC training data (employee compliance rates)

New Data Collection: Results of pending of IHS readiness assessment, policy and training development

Study Design or Approach: The focus of this study is to evaluate the TIC training and policy roll-out. IHS will evaluate the fidelity of the training through a phased approach. Initial steps will include a comprehensive review to generate a gap analysis report for TIC implementation standards to be detailed in mandatory training, policy and published literature. The next phase will focus on the development of a survey instrument to identify and assess existing/developing evidence-based activities (including cultural factors) that can be scaled at the national level for IHS facilities. Results, key informant interviews, and focus groups with tribal entities will support guidance and resource materials with identified metrics to evaluate the influence of the policy and training with regard to audience penetration and retention of content.

Anticipated Challenges and Mitigation Strategies: Lack of current data regarding policy/training influence. As this is the implementation of a new policy directive, year 1 data would serve as baseline.

Dissemination plan: Dissemination to IHS Senior Staff and all employees. Continue to guide further refinements to the newly developed TIC training. Continue to inform IHS Manual updates regarding TIC.

Indian Health Service (IHS) Evaluation Policy Roll-out Evaluation

Priority Area: Research and Evidence

Priority Question: How does HHS improve the design, delivery, and outcomes of HHS programs by prioritizing science, evidence, and inclusion? What improvements are needed to HHS programs and policies for data collection, use, and evaluation to increase evidence-based knowledge that leads to better health outcomes, reduced health disparities, and improved social well-being, equity, and economic resilience?

Description: IHS Evaluation Policy was approved and added as a chapter to the IHS Manual. Policy focused on three main activities: Establish agency-wide work group, work with agency to increase

evaluation practice into program development/planning and develop sufficient capacity to implement the policy.

Time Period for the Activity (estimated start and end dates): December 2023 – November 2024

Existing Data Sources Held by the Division: Evaluation Policy, roll-out materials, resources used. Working Group meeting agenda/notes and logic model, IDIQ activities

Existing Data from Other Sources: Review of policy/practice changes in other sub-sets of IHS.

New Data Collection: Focus group/key informant interviews

Study Design or Approach: Assess the manner and extent to which IHS achieves intended objectives and use evaluative information to make management decisions. Assess if/how much evaluation has been incorporated into IHS infrastructure and business processes. Determine any increase in ability to aggregate data and respond to stakeholder requests. This will be done through reviewing policy and practice changes, as well as through key informant interviews and focus groups.

Anticipated Challenges and Mitigation Strategies: Lack of quantitative data will limit depth. Review past practices for comparison and use qualitative methods

Dissemination plan: Dissemination to IHS Working Group and senior staff and publish on IHS Program Evaluation Webpage. Guide the revision of Program Evaluation chapter in IHS Manual, including formalizing responses to HHS Evidence Act deliverables.

National Institutes of Health (NIH)

Evaluation of Oral Health in America: Challenges and Opportunities

Priority Area: Research and Evidence

Priority Question: How does HHS improve the design, delivery, and outcomes of HHS programs by prioritizing science, evidence, and inclusion?

Description: *Oral Health in America: Advances and Challenges*, a report released by NIH in December 2021, is the culmination of two years of research and writing by over 400 contributors. As a follow-up to the Surgeon General's Report on Oral Health in America, this report explores the nation's oral health over the last 20 years. The goal of the evaluation is to determine the reach and impact of the report and has four phases**:**

- Phase 1: Dissemination
- Phase 2: Knowledge transfer
    - Research priorities in strategic plans of research institutions and funders
    - Curriculum changes in dental schools and post-graduate programs
    - National Institute of Dental and Craniofacial Research (NIDCR) concept clearances and research priorities
- Phase 3: Outcomes
    - Social network analysis and bibliometric analysis of presentations, publications, NIH applications
- Phase 4: Effects
    - National public health surveillance statistics
    - Oral health program and policy changes

- Oral health treatment standards and guidelines

Time Period for the Activity (estimated start and end dates): 2022-2026

Existing Data Sources Held by the Division:

- User statistics for the NIDCR website.
- User statistics for presentations from NIDCR to specific groups.
- NIDCR concept clearances, grant applications, grant progress reports.
- NIDCR will use digital applications from the NIH Office of Portfolio Analysis (OPA) to summarize and analyze grant data and conduct social network analyses.

Existing Data from Other Sources: Publications and presentations by the authors and contributors about the report.

New Data Collection:

- Interviews with key informants.
- Review of curriculum documents and webpages from dental schools and dental post-graduate programs.
- Comments and survey responses during and after presentations in a variety of settings by NIDCR leadership

Study Design or Approach: The evaluation uses a variety of methods, quantitative and qualitative, including digital visualization techniques and data retrieval and summary applications available from the NIH OPA. Methods include document reviews, social network analyses, bibliometric analyses, and key informant interviews.

Anticipated Challenges and Mitigation Strategies: Data of interest might not become available in a timely fashion. NIDCR will modify the evaluation plan as needed to identify alternative data sources and evaluation methods.

Dissemination plan: The results will be of interest to NIDCR leadership and to federal agencies that prepare and release major public health research results.

Office of the National Coordinator for Health Information Technology (ONC)

Evaluation of the Trusted Exchange Framework and Common Agreement (TEFCA)

Priority Area: Research and Evidence

Priority Question: What improvements are needed to HHS programs and policies for data collection, use, and evaluation to increase evidence-based knowledge that leads to better health outcomes, reduced health disparities, and improved social well-being, equity, and economic resilience?

Description: The goal of TEFCA is to establish a floor of universal interoperability across the country. TEFCA will do this by creating health information networks that operate under agreed upon policies, technical requirements, and network connectivity requirements. The evaluation will assess whether TEFCA is successful in increasing interoperable exchange, increasing the availability of health data, and simplifying exchange by healthcare providers, such as reducing the number of different networks that providers have to join.

Time Period for the Activity (estimated start and end dates): FY 2024 - FY 2028

Existing Data Sources Held by the Division: None

Existing Data from Other Sources: Health IT Surveys (e.g. AHA, HIE Survey)
New Data Collection: Direct data from Recognized Coordinated Entity (RCE) that manages the TEFCA

Study Design or Approach: The study will use a mixed methods approach. It will consist primarily of quantitative results assessing milestone achievements, TEFCA participation, and quantifiable results of TEFCA participation on health IT interoperability. This analysis will be supplemented with interviews with TEFCA participants, health IT end users, and the RCE.

Anticipated Challenges and Mitigation Strategies: Data collection will likely be the biggest challenge. ONC can leverage TEFCA program milestones and data from RCE process and outcome metrics, once available. In addition, assessing the effect will require use of data from outside of TEFCA, such as national surveys which may not completely captures TEFCA's role in interoperability.

Dissemination plan: The results of the evaluation will be published on an ongoing basis through peer-reviewed publications and data briefs. ONC will use these publications to assess the progress and success of TEFCA and inform recommendations for the program going forward.

Substance Abuse and Mental Health Services Administration (SAMHSA)

Evaluation of the Garrett Lee Smith (GLS) State/Tribal Youth Suicide Prevention and Early Intervention Program

Priority Area: Healthcare

Priority Question: To what extent do HHS programs and policies strengthen and expand access to mental health and substance use disorder treatment and recovery services for individuals and families?

Description: The evaluation aims to assess the effect of GLS State/Tribal Youth Suicide Prevention and Early Intervention Program on reducing suicide attempts and mortality due to suicide, continue to build the evidence base for suicide prevention programming, to develop a portfolio of evaluations that address key issues related to influence on deaths by suicide and non-fatal attempts, to inform future program development, and to establish standards for developing, implementing, and evaluating suicide prevention programs. The evaluation is designed to gather detailed outcome and impact data to provide information and evidence needed to understand what works, why it works, and under what conditions, relative to program activities. A behavioral health equity and cultural equity lens will be applied to each area of evaluation to ensure a culturally specific understanding of intervention implementation, outcomes, and impacts.

Time Period for the Activity (start and estimated end dates): September 2022-September 2027

Existing Data Sources Held by the Division: TBD

Existing Data from Other Sources: Deidentified, abstracted case records, electronic health records, and referral forms

New Data Collection: Web-based surveys of trainees and youth, trainee phone simulation (Training Skills Assessment-Phone Simulation [TSA-PS])

Study Design or Approach: The evaluation will examine whether effects vary across different groups of intended beneficiaries (males, females, indigenous people, military families/veterans, etc.), regions, and over time with particular emphasis on priority and high-risk populations. Three areas of evaluation – Implementation, Outcome, and Impact – will provide a robust understanding of effective implementation of strategies and effectiveness of the strategies themselves in improving trainee skills in working with youth to prevent suicide and connect them with services and supports when needed, as well as the impact on suicide morbidity and mortality. The evaluation will use data to examine how grantees effectively assess the effect among populations at risk from marginalized communities such as AI/AN, black youth, LGBTQ+ where there may be insufficient numbers to analyze mortality.

Anticipated Challenges and Mitigation Strategies: Participant burden, which has been mitigated through reduction and streamlining of instruments. Instruments underwent cognitive and/or pilot testing or expert review, and web-enabled instruments will undergo usability testing prior to fielding.

Dissemination plan: Results of this evaluation will be shared internally to increase the quality of the program and externally through SAMHSA's website. Local Annual Evaluation Reports and two congressional reports summarizing the results of the evaluation are required. At least one article for submission to a peer-reviewed journal annually is expected.

Internal Formative Evaluation of the Projects for Assistance in Transition from Homelessness (PATH)

Priority Area: Healthcare

Priority Question: How do HHS programs and policies expand equitable access to comprehensive, community-based, innovative, and culturally competent health care services while recognizing social determinants of health?

Description: The PATH evaluation report includes information on funding, staffing, numbers served/contacted and enrolled, client demographics, service provision and service referrals made and attainment. Data are submitted by the PATH providers via the SAMHSA PATH Data Exchange (PDX), though parts are to be provided through local Homeless Management Information Systems (HMIS). The PATH grantees' State PATH Contacts (SPCs) approve the data submitted by their providers. The evaluation will include performance measurement, a feasibility study, and outcome evaluation.

Time Period for the Activity (estimated start and end dates): Ongoing annually

Existing Data Sources Held by the Division: Path Data Exchange (PDX)

Existing Data from Other Sources: HMIS and Web-based survey

New Data Collection: Focus groups with clients and key informant interviews with PATH grantees, and program and provider staff.

Study Design or Approach: Mixed method approach using program performance and qualitative data.

Anticipated Challenges and Mitigation Strategies: Delay in data collection

Dissemination plan: The PATH evaluation report is both an annual report (shared online) and a triannual report required by Congress. Previous reports have been shared online at: https://www.samhsa.gov/data/report/path-2020-evaluation.