2024 HHS EVALUATION PLAN

The Fiscal Year (FY) HHS 2024 Evaluation plan lists a total of thirty-two (32) evaluations from ten (10) Operating and Staff Divisions across the U.S. Department of Health and Human Services (HHS). The evaluations include ten (10) new evaluations proposed to start in FY 2024, thirteen (13) on-going evaluations that are described in the FY 2023 plan and nine (9) additional ongoing evaluations not previously included in an HHS Evaluation Plan but which make an important contribution to HHS' evidence building efforts.

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Letter from 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 agency evaluation policy, and upholds the standards 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 Assistance 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.

The FY 2024 HHS Evaluation Plan includes a range of evaluations that are planned to continue into or to start in FY 2024. While they 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. 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.

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.

Background and Introduction

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

The Department of Health and Human Services (HHS) is a large, decentralized agency with 12 operating divisions[1], 10 staff divisions, and 10 regional offices whose programs and policies touch the lives of nearly all people living in the United States and its territories. Understanding the evaluation, research, and analysis efforts and coordinating plans across HHS is a significant undertaking and is conducted by the Office of the Assistant Secretary for Planning and Evaluation (ASPE). Through the Evaluation Officer, ASPE plays a significant leadership role, especially for evaluation and evidence-building activities.

Evaluation and analysis provide essential evidence for HHS to understand how its programs work, for whom, and under what circumstances. HHS builds evidence to inform decisions in budget, legislative, regulatory, strategic planning, program, and policy arenas. 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 how they can be improved.

Across HHS, evaluation comes in many forms and focuses on "systematic analysis of a program, policy, organization, or component of these to assess effectiveness and efficiency".[2] HHS uses both classic and innovative methods to achieve the Evidence Act's goal of improving the infrastructure needed to produce and use evidence for policy development, and to better obtain and make use of existing data. The HHS evaluations presented in this report include formative studies focused on program design and implementation and summative designs focused on measuring program results. 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 evidence-building activities.

ASPE coordinates the HHS evaluation community by regularly convening the HHS Evidence and Evaluation Policy Council (the 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. The Council predates the Evidence Act and is made up of senior evaluation staff and subject matter experts from each HHS Division. Members of the Council

[1] In July 2022 HHS Secretary Becerra elevated the Administration for Strategic Preparedness and Response (ASPR) from an HHS Staff Division to an Operating Division.
[2] MEMORANDUM FOR HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES M-19-23

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, 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 will strengthen evaluation and evidence-building activities in HHS and will inform the development and conduct of capacity building activities in accordance with the principles and foundations for scientific integrity.

Plan Development

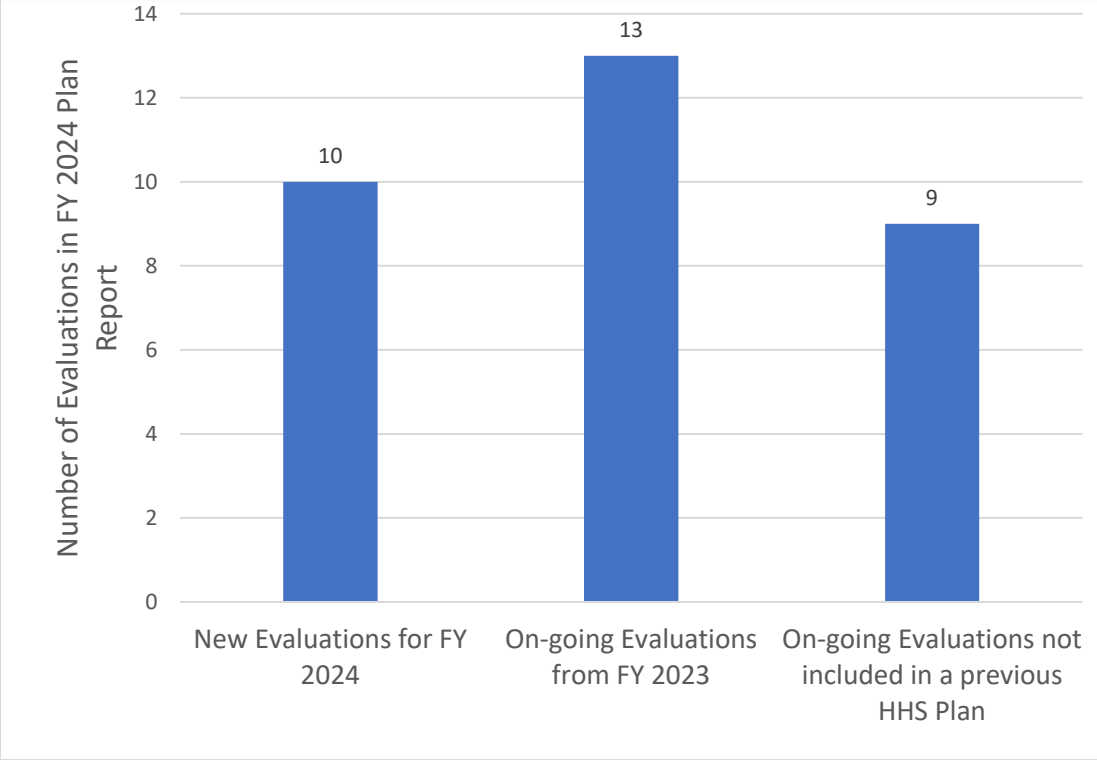
To develop this plan, HHS Op/Staff Divs were asked to list up to five significant[3] new evaluations that will start in fiscal year (FY) 2024, indicate which evaluations described in the FY 2023 Evaluation Plan are expected to continue in FY 2024, and add relevant ongoing evaluations that were not included in a previous HHS Evaluation Plan (see Table 1).

The FY 2024 Evaluation plan lists a total of thirty-two (32) significant evaluations across ten (10) Op/Staff Divs. The evaluations include ten (10) new evaluations proposed to start in FY 2024, thirteen (13) on-going evaluations described in the FY 2023 plan, and nine (9) additional ongoing evaluations that were not included in a previous HHS evaluation plan (Figure 1). The latter resulting from the gap between when Op/Staff Divs provide information about planned evaluations and when final Op/Staff Div budgets are approved. Descriptions of each of these

[3] For purposes of this plan, HHS has defined "significant" as evaluation activities that support answering questions from the HHS FY 2023-2026 Evidence-Building Plan. This definition for significance is consistent across all evaluations included in the plan; however, each Op/Staff Div may have considered additional criteria in selecting evaluations for inclusion in this plan.

evaluations can be found in the Evaluations section at the end of this document. All activities described in this plan are subject to availability of appropriations.

Figure 1: Total Number of Evaluations by Category



Across the evaluation categories, Table 1, below, shows that most of the Divisions that had two or more on-going evaluations from FY 2023, have fewer or no new evaluations for FY 2024, for example, ACF, CDC, CMS, HRSA, and FDA. On the other hand, some Divisions, such as IHS and NIH, have two or more new evaluations for FY 2024 and no on-going evaluations from previous years. The new FY 2024 Evaluations cut across various topics including program assessments, assessment of health care services, organizational performance assessments, health care workforce development studies, and outcomes evaluation of scientific research collaborations.

Table 1: List of Planned and Ongoing FY 2024 Evaluations by Category

Administration for Children and Families (ACF)

- **New evaluations in FY 2024:** N/A
- **On-going evaluations from FY 2023:**
  - Supporting Evidence Building in Child Welfare
  - Building Evidence on Employment Strategies for Low-Income Families
- **Evaluations not included in a previous HHS Evaluation plan:**
  - Next Generation of Enhanced Employment-Strategies (NextGen) Project

Administration for Community Living (ACL)

- **New evaluations in FY 2024:** N/A
- **On-going evaluations from FY 2023:**
  - Process and Outcome Evaluation of the National Paralysis Resource Center (NPRC)
- **Evaluations not included in a previous HHS Evaluation plan:** N/A

Centers for Disease Control and Prevention (CDC)

- **New evaluations in FY 2024:** N/A
- **On-going evaluations from FY 2023:**
  - Evaluation of the Preventive Health and Health Services (PHHS) Block Grant
- **Evaluations not included in a previous HHS Evaluation plan:**
  - 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
  - Evaluation of the Public Health Associate Program (PHAP): Class Diversity, Attrition, Engagement and Satisfaction, and Retention in the Public Health Workforce After Program Completion
  - Evaluation of the National Education and Awareness Social Marketing Campaign Employer Efforts to Support the Mental Health of Health Workers

Centers for Medicare & Medicaid Services (CMS)

- **New evaluations in FY 2024:** N/A
- **On-going evaluations from FY 2023:**
  - Maternal Opioid Misuse (MOM) Model Evaluation
  - Integrated Care for Kids (InCK) Model Evaluation
  - Evaluation Network of Quality Improvement and Innovation Contractors (NQIIC) Independent Evaluation
  - Evaluation of the Value-Based Insurance Design (VBID) Model
- **Evaluations not included in a previous HHS Evaluation plan:**
  - 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

Food and Drug Administration (FDA)

- **New evaluations in FY 2024:**
  - The Center for Veterinary Medicine (CVM) Environmental Scan (ES)
- **On-going evaluations from FY 2023:** N/A
- **Evaluations not included in a previous HHS Evaluation plan:**
  - Evaluation of the reach and utility of CTP's tobacco regulatory science research program
  - Evaluation of Tobacco 21 on tobacco product behaviors
  - Evaluation of CTP's tobacco product application marketing decisions

Health Resources and Services Administration (HRSA)

- **New evaluations in FY 2024:**
  - Evaluation of the Telehealth Technology Enabled Learning Program (TTELP)
  - Provider Resiliency Evaluation

- **On-going evaluations from FY 2023:**
  - Healthy Start (HS) Evaluation & Capacity Building Support
  - Evaluation of the Rural Maternity and Obstetrics Management Strategies (RMOMS) Program
  - Ryan White HIV/AIDS Program (RWHAP) Special Projects of National Significance (SPNS): Improving Care and Treatment Coordination: Focusing on Black Women with HIV
- **Evaluations not included in a previous HHS Evaluation plan:** N/A

Indian Health Service (IHS)

- **New evaluations in FY 2024:**
  - Evaluation Implementation of Trauma Informed Care (TIC) in Federal Healthcare Settings: Policy manual & training development
  - IHS Evaluation Policy Roll-out evaluation
- **On-going evaluations from FY 2023:** N/A
- **Evaluations not included in a previous HHS Evaluation plan:** N/A

National Institutes of Health (NIH)

- **New evaluations in FY 2024:**
  - Centers of Excellence in Genomic Science (CEGS) Program Evaluation
  - Strategic Focus on Evaluation at the National Institute of General Medical Sciences
  - Effect Evaluation of Oral Health in America: Challenges and Opportunities
- **On-going evaluations from FY 2023:** N/A
- **Evaluations not included in a previous HHS Evaluation plan:** N/A

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

- **New evaluations in FY 2024:** N/A
- **On-going evaluations from FY 2023:**
  - Evaluation of the Trusted Exchange Framework and Common Agreement (TEFCA)
- **Evaluations not included in a previous HHS Evaluation plan:** N/A

Substance Abuse and Mental Health Services Administration (SAMHSA)

- **New evaluations in FY 2024:**
  - Evaluation of the Garrett Lee Smith (GLS) State/Tribal Youth Suicide Prevention and Early Intervention Program
- **On-going evaluations from FY 2023:**
  - Internal Formative Evaluation of the Projects for Assistance in Transition from Homelessness (PATH)
- **Evaluations not included in a previous HHS Evaluation plan:** N/A

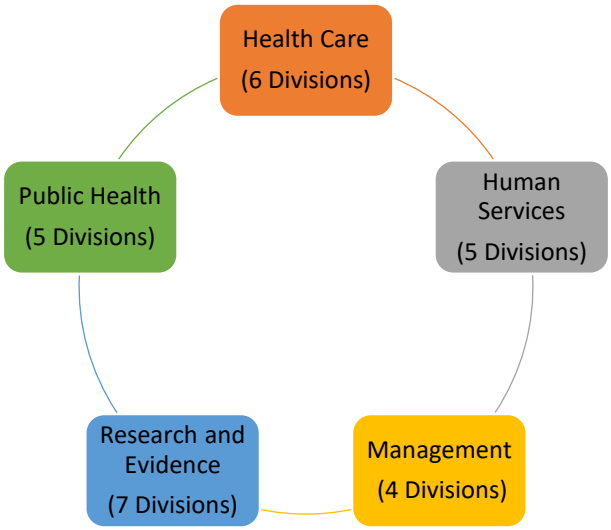
Significant Evaluations by HHS Priority Area

The FY 2024 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 2). Taken together these plans support and coordinate efforts of the Op/Staff Divs in achieving key HHS priorities, especially related to research and evidence programs, policies, capacity-building, resource needs, and agency processes. Figure 2 is a graphical representation of the number of Op/Staff Divs carrying out evaluations under each of the five Evaluation Plan Priority Areas.

Table 2: Alignment of the Evaluation Plan Priority Areas with the HHS Strategic Plan Goals

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

Figure 2: Number of Op/Staff Divs carrying out Evaluations under each of the HHS Evaluation Plan Priority Areas



The evaluations included in this document are planned efforts that are subject to receiving appropriate approvals such as those related to Paperwork Reduction Act or institutional review board (IRB) approvals. Some evaluations may also be subject to agency priorities related to funding and resources that can be subject to change. As shown in the Evaluations section at the end of this report, some evaluations contribute to multiple priority areas and address multiple evaluation questions. The Evaluations section also provides information about the data sets,

methodological approaches, anticipated challenges and mitigation strategies, and dissemination plans.

Evaluation Priority Area 1: Healthcare

HHS works to protect and strengthen equitable access to high quality and affordable healthcare. Increasing choice, affordability, and enrollment in high-quality healthcare coverage is a focus of the Department's efforts in addition to reducing costs, improving quality of healthcare services, and ensuring access to safe medical devices and drugs. HHS also works to expand equitable access to comprehensive, community-based, innovative, and culturally competent healthcare services while addressing social determinants of health. HHS is driving the integration of behavioral health into the healthcare system to strengthen and expand access to mental healthcare and substance use disorder treatment and recovery services for individuals and families. HHS also bolsters the health workforce to ensure the delivery of quality services and care. This evaluation priority area aligns with the HHS Strategic Plan goal: *Protect and Strengthen Equitable Access to High Quality and Affordable Healthcare*

Healthcare Evaluation Activities

Six Op/Staff Divs across HHS are conducting evaluations in this area.

Contributing Division	Activity Title
ACL	Process and Outcome Evaluation of the National Paralysis Resource Center (NPRC)
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
	Evaluation of the National Education and Awareness Social Marketing Campaign Employer Efforts to Support the Mental Health of Health Workers
CMS	Evaluation of the Community Health Access and Rural Transformation Model
	Maternal Opioid Misuse (MOM) Model Evaluation
	Integrated Care for Kids (InCK) Model Evaluation
	Evaluation of the Value-Based Insurance Design (VBID) Model
	CMS Pilot to Develop Targeted Oversight of Inappropriate Antipsychotic Prescribing Behavior in Nursing Homes
HRSA	Evaluation of the Telehealth Technology Enabled Learning Program (TTELP)

Contributing Division	Activity Title
	Provider Resiliency Evaluation
	Evaluation of the Rural Maternity and Obstetrics Management Strategies (RMOMS) Program
IHS	Implementation of Trauma Informed Care (TIC) in Federal Healthcare Settings: Policy manual & training development
SAMHSA	Internal Formative Evaluation of the Projects for Assistance in Transition from Homelessness (PATH)

Populations impacted by the evaluations for this priority area include older adults, mothers, individuals with disabilities, children, health care workforce, individuals experiencing homelessness, and those recovering from substance use disorders.
The aims of these activities are to improve services, assess intervention effectiveness, advance telehealth capabilities, support healthcare workers well-being and welfare, improve healthcare quality and access. Evaluation methods used were mixed methods, secondary data analysis, descriptive analysis, quasi-experimental design, thematic analysis, descriptive statistics and trend analyses, and non-experimental studies.

For these evaluation activities, existing HHS data were used including claims data, administrative data, clinical and non-clinical performance measure data, healthcare facilities data, performance reports, policy guidance, workplans, annual progress reports, evaluation plans, surveys, data dissemination plans, workplans, and other sources. Existing data from other sources may include vital records data, literature reviews and environmental scans, census data, Health Outcomes Surveys, Healthcare Effectiveness Data and Information Set, other available survey data, training data, web-based surveys, health system site data systems, legislation, regulations, published and grey literature, secondary data analysis of Federal and State telehealth statues, behavior and policy data, profiles data, surveillance data, and other sources. Additional data will be collected through interviews, site visits, key informant interviews, focus groups, Photovoice, service delivery observations, survey of grantees and program participants, performance metrics, among other approaches.

Evaluation Priority Area 2: Public Health

HHS is dedicated to safeguarding and improving health conditions and health outcomes for everyone. HHS improves capabilities 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 also mitigates the impacts of environmental factors, including climate change, on health outcomes. This evaluation priority area aligns with the Strategic Plan goal: *Safeguard and Improve National and Global Health Conditions and Outcomes*

Public Health Evaluation Activities

Five Op/Staff Divs across HHS are conducting evaluations in this area.

Contributing Division	Activity Title
CDC	Evaluation of the Preventive Health and Health Services (PHHS) Block Grant
CMS	Evaluation of the Community Health Access and Rural Transformation 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
FDA	Evaluation of Tobacco 21 on tobacco product behaviors
	Evaluation of CTP's tobacco product application marketing decisions
HRSA	Ryan White HIV/AIDS Program (RWHAP) Special Projects of National Significance (SPNS): Improving Care and Treatment Coordination: Focusing on Black Women with HIV
SAMHSA	Evaluation of the Garrett Lee Smith (GLS) State/Tribal Youth Suicide Prevention and Early Intervention Program

HHS plays a significant role in both the American and global public health infrastructure and advances. The COVID-19 Pandemic highlighted the importance of public health and the widespread impact of public health policies, programs, and decisions on individuals and entities, including governments, schools, and private businesses. HHS has made substantial investments to develop strong, timely, and rigorous evidence supporting ongoing and changing public health conditions.

Evaluations in this area aim to assess operations and technical support for enhancing the capacity of rural healthcare providers, healthcare systems resiliency and preparedness for responding to public health emergencies, impact of policies and programs on healthy lifestyles, increased access for underserved populations to Telehealth services, including special projects aimed at improving care and treatment coordination.

Specifically, the evaluations focus on topics such as the Community Health Access and Rural Transformation Model, the effectiveness of CMS COVID-19 flexibilities, legislation in relation to consumer products consumption and consumer behavior, Ryan White HIV/AIDS Program (RWHAP) Special Projects of National Significance, the Garrett Lee Smith (GLS) State/Tribal Youth Suicide Prevention and Early Intervention Program, and telehealth strategies for addressing health conditions and diseases.

Many public health evaluations target the entire American population. However, some activities have a narrower focus, such as on youth or individuals of color. Additionally, some activities incorporate equity by assessing policies and programs for innovativeness and inclusive strategies, cultural-competency, and community-based approaches for healthcare services, such as the Evaluation of the Community Health Access and Rural Transformation Model.

Evaluation methods include mixed methods evaluations, comparison group selection methodologies, implementation science, quasi-experimental methods, policy analysis, qualitative analysis, descriptive statistics and trend analysis, quantitative analysis, descriptive analysis, among others.

The evaluations will utilize existing HHS data, including administrative data, claims data, Field Accomplishments and Compliance Tracking System (FACTS), Observation and Corrective Action Reporting (OCAR) system, program services reports, surveys, interviews, recipient work plans, data in Block Grant management information systems, programmatic data, population assessments, Nielsen retail scanner data, and others. Data from other sources may include National Reporting Systems, surveillance data, The Web Block Grant Application System (WebBGAS), secondary data analysis using data extracted from health system site data systems, secondary data analysis of Federal and state telehealth statutes, legislation, and regulations, secondary data analysis of published and grey literature, secondary databases, and more. Finally, these evaluations collect new data through interviews, site visits, surveys, workplans, focus groups, data entry in Block Grant management information systems, and other methods as needed.

Evaluation Priority Area 3: Human Services

HHS works 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 strengthens early childhood development and expands opportunities to help children and youth thrive equitably within their families and communities. HHS expands 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 also

increases safeguards to empower families and communities to prevent and respond to neglect, abuse, and violence, while supporting those who have experienced trauma or violence. This evaluation priority area aligns with the HHS Strategic Plan goal: *Strengthen Social Well-being, Equity, and Economic Resilience.*

Human Services Evaluation Activities

Five Op/Staff Divs are conducting evaluations in this area.

Contributing Division	Activity Title
ACF	Supporting Evidence Building in Child Welfare
	Building Evidence on Employment Strategies for Low-Income Families
	Next Generation of Enhanced Employment Strategies (NextGen) Project
ACL	Process and Outcome Evaluation of the National Paralysis Resource Center (NPRC)
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
CMS	Maternal Opioid Misuse (MOM) Model Evaluation
	Integrated Care for Kids (InCK) Model Evaluation
HRSA	Healthy Start (HS) Evaluation & Capacity Building Support

The evaluations in this area aim to assess programs and models like child welfare, employment strategies for low-income families, enhanced employment strategies for individuals with complex challenges to employment, Maternal Opioid Misuse (MOM), Integrated Care for Kids, Healthy Start and grant programs like the National Paralysis Resource Center (NPRC). These human services evaluations focus on a variety of populations, including mothers, children, individuals with disabilities, previously incarcerated individuals, and low-income families. Evaluations support HHS programs and policies related to underserved communities, child welfare, services for individuals with disabilities, maternal health, and health equity.

The significant focus on health equity is salient throughout the evaluations contained in this plan and is especially significant among human services-focused activities, such as the CMS Evaluation of the Maternal Opioid Misuse Model, which seeks to improve outcomes and reduce costs for pregnant and postpartum individuals with opioid use disorder who are enrolled in Medicaid and their infants. The evaluation seeks to build the evidence base for what works best for treating pregnant individuals with opioid use disorder. The ACL's Process and Outcome Evaluation of the National Paralysis Resource Center (NPRC) aims to enhance support, services,

care, independence, and community living for individuals with paralysis and their families. Evaluations by ACF place emphasis on building evidence for supporting and enhancing interventions to improve employment for individuals and populations.

The evaluation methods include mixed-methods, pre-post analysis and forms of descriptive statistical analysis, cost and experimental analysis, case studies. These evaluations will utilize existing HHS data, data from external sources, and develop new data. Existing HHS data will include National Directory of New Hires data, demographic and eligibility data, inpatient data, pharmacy data, other transformed Medicaid Statistical Information System (T-MSIS) data files, Medicaid T-MSIS data for MOM Model awardees and potential comparison States, demographic and eligibility data, in-patient data, pharmacy data, analytical research identifiable files, progress reports, operational plans, standard operating procedures, clinical and non-clinical performance measure data, Healthy Start Monitoring & Evaluation Data System (HSMED), and grantee data. Key data held by other sources include state and local administrative data, such as for the Temporary Assistance for Needy Families Program, vital health records data, Area Health Resource File, census and community surveys, justice system data, food security data, child welfare administrative data, surveillance data, behavior and policy data, profiles data, including other sources. As needed, new data will be collected through surveys, interviews, focus groups, structured observation, in-depth interviews, Photovoice, and Service Integration Level (SIL) Checklists.

Evaluation Priority Area 4: Research and Evidence

HHS is dedicated to restoring trust and accelerating advancements in science and research. HHS is prioritizing science, evidence, and inclusion to improve the design, delivery, and outcomes of HHS programs. It 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. This evaluation priority area aligns with the HHS Strategic Plan goal: *Restore Trust and Accelerate Advancements in Science and Research for All.*

Research and Evidence Evaluation Activities

Seven Op/Staff Divs across HHS are conducting evaluations in this area.

Contributing Division	Activity Title
ACF	Supporting Evidence Building in Child Welfare

Contributing Division	Activity Title
CMS	Network of Quality Improvement and Innovation Contractors (NQIIC) Independent Evaluation
FDA	Evaluation of the reach and utility of CTP's tobacco regulatory science research program
HRSA	Ryan White HIV/AIDS Program (RWHAP) Special Projects of National Significance (SPNS): Improving Care and Treatment Coordination: Focusing on Black Women with HIV
IHS	IHS Evaluation Policy Roll-out evaluation
NIH	Centers of Excellence in Genomic Science (CEGS) Program Evaluation
	Strategic Focus on Evaluation at the National Institute of General Medical Sciences
	Effect Evaluation of Oral Health in America: Challenges and Opportunities
ONC	Evaluation of the Trusted Exchange Framework and Common Agreement (TEFCA)

HHS is dedicated to fostering sound and sustained advances in the sciences underlying medicine, public health, and social services. These advancements underpin evidence-building efforts to strengthen the impact of health and human services in a sustainable manner.

These evaluations address programs across HHS, including child welfare, patient centered outcomes research, public health emergencies, allocation and accountability of monetary and other resources, quality improvement and innovation contracts, program and business process improvements and enhancements, regulatory science research, and the effects of having an evaluation policy.

The evaluation activities in this area address topics such as the use and application of evidence for strengthening policy and practice for interventions, financial stewardship of HHS resources, developing evaluation policy, investments in research enterprise, research capacity and grant-making processes, scientific workforce development and diversity, outcomes of scientific initiatives and dissemination strategies, quality improvement, programming processes and innovation. The majority of these evaluations focus on grantees, providers, and communities, rather than individual beneficiaries.

Approaches include mixed-methods evaluations, savings metrics and methodologies, multi-site evaluations, social network analyses, review of grants funding and patents, comparison group

analysis, grantee surveys, digital visualization techniques, data retrieval and summary applications, document reviews, bibliometric analyses, quantitative and qualitative analyses, thematic analyses, descriptive analyses, citation analyses, and more.

The activities utilize existing HHS data, including program and other administrative data, claims data, provider performance measures, program services reports, evaluation policy documents, roll-out materials, working group meeting agendas/notes, research and publication databases, grants databases, research progress reports, facilitated discussion notes, participant surveys, program office records, and web metrics. They also incorporate external data such as electronic health records, healthcare networks data, data from service providers, surveillance data, review of changes in policy and practice, U.S. Patent and Trademark Office database, authors publications and presentations, health IT surveys, Handshake and Zoom platform data exports, partnership portals, and bibliometrics. Finally, these evaluations will collect new data through organizational outcomes data, stakeholders' interviews, cost study data, focus groups, review of curriculum documents and webpages, and Division reports.

Evaluation 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 works 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 also ensures the security of HHS facilities, technology, data, and information, while advancing environment-friendly practices. This evaluation priority area aligns with the HHS Strategic Plan goal: *Advance Strategic Management to Build Trust, Transparency, and Accountability.*

Management Evaluation Activities

Four Op/Staff Divs across HHS are conducting evaluations in this area.

Contributing Division	Activity Title
CDC	Evaluation of the Public Health Associate Program (PHAP): Class Diversity, Attrition, Engagement and Satisfaction, and Retention in the Public Health Workforce After Program Completion
CMS	Network of Quality Improvement and Innovation Contractors (NQIIC) Independent Evaluation

FDA	The Center for Veterinary Medicine (CVM) Environmental Scan (ES)
NIH	Strategic Focus on Evaluation at the National Institute of General Medical Sciences

HHS prioritizes effective management of its resources, programs, and policies through coordinated efforts across HHS as well as through division-level initiatives. As with other priority areas, addressing major management priorities and challenges requires division-level and cross-department activities. These evaluations seek to understand the extent to which data are used for policy and program development, identify problematic practices and structures, develop research agendas, build and strengthen programmatic and operational evaluation capacity, assess effectiveness of funding models, measure program progress, inform future policy making, support health sector workforce professional development, and more. They especially target programs, policies, and practices influencing the Department's ability to achieve its mission.

These evaluations utilize mixed-methods evaluation approaches, combining qualitative and quantitative methods and analyses, iterative data collections, environmental scans, and surveys. The evaluations utilize existing HHS data such as environmental scan data, participant survey data, service claims data, provider performance data, administrative data, grant databases, and research progress reports. External data such as electronic health records are also used. Finally, these activities include collection of new data as needed through methods such as surveys, focus groups, stakeholder feedback, benchmark research, and interviews.

Evaluations

More information concerning the significant evaluations provided to the HHS Evidence and Evaluation Policy Council by operating divisions and staff divisions can be found below.

Administration for Children and Families

Activity: 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.

Activity: 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 low-income families 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 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 data

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. ACF will use 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.

Activity: 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

Activity: 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

Activity: Evaluation of the Preventive Health and Health Services (PHHS) Block Grant

Priority Area: Public Health

Priority Question: How can HHS sustain strong financial stewardship of HHS resources to foster prudent use of resources, accountability, and public trust?

Description: The formative evaluation consists of several activities based on the CDC Framework for Program Evaluation, including implementing a measurement framework to assess recipient achievements, analyzing recipient allocation of funding to Healthy People 2030 objectives to assess priority public health needs, and exploring the relationship between PHHS Block Grant funding and agency performance and health outcomes. The PHHS Block Grant Measures Assessment will be fielded in Fall 2022 and the findings will be shared in 2023.

Time Period for the Activity (estimated start and end dates): 2020- November 2023

Existing Data Sources Held by the Division: PHHS Block Grant Measures Assessment (survey), interviews, recipient work plans, and data in Block Grant management information system.

Existing Data from Other Sources: Data from Evaluation of the Preventive Health and Health Services Block Grant.

New Data Collection: 2022 PHHS Block Grant Measures Assessment, 2022 interviews, 2021-2023 work plans, data entry in Block Grant management information system.

Study Design or Approach: Descriptive, quantitative, and qualitative methods are employed to analyze the primary evaluation questions across the various data collection methodologies.

Anticipated Challenges and Mitigation Strategies: The PHHS Block Grant provides flexible funds to recipients allowing them to set their own priorities for the Healthy People 2030 objectives they will meet. The measurement framework is designed to apply to recipient activities regardless of how funds are invested, or which Healthy People 2030 objectives are selected.

Dissemination plan: Results disseminated via evaluation report, link to webpage, internal key messages document, PowerPoint presentation, internal and external meetings, conferences, publications, and manuscripts. Tailored messages and products will serve to demonstrate the value of the PHHS Block Grant to Congress, US Government Agencies, the public, States, Tribes, Local and Territorial Health Departments. More information on the evaluation efforts can be found online at: https://www.cdc.gov/phhsblockgrant/evaluation.htm.

Activity: 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.

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.

Activity: Evaluation of the Public Health Associate Program (PHAP): Class Diversity, Attrition, Engagement and Satisfaction, and Retention in the Public Health Workforce After Program Completion

Priority area: Management

Priority questions: 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?

Description: The Public Health Associate Program (PHAP) is a service-learning program that aims to provide the public health workforce with a diverse pipeline of early-career professionals. PHAP places these associates in public health organizations across the country in work that includes addressing health disparities and promoting health equity in those jurisdictions. The purposes of the PHAP evaluation are to assess the effectiveness and influence of the program and inform continuous program improvement efforts.

Time period of the activity: Each PHAP class/cohort is assessed throughout the duration of their service-learning assignment (2 years). This longitudinal study was initiated in 2014. Evaluation activities are currently on-going, and at various stages for three active class cohorts.

Existing Data Sources Held by the Division: Longitudinal data collected from PHAP cohorts dating back to CY 2014. For nine previous cohorts (PHAP 2012-2020), Welcome Survey (beginning of program) and Graduate Survey (end of program) data are available. For five previous cohorts (PHAP 2012-2016), Alumni Survey (post-program) data are available. For one currently active cohort (PHAP 2021), only Welcome Survey data are available. Additionally, resignation data are available for most cohorts CY 2015-2022 (PHAP 2013-2021).

Existing Data from Other Sources: Enterprise Fellowship Management System (eFMS) is the source for participant resignations.

New data collection: The PHAP Welcome, Resignation, Graduation, and Alumni surveys are administered annually, so new data are added to existing data on an ongoing basis.

Study design or approach: Data are gathered using a phased approach, with each PHAP cohort participating in multiple data collections both during their time in PHAP and as alumni. Data collections are implemented in an iterative manner to ensure that data are collected at appropriate points in the cycle of each cohort (e.g., associates completing their final year in PHAP participate in a graduation survey). The evaluation team strategically juggles multiple data collection activities from various populations at any given time.

Anticipated challenges and mitigation strategies: Timely notification of participant resignations is critical to monitoring and assessing participant attrition. This has been a challenge in the past. The evaluator team is closely monitoring notification processes and working with program

leadership to address system issues. Additionally, because of the longitudinal design of the evaluation plan, we naturally see a decline in participation rates over time. To address this challenge, the evaluation team continuously works to keep PHAP alumni engaged in the evaluation activities by reaching out to them regularly to remind them of survey collections and by sharing all survey findings with participants.

Dissemination plan for results: After each survey's data are analyzed, a report is made highlighting important findings, and are shared with PHAP leadership and participants of the survey featured in the report. Findings are also presented to PHAP staff and associates at trainings and other meetings. Evaluation findings are additionally featured in manuscripts to help fill an existing gap in the literature on service-learning and fellowship evaluation.

Activity: Evaluation of the National Education and Awareness Social Marketing Campaign Employer Efforts to Support the Mental Health of Health Workers

Priority area: Healthcare

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

Description: For many years now, health workers have reported feeling undervalued, overworked, and overwhelmed. NIOSH (National Institute for Occupational Safety & Health) and its contractor will develop, implement, and evaluate a social marketing campaign that aims to raise health worker and healthcare executive awareness of mental health risks, promote help seeking and treatment among health workers experiencing burnout and job-related distress, reduce stigma associated with health workers' mental health help seeking, and establish organizational policies and practices that support worker mental health. This project will collect quantitative and qualitative data to document campaign outcomes (e.g., mental health help seeking, modifications to working conditions, and health worker well-being) associated with implementation of the campaign. This knowledge will be used to inform future campaign efforts that aim to reach health workers and their employers, and share findings to advance the health communications, mental health, and occupational health and safety fields.

Time period of the activity: June 2022-May 2024

Existing Data Sources Held by the Division: None

Existing Data from Other Sources: None

New data collection: Surveys and interviews with healthcare employers, workers, and partners.

Study design or approach: Campaign effectiveness will be assessed by implementing a non-experimental study that includes baseline and 12-month follow-up surveys with a representative sample of health workers and healthcare executives from partner health care organizations. A smaller, mixed-methods, quasi-experimental study will be conducted with one

healthcare organization. Baseline and 12-month surveys will be conducted with a representative sample of health workers and healthcare executives affiliated with 6 clinical sites receiving an enhanced healthcare employer campaign component and with 6 matched clinical sites receiving general campaign messaging. To better understand the survey data collected, 2 rounds of interviews with 9 health workers in each round, and interviews with two senior leaders will be conducted at each of the 6 clinical sites receiving the enhanced employer intervention.

Anticipated challenges and mitigation strategies: Administrative or logistical items such as timely approval to administer surveys and interviews, as well as security IT security approval for software used to collect and store data will be challenging. However, we are working closely with our Federal partners on these issues. Furthermore, given the continued burden placed upon our healthcare system, participation may be an issue. However, we have and will continue to engage partners in labor and industry to encourage participation.

Dissemination plan for results: Not only will process results be used to make adjustments as needed to the campaign in real time, once the evaluation is concluded we will share findings through peer reviewed publications and relevant presentations to inform future campaign efforts. We also plan to develop one-page impact sheets for policymakers to concisely summarize key findings.

Centers for Medicare & Medicaid Services

Activity: 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 - January 2027

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

Existing Data from Other Sources: State Vital records data provided (birth and death certificates) linked to T-MSIS data.

New Data Collection: Health and social needs data collected through individual screening and/or patient health records. Primary data collection in the form of key informant interviews, focus groups/in-depth interviews with MOM Model participants, Photovoice with MOM Model participants, and structured observations of care delivery sites.

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:

- Data sharing across providers and across service sectors is challenging.
- Engaging beneficiaries and maintaining engagement can be challenging.
- Maintaining clinical and lay provider staff can be challenging.
- 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

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.

Activity: 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, data from care delivery partners collected through program deliverables, implementation, monitoring and evaluation.

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 first annual report can be found online at : https://innovation.cms.gov/data-and-reports/2022/inck-model-pre-imp-first-eval-rpt.

Activity: 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 achieved outcomes are attributable to the QIOs *with the greatest estimated return on investment (ROI)*
- Which aspects of QIO interventions are effective*)*;
- 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, Physician Compare); Medicare Current Beneficiary Survey (MCBS); Provider Survey Inspection Data.

Existing Data from Other Sources: National Healthcare Safety Network (NHSN)—Centers for Disease Control and Prevention data source; Quality and Safety Review System (QSRS) inpatient safety data: a multi-stage sample of medical charts from Medicare beneficiaries from a small sample of hospitals. (See: AHRQ National Scorecard on Hospital-Acquired Conditions).

New Data Collection: QIN-QIO real-time collected data regarding the activities implemented and performance metrics monitored (Qualtrics); OMB cleared survey of providers' satisfaction with NQIIC services (not yet executed).

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: Not yet determined.

Activity: 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?

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. Participating 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. The primary aim of the evaluation is to rigorously assess the impact of the VBID model on enrollee health outcomes, behavior, service use, and quality of care, and on costs to health plans, enrollees and Medicare.

Time Period for the Activity (estimated start and end dates): 2020 - 2028

Existing Data Sources Held by the Division: Medicare Advantage plan enrollment/disenrollment files, Fee-for-Service claims, Medicare Advantage Organizations, Part D Event, MA encounter, Bid Pricing Tool, HEDIS, HOS.

Existing Data from Other Sources: CAHPS, Health Outcomes Survey, Healthcare Effectiveness Data and Information Set.

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 will use these data to calculate the number of VBID-eligible beneficiaries enrolled by participating MAOs, 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 (up to an 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
- 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

Activity: 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 will begin as soon as possible and must be completed within 9 months of the end of the PHE. Exact timeline TBD

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

Activity: 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?

Description: The pilot uses 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): ongoing

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 examines 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 can prompt further action by CMS and other federal partners, including the HHS Office of the Inspector General and the Department

of Justice, and this pilot will test new referral pathways from the Beneficiary and Family Centered Care-Quality Improvement Organizations reviews. Even if enforcement action is not warranted, the findings may present high-potential opportunities for education and quality improvement activities.

Food and Drug Administration

Activity: The Center for Veterinary Medicine (CVM) Environmental Scan (ES)

Priority area: Management

Priority questions: 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 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 strategies can HHS implement to ensure the security of HHS facilities, technology, data and information, while advancing environment-friendly practices?

Description: In order to effectively set a future course of action, CVM must strategically assess its existing internal and external environment by analyzing the influences that can both facilitate and inhibit organizational performance. As a best practice, CVM is committed to conducting an environmental scan every two to three years to maintain momentum and support continuous improvement. The proposed research activities embody analytical processes and the use of analytical tools to assess the influence of existing internal and external environment factors that affect organizational performance. By continuing to survey internally and our external partners, as well as to stay aware of the trends, and act upon those data, CVM will sustain, inform, and vastly improve its short-term and long-term strategic planning.

Time period of the activity: October 2023 – September 2024

Existing Data Sources Held by the Division: Previous CVM Environmental Scan data from scans conducted in 2009, 2012, 2015, 2018, and 2021.

Existing Data from Other Sources: Other FDA Centers with existing Environmental Scan data available on the Intranet.

New data collection: Survey Monkey responses from internal participants, data gathered from focus group discussions, research gathered during benchmarking process, and feedback from external stakeholders

Study design or approach: Phase I: Environmental Scan Preparation - Key activities in this phase include assessing past survey questions to ensure relevance to the process, building survey tool, and researching and benchmarking against other organizations**. Phase II:** Conduct Environmental Scan – Key activities include, conducting surveys and focus groups and reaching out to stakeholders external to the FDA for their participation. **Phase III:** Analyze Results and Develop Action Plan – Key activities include analyzing survey results and identifying themes, analyzing and summarizing focus group discussion results, assessing external responses, compiling an Environmental Scan report, presenting final Environmental Scan report to the Center Executive Board (CEB), and posting executive summary on the Intranet.

Anticipated challenges and mitigation strategies: Challenge: Attaining full engagement and participation of the designated survey pool. **Action:** We plan on addressing this challenge by sending out reminders to complete survey and join focus group sessions, providing participants with flexible time slots to join focus groups, and keeping questionnaire short and concise.

Dissemination plan for results: Results will be compiled into an Environmental Scan report, including Executive Summary, comprised of survey, focus group, and external feedback. Once recommendations are shared, CEB will decide on commitments and actions.

Activity: Evaluation of the reach and utility of CTP's 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: Bibliometrics

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.

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. Examples of prior publications based on the ongoing evaluation: 1) Price S, Chansky MC, Meissner HI, Engstrom MC, Dunderdale T, Mayne RG, et al. Methods Development and Modeling Research: Contributions to Advancing TRS and Informing Regulations. Tobacco Regulatory Science. 2020;6(6):436-9.; Frechtling JA, Dunderdale T, Price S, Meissner HI, Mayne RG, McCrae T, et al. Establishing a Research Base to Inform Tobacco Regulation: Overview. Tobacco Regulatory Science. 2021;7(2):144-54.

Activity: Evaluation of Tobacco 21 on tobacco product behaviors

Priority area: Public Health

Priority questions: How do HHS policies and programs enhance promotion of healthy lifestyle behaviors to reduce occurrence and disparities in preventable injury, illness, and death?

Description: Assessment of the of Federal Tobacco 21 legislation on tobacco product behaviors among youth and adults. On December 20, 2019, the President signed legislation amending the Federal Food, Drug, and Cosmetic Act, raising the federal minimum age of sale of tobacco products from 18 to 21 years. Effective immediately, the legislation made it illegal for a retailer to sell tobacco products (including cigarettes, smokeless tobacco, hookah tobacco, cigars, pipe tobacco, electronic nicotine delivery systems including e-cigarettes and e-liquids) to anyone under the age of 21. This evaluation consists of two quantitative analytic studies assessing the influence of Tobacco 21 on tobacco product behaviors using existing data from the Population Assessment of Tobacco and Health (PATH) Study. The first study, entitled "Changes in tobacco product use and access to tobacco products among youth and young adults, PATH Study 2018-2020" will examine changes in prevalence of tobacco product use and access to tobacco products among youth and young adults using cross-sectional data from the PATH Study Waves 5 (December 1, 2018 - November 30, 2019) and 5.5 (July 3, 2020- December 31, 2020).

The second study, entitled "Impact of Tobacco 21 on tobacco product initiation rates: Longitudinal findings from the PATH Study 2013-2021" will examine changes in tobacco product

initiation rates using longitudinal data from the PATH Study Waves 1 - 6. Tobacco product initiation rates and changes in mediator measures will be evaluated between Wave 4 – Wave 5 and Wave 5 - Wave 6. Data from these waves will be evaluated as wave pairs, with each wave pair yielding a set of longitudinal tobacco product initiation rates. Wave 4 – Wave 5, which have pairs that span time prior to December 2019 (i.e., prior to federal T21, COVID, ENDS enforcement priorities) will serve as comparison rates for Wave 5 – Wave 6 wave pairs that span time after December 2019 (which captures the time during which federal T21 was in effect and these other key events were occurring).

Time period of the activity: FY 2022 – FY 2024

Existing Data Sources Held by the Division: Data from the Population Assessment of Tobacco and Health (PATH) Study

Existing Data from Other Sources: None

New data collection: None

Study design or approach: Quantitative analyses assessing tobacco product use, initiation, and related behaviors (e.g., tobacco product access) cross-sectionally and longitudinally. The first study entitled "Changes in tobacco product use and access to tobacco products among youth and young adults, PATH Study 2018-2020" will examine changes in prevalence of tobacco product use and access to tobacco products among youth and young adults from 2018-2020 using cross-sectional data from the PATH Study. Study aims are:

1. Examine changes in prevalence of past 30-day tobacco product use overall and by tobacco product category for the tobacco products most commonly used by youth (13-17 years), young adults (18-20 years), and older young adults (21-24 years) before and after the federal minimum age of sale was raised from 18 to 21.
2. Describe changes in prevalence of how and where youth (13-17 years) and young adult (18-20 years) tobacco users access tobacco products before and after the federal minimum age of sale was raised from 18 to 21
3. Examine changes in prevalence of past-30-day tobacco product use and product access before and after the federal minimum age of sale was raised from 18 to 21 among youth (13-17 years), young adults (18-20 years), and older young adults (21-24 years), stratified by state-level T21 policy status

The second study entitled "Impact of Tobacco 21 on tobacco product initiation rates: Longitudinal findings from the PATH Study 2013-2021" will examine changes in tobacco product initiation rates using longitudinal data from the PATH Study Waves 1-6. Study aims are:

1. Determine tobacco product initiation rates and changes in potential mediator measures (measures of access and appeal) before and after the federal minimum age of sale was increased, stratified by age group.

2. Determine whether or not tobacco product initiation rates and changes in potential mediator measures differ before and after the federal minimum age of sale was increased, overall, and stratified by age group.

Anticipated challenges and mitigation strategies: Challenges may include potential small sample sizes for certain variables, potential confounding events that occurred during the periods covered (e.g., outbreaks of EVALI and COVID-19), and survey mode differences between study waves which occurred as a result of COVID-19. We plan to modify analytic approach to address these challenges as appropriate and feasible. If there are no scientifically sound ways to modify the analytic approach to address these concerns, it may not be possible to publish or report results.

Dissemination plan for results: Findings will be published in scientific journal. Plan to disseminate key results in presentations to stakeholders.

Activity: Evaluation of CTP's tobacco product application marketing decisions

Priority area: Public Health

Priority questions: How do HHS policies and programs enhance promotion of healthy lifestyle behaviors to reduce occurrence and disparities in preventable injury, illness, and death?

Description: Assessment of the effect of CTP's tobacco product application marketing decisions on availability of tobacco products; sales of tobacco products; and tobacco product use behaviors among youth and adults. On July 11, 2019, the United States District Court for the District of Maryland ordered the FDA to require manufacturers of e-cigarettes, cigars and other deemed new tobacco products that were on the market as of August 8, 2016, to submit applications for premarket review, also known as premarket tobacco product applications (PMTAs), by May 12, 2020. Due to the COVID-19 pandemic, FDA requested the deadline be extended to September 9, 2020, and the court granted the request. In accordance with the court order, applications submitted by the deadline could generally "remain on the market without being subject to FDA enforcement actions for a period not to exceed one year from the date of application while FDA considers the application" or until September 9, 2021, at the latest, unless a negative action is issued by the FDA on an application during that time. FDA is currently reviewing PMTAs on an ongoing basis, which results in marketing granted orders (MGOs) or negative actions, such as refusal to accept (RTA), refusal to file (RTF), or marketing denial orders (MDOs). This evaluation will consist of two quantitative analytic studies to assess potential effects of CTP's tobacco product application marketing decisions from 2020 - 2022: a study examining changes in availability and sales of tobacco products in the marketplace using Nielsen retail scanner data; and a study examining changes in youth and adult tobacco product use behaviors using population survey data from the National Youth Tobacco Survey (NYTS), and the Population Assessment of Tobacco and Health (PATH) Study.

Time period of the activity: FY 2022 – FY 2024

Existing Data Sources Held by the Division: Nielsen retail scanner data; Tobacco use data from existing data sources, e.g., Population Assessment of Tobacco and Health (PATH) Study; National Youth Tobacco Survey (NYTS)

Existing Data from Other Sources: None

New data collection: None

Study design or approach: Quantitative analyses assessing tobacco product availability, tobacco product sales, and tobacco use behaviors. The first study will use Nielsen retail scanner sales data (in weekly increments) to assess changes in availability and sales of electronic nicotine delivery system (ENDS) and other tobacco products over time from January 2019 (for 1 year of baseline data) to December 2022. Study aims include:

1. To assess changes in U.S. tobacco product availability
2. To assess changes in U.S. tobacco product sales

Nielsen retail scanner data are cross-sectional scanner data collected through retailers on sales of nicotine and tobacco products. Nielsen's data collection methods include collection of electronic point-of-sale data from stores through product barcode checkout scanners at registers, coding of retail circulars (e.g., in-store flyers, ads promoting products), and in-store data collection (i.e., field auditors who capture in-store display information promoting products). Nielsen uses proprietary statistical methods to create estimated weekly dollar and unit sales of nicotine and tobacco products by Universal Product Code (UPC). The second study will use existing population survey data from the NYTS and the PATH Study to assess potential changes in youth and adult tobacco product use behaviors from 2019 - 2022. Study aims include:

1. To examine changes in prevalence of any tobacco use; and use prevalence by tobacco product category (i.e., e-cigarettes, cigarettes, cigars, smokeless tobacco) among youth and adults across the U.S. from 2019-2022.
2. To examine changes in tobacco cessation attempts and successful cessation by tobacco product category among youth and adults across the U.S. from 2019-2022.
4. To examine tobacco use behavior transitions among youth and adults from 2019-2022
5. To examine changes in youth and adult tobacco access behaviors (i.e., usual tobacco source) from 2019-2022.

NYTS is a cross-sectional school-based survey that collects information on tobacco use from students in grades 6-12, and data are collected and released annually to the public. Using NYTS data collected from 2019, 2020, 2021, and 2022, we will examine use of tobacco products among youth. PATH is a longitudinal household survey that collects information on tobacco use

and how it affects the health of the U.S. population ages 12 and older. We will use youth and adult data from PATH Study wave 5 (December 1, 2018- November 30, 2019), wave 6 (March – November 2021), and wave 7 (January-November 2022) to examine variables of interest listed above for adults and youth.

Anticipated challenges and mitigation strategies: 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 to use as well. Regarding the tobacco use behavior analyses, challenges may include potential small sample sizes for certain variables, especially for sub-population analyses (e.g., race/ethnicity, socioeconomic status, mental health comorbidities, or sexual or gender minorities). We plan to modify analytic approach as appropriate. Regarding the NYTS data analyses, differences in survey methods across data collection cycles (e.g., differences in mode of NYTS survey administration) may limit comparability of some measures over times. For both studies: It is important to note that other events such as manufacturer actions, public health events, and tobacco policies at federal, state, local levels may have contributed to any observed changes in the tobacco marketplace and tobacco use behaviors during the proposed studies' time periods. These events will be considered (when applicable) and discussed when analyzing data and interpreting study findings.

Dissemination plan for results: Findings will be published in scientific journals. Plan to disseminate key results in presentations to stakeholders.

Health Resources and Services Administration

Activity: 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.

Activity: 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.

Activity: 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/

Activity: 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.

Activity: Ryan White HIV/AIDS Program (RWHAP) Special Projects of National Significance (SPNS): Improving Care and Treatment Coordination: Focusing on Black Women with HIV

Priority Area: Public Health; Research and Evidence

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

Description: The awarded Evaluation and Technical Assistance Provider (ETAP) will lead a multi-site evaluation and provide technical assistance (TA) to a cohort of 12 demonstration sites (also supported by the project) to evaluate the design and implementation of demonstration sites' bundled interventions (a group of evidence-informed practices) and their outcomes and

effectiveness on the HIV care continuum for Black women with HIV for future replication and scale-up.

Time Period for the Activity (estimated start and end dates): Sept 1, 2020 - August 31, 2024

Existing Data Sources Held by the Division: Ryan White HIV/AIDS Program Services Report (RSR)

Existing Data from Other Sources: HIV Surveillance Data

New Data Collection: Data will come from Funded demonstration sites; Organizational outcomes data; key informant and stakeholder information; cost study data.

Study Design or Approach: The ETAP will design and implement a rigorous multisite evaluation plan to assess the effectiveness of the demonstration sites' bundled interventions. The evaluation plan proposed by the ETAP includes process and outcome measures and assesses the cost of adapting and implementing the bundled interventions.

Anticipated Challenges and Mitigation Strategies: To date the project has encountered some of the following challenges: 1) hiring staff at some of the sites; 2) the realities of the current conditions – recruitment in the middle of a pandemic; and 3) ambitious recruitment and samples sizes of the sites. However, the ETAP and HRSA POs are working with the sites to ensure they come up with innovative approaches to connect with clients, and to ensure an overall successful project.

Dissemination plan: The results will be disseminated via toolkits, lessons learned, materials, and products, such as blogs, a website, implementation manuals and intervention protocols. Some of these resources can be found online at : https://targethiv.org/BlackWomen. Additionally, the ETAP will convene a publication and disseminations committee, consisting of HRSA staff, the ETAP, and demonstration site representatives, to generate topics for presentations and publications; concept sheets and analyses; and an overall dissemination plan for the initiative's products.

Indian Health Service

Activity: 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): September 2023 – January 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.

Activity: 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): May 2023 – April 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

Activity: Centers of Excellence in Genomic Science (CEGS) Program Evaluation

Priority Area: Research and Evidence

Priority Question: 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: CEGS is an extramural grant program that supports the formation of multi-investigator, interdisciplinary research teams to develop novel and innovative genomic research projects, using the data sets and technologies developed by the Human Genome Project. The National Human Genome Research Institute (NHGRI) awarded the first CEGS grant in FY 2001, and the program has offered funding through both the P50 and RM1 funding mechanisms. As the program has recently passed the 20-year mark, NHGRI seeks to evaluate the outcomes of the CEGS program to date, using both quantitative and qualitative measures.

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

Existing Data Sources Held by the Division:

- PubMed/Medline
- ExPORTER/RePORTER
- IMPAC II database of extramural research applications and awards
- Query/View/Report (QVR) system
- iCite

Existing Data from Other Sources:

- SPIRES (Scientific Publication Information Retrieval and Evaluation System)
- U.S. Patent and Trademark Office database
- Web of Science
- CrossRef

New Data Collection:

- Qualitative interviews with principal investigators supported by CEGS grants
- **Study Design or Approach:** An independent contractor will review quantitative outcomes, including publication counts and trends, citations, citation lags, relative citation ratio, subsequent NIH grant funding, and patents. These quantitative findings will be used to complement other evaluation methods that NHGRI is conducting on its own, including interviews with CEGS grantees. Additional methods that NHGRI might include are a comparison group analysis and surveys of CEGS grantees.

Anticipated Challenges and Mitigation Strategies: One difficulty is identifying a comparison group of grants for the CEGS, as they use a special RM1 funding mechanism. NHGRI will look to an analysis previously conducted by another NIH institute, which addressed the same concern. Another difficulty is in selecting the appropriate outcomes when assessing “success” of the CEGS grants in meeting the program’s objectives. There are existing examples of NIH grant

program evaluations for reference, and NHGRI can also work with stakeholders such as its extramural research program officers and scientists on CEGS grants.

Dissemination plan: NHGRI foresees the possibility of a white paper/report from these analyses and hopes for a scientific publication as well. A recent report from the COVID-19 Genomics UK Consortium may also serve as a model for reporting on specific outcomes and their relevance to and importance for the public.

Activity: Strategic Focus on Evaluation at the National Institute of General Medical Sciences

Priority Area: Research and Evidence; Management

Priority Question: 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? Where does HHS need to further invest in the scientific workforce to maintain 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? 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: Regularly performing analyses that support the effective administration of programs ensures the efficient stewardship of taxpayer resources. Application of this principle is a central tenet of operations at the National Institute of General Medical Sciences (NIGMS), as the Institute continues to support multiple types of programmatic analyses (e.g., portfolio, descriptive, predictive) and evaluations (e.g., outcomes, process, needs-based) that inform program and business process improvements and enhancements. NIGMS' commitment to careful stewardship of public funds is reflected in its 2021-2025 Strategic Plan, which includes measurable targets for assessing progress towards NIGMS strategic goals and conducting regular evaluations.

Time Period for the Activity (estimated start and end dates): NIGMS plans to evaluate 2-3 programs in FY 2024

Existing Data Sources Held by the Division:

- NIH grants databases
- Data from research progress reports

Existing Data from Other Sources: None

New Data Collection: None

Study Design or Approach: NIGMS has several targets within its strategic plan that focus on evaluation, including:

- Ensure that at least 30% of NIGMS programs have been evaluated in the past five years.
- Ensure that all training and workforce development programs older than 10 years have been evaluated at least once in the past decade (currently includes an ongoing evaluation of the Bridges to the Baccalaureate training program).
- Ensure that all research capacity building programs older than 10 years have been evaluated at least once in the past decade (currently includes an ongoing evaluation of the IDeA Networks of Biomedical Research Excellence (INBRE) program).

Anticipated Challenges and Mitigation Strategies: NIGMS will need appropriate resources and staff time in order to maintain a pace of 2-3 evaluations per fiscal year.

Dissemination plan: NIGMS has in its strategic plan a goal to post all outcomes assessments and program evaluations on the NIGMS website, along with descriptions of any changes made to the programs based on the findings.

Activity: 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
    - NIDCR (National Institute of Dental and Craniofacial Research) 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 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 Office of Portfolio Analysis. 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

Activity: 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 establishes the infrastructure model and governing approach for users in different networks to securely share information with each other 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. American Hospital Association, Health Information Exchange Survey)

New Data Collection: Direct data from Recognized Coordinated Entity (RCE) that manages the Common Agreement.

Study Design or Approach: The study consists primarily of quantitative results assessing milestone achievements, TEFCA participation, and quantifiable results of TEFCA participation on health IT interoperability.

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 data briefs, reports and peer-reviewed publications. 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

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

Priority Area: Public Health

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 at reducing suicide attempts and mortality due to suicide and to provide training and technical assistance to grantees related to evaluation, data collection and surveillance. By assessing the effect of the GLS State/Tribal Youth program, the evaluation will allow SAMHSA to 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.

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

Existing Data Sources Held by the Division: GPRA/National Outcome Measures and National Survey on Drug Use and Health (NSDUH)

Existing Data from Other Sources: TBD

New Data Collection: TBD

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. 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: TBD

Dissemination plan: Results of this evaluation will be shared internally to increase the quality of the program and externally through SAMHSA's website

Activity: 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.