

FY 2023-2026 Evidence-Building Plan

Department of Health & Human Services

Background and Introduction

The Foundations for Evidence-Based Policymaking Act of 2018 (Evidence Act) intends 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 11 operating divisions, 11 staff divisions, and 10 regional offices whose programs and policies impact the lives of nearly every American. Understanding the evaluation, research, and analysis efforts and coordinating plans across the Department is a significant undertaking and is conducted by the Office of the Assistant Secretary for Planning and Evaluation (ASPE). In particular, 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 through evaluation and analysis in order 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 understand how the effect of programs and policies and how they can be improved.

Across HHS, evidence-building comes in many forms, including:

- Program evaluations using the most rigorous designs appropriate;
- Capacity-building initiatives to improve administrative data collection, accessibility, and use for management;
- Exploratory and preliminary quantitative and qualitative analysis to build evidence;
- Pilots and demonstrations; and
- Statistical analysis of factors related to health and human services programs and policies.

ASPE coordinates the evaluation community by regularly convening the HHS Evidence and Evaluation Policy Council (the Council), which 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 agency within HHS. The Council meets monthly to address issues related to evidence-building and evaluation policies or activities across HHS, with a recent focus on Evidence Act implementation activities, especially within Title I. ASPE tasked the Council with developing guidance for Operating and Staff Divisions regarding contributions to the HHS Evidence-Building and Evaluation Plans. Based on the contributions of Operating and Staff Divisions, ASPE developed this Evidence-Building Plan.

What is this document?

As part of the Evidence Act, HHS is required to submit “a systematic plan for identifying and addressing policy questions relevant to the programs, policies, and regulations of the agency,” or the Department of Health and Human Services (HHS) Evidence-Building Plan (the plan), also referred to as the Learning Agenda. All activities described in this document are subject to availability of appropriations.

The Evidence-Building Plan must include the following elements:

- Strategic goals and objectives that the plan will address (referred to as “priority areas” in this document)
- Priority questions to be answered
- Activities that the agency will engage in to address priority questions
- Timing of activities
- Potential data, tools, methods and analytic approaches to be used to answer priority questions
- Anticipated agency-specific challenges and proposed solutions to developing evidence to support agency priorities

This document provides a summary of these components and additional details are included in the Appendix.

Plan Development

A subcommittee of the Council provided input on the Evidence-Building Plan development process and helped create a template and instructions which were used to collect information on significant evidence-building activities across the Department. Because HHS is such a large, decentralized agency, with a vast number of evidence-building activities, Operating Divisions submitted a sample of up to 5 significant evidence-building activities, which have been compiled in this plan. This plan includes 30 examples of significant evidence-building activities from divisions including the Administration for Children and Families (ACF), the Administration for Community Living (ACL), the Agency for Health Research and Quality (AHRQ), the Office of the Assistant Secretary for Planning and Evaluation (ASPE), the Office of the Assistant Secretary for Preparedness and Response (ASPR), the Centers for Disease Control and Prevention (CDC), the Centers for Medicare and Medicaid Services (CMS), the Food and Drug Administration (FDA), the Health Resources and Services Administration (HRSA), the National Institutes of Health (NIH), and the Substance Abuse and Mental Health Services Administration (SAMHSA).

This document details significant evidence-building activities related to each priority area that are ongoing or will occur during FY 2023-FY 2026. Some evidence-building activities fall into multiple priority areas and address multiple priority questions. The activities included are planned efforts that are subject to receiving appropriate approvals and resources, and they are subject to change.

HHS organized the plan by priorities aligned with the HHS Strategic Plan Goals. These areas are:

- Strategic Goal 1: Protect and Strengthen Equitable Access to High Quality and Affordable Healthcare
- Strategic Goal 2: Safeguard and Improve National and Global Health Conditions and Outcomes
- Strategic Goal 3: Strengthen Social Well-being, Equity, and Economic Resilience
- Strategic Goal 4: Restore Trust and Accelerate Advancements in Science and Research for All
- Strategic Goal 5: Advance Strategic Management to Build Trust, Transparency, and Accountability

The five (5) priority areas, each with associated priority questions, align with the HHS Strategic Plan FY 2022-2026 Goal and Objective Framework and are recognized administration priorities. Each set of

priority questions includes a sample of planned or ongoing evidence-building activities HHS will perform during FY 2023-2026. Given the plan encompasses a four-year period, these questions are high-level in nature, and many may take several years and various approaches, methods, and data sources to examine. Those priority questions without listed activities do not necessarily indicate that no activities are planned; the number of activities described is constrained by the limit on the number of evidence-building activities requested from Operating and Staff Divisions. In addition, new activities may be planned and included in future HHS Annual Evaluation Plans or in subsequent updates to the HHS Evidence-Building Plan.

The HHS Evidence-Building Plan, Annual Evaluation Plan, and Strategic Plan have been developed and will be published on the same timeline. This poses several challenges regarding alignment, especially because the planning teams for the three plans were simultaneously and respectively convening stakeholders, coordinating across operating and staff divisions, executing data calls, and drafting plan content. In particular, developing evidence-building activities takes time, and as such, many of the activities included in this plan began development before the current HHS Strategic Plan Goal and Objective Framework was in place. Thus, some priority questions do not have evidence-building activities included in this plan. That may be a result of the timing of the identification of activities for inclusion in the Evidence Building Plan. HHS will continue to assess evidence-building activities to address the questions in the HHS Strategic Plan Goal and Objective Framework, and will plan activities to fill knowledge gaps. The annual plan updates will include these new activities.

[HHS Priority Areas for Developing and Using Evidence for Decision-Making, 2023–2026](#)

This section details a sample of evidence-building activities related to each priority area that are ongoing or will occur in FY 2023-2026. The activities included in this document are planned efforts that are subject to receiving appropriate approvals and resources, and they are subject to change. Some evaluations fall into multiple priority areas and address multiple priority questions.

Each priority area includes the priority questions and a discussion of how HHS plans to address them during the four-year period. The separate list of evidence-building activities in the appendix includes the sample of activities provided by divisions, including full details for each activity (timing, potential data, tools, methods, analytic approaches, anticipated challenges and proposed solutions).

Strategic Goal 1: Protect and Strengthen Equitable Access to High Quality and Affordable 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. The Department is driving the integration of behavioral health into the healthcare system to strengthen and expand access to mental health and substance use disorder treatment and recovery services for individuals and families. HHS also bolsters the health workforce to ensure delivery of quality services and care.

The activities in this priority area include increasing affordability and enrollment in high quality healthcare coverage; equitable access to quality health-care services; integrating behavioral healthcare into the healthcare system; expanding access to mental health and substance use disorder treatment and recovery services; and bolstering the healthcare workforce.

Healthcare Priority Questions

- How do HHS policies and programs increase choice, affordability and enrollment in high-quality healthcare coverage?
- To what extent do HHS programs and policies reduce costs and improve quality of healthcare services?
- How and to what extent do HHS programs and policies ensure access to safe medical devices and drugs?
- How do HHS programs and policies expand equitable access to comprehensive, community-based, innovative, and culturally-competent healthcare services while addressing social determinants of health?
- How effective are HHS programs and policies at integrating behavioral health services into the healthcare system?
- 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?
- How do HHS programs and policies bolster the primary and preventive healthcare workforce to ensure delivery of quality services and care?

Healthcare Evidence-Building Activities

Divisions across HHS are conducting evidence-building activities to address these questions, including ASPR, ACL, CDC, CMS, NIH, and SAMHSA. These activities address various HHS programs, such as Medicare, Medicaid, Community Health Centers, and grantmaking programs like the National Paralysis Resource Center (NPRC). Eight identified evidence-building activities address healthcare priority questions. Full details on these activities are provided in the appendix.

Populations impacted by the healthcare evidence-building activities contained in this plan include mothers, individuals with disabilities (physical and cognitive disabilities), children, homeless individuals, and those recovering from substance use disorders. Notably, there are several instances of multiple divisions building evidence around the same populations and healthcare topics. An example includes the NIH impact assessment for The Role of Opioids in the Treatment of Chronic Pain Pathways to Prevention Workshop and the CMS evaluation of Maternal Opioid Misuse (MOM) Model. Additionally, some evidence-building activities that address the healthcare priority questions may seek to improve services, assess resource center effectiveness, advance telehealth capabilities, bolster preventative care, and identify promising value-based insurance models.

HHS executes a broad range of evidence-building activities to answer these priority questions. Activities include but are not limited to policy analysis, descriptive analysis, program evaluation, foundational fact-finding, and performance measurement. Most of the activities in this plan use a combination of methods to address a priority question. For example, using administrative data and program participant interviews to evaluate telehealth strategies to address hypertension management and control or site visits along with claims analysis to evaluate the Maternal Opioid Misuse Model. The activities utilize

existing HHS data, including program enrollment data, administrative claims, grant applications, survey data, and the Area Health Resource File (AHRF). They also incorporate external data such as electronic health records, data provided by program participants, and area-level measures of social deprivation (such as the Area Deprivation Index). Finally, activities also collect new data through surveys, interviews, focus groups, and site visits.

Strategic Goal 2: Safeguard and Improve National and Global Health Conditions and Outcomes

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

The activities in this priority area include improving capabilities related to public health emergencies and disasters; protection against communicable and infectious disease; promotion of healthy behaviors, and mitigation of environmental risk factors.

Public Health Priority Questions

- What improvements are needed to HHS capabilities to predict, prepare for, respond to, and recover from public health emergencies and threats in the nation and across the globe?
- 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 do HHS policies and programs enhance promotion of healthy lifestyle behaviors to reduce occurrence and disparities in preventable injury, illness, and death?
- How effective are HHS programs and policies at mitigating the impacts of environmental factors, including climate change, on health outcomes?

Public Health Evidence-Building Activities

HHS plays a significant role in both the American and global public health infrastructure and advances. The COVID-19 pandemic has 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. That said, HHS invests substantially in developing strong, timely, and rigorous evidence supporting ongoing and changing public health conditions.

Several divisions across HHS are conducting evidence-building activities to address these questions, including ASPR, ASPE, CDC, FDA, NIH, and SAMHSA. Most of the public health activities included in this plan focus on programs related to the COVID-19 pandemic, such as vaccinations, the National Hospital Preparedness Program, the Strategic National Stockpile, and the HHS emPOWER Program. However, the area also includes other public health programs, such as the Garrett Lee Smith Youth Suicide Prevention and Early Intervention Program, as well programs like Medicare and Medicaid. Eight identified evidence-

building activities address public health priority questions. Full details on these activities are provided in the appendix.

Many of the public health evidence-building activities target the entire American population. However, some activities have a more narrow focus, such as youth or individuals with hypertension. Additionally, some activities incorporate equity by assessing health disparities across sub-populations and focusing on building evidence to reduce the observed differences, such as helping communities protect the health of at-risk populations prior to, during, and after a disaster.

These activities address public health topics such as combating the opioid epidemic, vaccine hesitancy and confidence, and suicide prevention. Specifically, evidence-building activities contained in this document aim to assess long term effects of COVID-19 on vulnerable populations, analyze factors related to vaccine hesitancy and confidence, evaluate the National Healthcare Preparedness Program, and monitor programs focused on empowering at-risk populations, among others.

HHS utilizes a variety of methods and combinations of methods for the development of evidence supporting public health policies and programs. Research and other methodologies include case studies, descriptive and trend analysis, retrospective analysis, and literature reviews, performance measurement, outcome evaluation, quasi-experimental evaluation, and policy analysis, among others. Many of the public health activities in this plan use a combination of methods to address a priority question. For example, a review of existing literature, statistical analysis, and predictive modeling to understand COVID-19 vaccine hesitancy and confidence. These activities draw on internal resources, such as data held by the Centers for Medicare and Medicaid enrollment and claims, SAMHSA's Performance and Accountability Reporting System, SAMHSA's Infrastructure Development, Prevention and Mental Health Promotion (IPP) measures, as well as external data sources, including the U.S. Census Household Pulse Survey, the American Community Survey, and private medical supply distribution data. In addition to existing data, these evidence-building activities require development of new data through via sources including the program data, such as the Annual Hospital Preparedness Program Cooperative Agreement End-of-Year data, and qualitative interviews.

Strategic Goal 3: Strengthen Social Well-being, Equity, and Economic Resilience

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. The Department strengthens early childhood development and expand 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.

Human Services Priority Questions

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

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

Human Services Evidence-Building Activities

Answering these priority questions uses numerous activities, resources, and divisions and several divisions across HHS are conducting evidence-building activities to address these questions, including ACF, ACL, CMS, and HRSA. These activities address programs like child welfare, the African American Child and Family Research Center, the Medicaid innovation models, Healthy Start, and grant programs like those from the HRSA Maternal and Child Health Bureau. Seven identified evidence-building activities address human services priority questions. Full details on these activities are provided in the appendix.

Human services evidence-building activities focus on a variety of populations, including mothers, children, and individuals with disabilities. Activities support HHS programs and policies related to underserved communities, child welfare, services for individuals with disabilities, maternal health, and health equity, among others. Notably, ACF, CMS, and HRSA will all be conducting evidence-building activities for maternal and child health programs. Health equity is salient throughout the activities contained in this plan and is especially salient among human services focused activities, such as the African American Child and Family Research Center, which intends to identify promising approaches to promote social and economic well-being among low-income African American populations.

HHS executes a broad range of evidence-building activities to answer these human services priority questions. Activities include but are not limited to policy analysis, descriptive analysis, program evaluation, foundational fact-finding, and performance measurement. Most of the activities in this plan use a combination of methods to address a priority question, such as using a statistical analysis of claims data and participant focus groups to evaluate the Integrated Care for Kids Model or web-based grantee and stakeholder surveys and participant enrollment information to evaluate the Healthy Start program. The activities utilize existing HHS data, including program enrollment data, administrative claims, grant applications, survey data, and the Area Health Resource File (AHRF). They also incorporate external data such as electronic health records, data provided by program participants, and vital records. Finally, activities collect new data through surveys, interviews, focus groups, structured observation, site assessments, and site visits.

Strategic Goal 4: Restore Trust and Accelerate Advancements in Science and Research for All

HHS is dedicated to restoring trust and accelerating advancements in science and research. The Department 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 our understanding of disease, healthcare, public health, and human services resulting in more effective interventions, treatments, and programs. Strengthening surveillance, epidemiology, and laboratory capacity is another major focus to better understand and equitably address diseases and conditions. HHS is also increasing evidence-based

knowledge through improved data collection, use, and evaluation efforts to achieve better health outcomes, reduced health disparities, and improved social well-being, equity, and economic resilience.

Activities in this priority area include, but are not limited to, support of scientific research, data, evaluation, evidence, innovation, surveillance, epidemiology, and laboratory capacity.

Research and Evidence Priority Questions

- How does HHS improve the design, delivery, and outcomes of HHS programs by prioritizing science, evidence, and inclusion?
- Which HHS investments in the research enterprise are most effective for maintaining leadership in the development of innovations that broaden our understanding of 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 would most strengthen surveillance, epidemiology, and laboratory capacity to understand and equitably address diseases and conditions?
- 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?

Research and Evidence Evidence-Building Activities

HHS is dedicated to the mission of enhancing the health and well-being of all Americans, by providing for effective health and human services and by fostering sound and sustained advances in the sciences underlying medicine, public health, and social services. A large percentage of the Department's budget is devoted to supporting research, and as such, many evidence-building activities are undertaken to supplement and further understand research results. Divisions across HHS are conducting evidence-building activities to address research and evidence questions, including HRSA, NIH, ONC, and SAMHSA. These activities address programs across HHS, including child welfare, patient centered outcomes research, vaccination, CDC's Public Health Law Program, the HHS emPOWER program, Quality Improvement and Innovation Contracts, the Collaborative Health Equity Measurement Project in Maternal and Child Health, the Cancer Moonshot, and the ONC Health IT Certification Program. Fourteen identified evidence-building activities address research and evidence priority questions. Full details on these activities are provided in the appendix.

As such, the research and evidence focused activities contained in this document address topics such as the use and application of evidence, grant-making processes, health equity measurement, disease reporting and epidemiological approaches, data sharing, evidence capacity needs, quality improvement and innovation, and more. For the most part, research and evidence activities focus on grantees, providers, and communities, rather than individual beneficiaries.

These division-level evaluations, research, and analysis efforts support cross-cutting issues, major department-level goals, and time sensitive priority issues. In addition to division-level activities, departmental analyses laid out in the Strategic Plan and this Evidence-Building Plan support and coordinate efforts of divisions in achieving key priorities of HHS, especially related to research and

evidence programs, policies, capacity-building, resource needs, and agency processes. Long term goals are identified through HHS' Strategic Planning and Evidence-Building Plan processes.

HHS executes a broad range of evidence-building activities to answer these priority questions at the division- and department-levels. Activities include but are not limited to policy analysis, legal epidemiology, descriptive analysis, program evaluation, foundational fact-finding, impact analysis, and performance measurement. Most of the activities in this plan use a combination of methods to address a priority question. For example, using administrative data and semi-structured interviews to understand how ACF can continue to develop and improve its evidence infrastructure and culture. NIH is conducting a portfolio and outcomes analysis to assess the success of the Cancer Moonshot. The activities utilize existing HHS data, including program administrative data, claims data, legal databases, provider performance measures, grant applications, survey data, and area-level measures such as the CDC's Social Vulnerability Index. They also incorporate external data such as electronic health records, patent data, weather data, housing information, power outages, data provided by program participants, and survey data. Finally, activities collect new data through surveys, interviews, focus groups, real world testing data, and site visits.

Strategic Goal 5: Advance Strategic Management to Build Trust, Transparency, and Accountability

HHS is dedicated to advancing strategic management across the Department to build trust, transparency, and accountability. A major focus of the Department 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. The Department also ensures the security of HHS facilities, technology, data, and information, while advancing environment-friendly practices.

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 efforts are most effective for sustaining strong financial stewardship of HHS resources to foster prudent use of resources, accountability, and public trust?
- 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?

Management Evidence-Building Activities

HHS prioritizes effective management of HHS resources, programs, and policies through coordinated efforts across the Department as well as through division-level initiatives. Divisions across HHS are conducting evidence-building activities to address these questions, including ASPR, CMS, and FDA, across programs such as the Biomedical Advanced Research and Development Authority, quality

improvement contracts, and food safety. Three identified evidence-building activities address management priority questions. Full details on these activities are provided in the appendix.

As with other priority areas, addressing major management priorities and challenges requires division-level and cross-department activities. Evidence-building activities within this document address effective enterprise governance, equitable and transparent enterprise management, strong financial stewardship, innovative human capital resource management, and security of HHS facilities, technology, and data and information, among others. They target evidence-building within HHS' programs to improve the Department's ability to achieve its mission.

Management evidence-building activities utilize methods and approaches such as systematic needs assessments, administrative data analysis, performance measurement, portfolio analysis, statistical analysis, literature reviews, coding and qualitative analysis, outcome and impact evaluation, direct estimation, and small area analysis (SAE). Activities seek to understand the extent to which data is used for policy and program development, identify problematic practices and structures, develop research agendas, build and strengthen programmatic and operational evaluation capacity, translate evidence-based findings into translational federal-to-community level innovative data, mapping, and artificial intelligence tools, inform common measures for health equity, measure program progress, and inform future policy making.

These activities utilize existing HHS data such as administrative data, Medicare fee-for-service claims data, provider performance, and FDA inspections data. They also leverage external data such as data from contractors. Finally, these activities include collection of new data as needed. For example, the epidemiology on COVID-19 will continue to inform BARDA's portfolio, and CMS continuously uses provider satisfaction surveys to inform policy and program decisions.

Data Sources

HHS has identified a range of data sources to support the evidence-building activities identified in this plan, including data held by the Department, data held by other entities, and new research and data collection, as discussed in the priority areas above. Although each activity relies on data sources specific to the question and program being addressed, there are some data sources that are used frequently. In particular, Medicare and Medicaid administrative and claims data are used for a number of program and policy analyses. Specific programs use provider and enrollee information, including ACF program administrative data and vital records provided by Maternal Opioid Misuse (MOM) Model awardees. Many evidence-building activities rely on information submitted through grant applications or provided by grantees, such as grant applications to the National Paralysis Resource Center. Program specific information is often supplemented with area-level measures, such as those included in the Area Health Resource File or CDC's Social Vulnerability Index. Other major sources of Federal data will also be utilized, including the American Community Survey, the Census Pulse Survey, and national weather and climate data.

Many of the activities identified will also collect qualitative data to supplement quantitative analyses. These may be interviews, focus groups, or site visits. They may also field activity-specific surveys to gather additional information from grantees or program participants.

Additional details on the data sources for all evidence-building activities are provided in the appendix in sections titled "Existing Data Sources Held by the Division", "Existing Data from Other Sources", and

“New Data Collection”. The first of these sections describes existing data sources held by the division, which are used for each analysis; the second describes existing data from other sources that are utilized; the third describes any new data collection undertaken for each activity.

Methods

HHS uses a wide variety of methods and approaches to develop and use evidence to inform decision-making. These include the four interdependent components of evidence according to Evidence Act: policy analysis, program evaluation, performance measurement, and fact-finding, among others.

As mentioned previously, many, if not all, of these methods and approaches will be used to answer the priority questions, and many activities will use a combination of multiple approaches. HHS agencies will utilize both quantitative and qualitative data collection and analysis strategies to inform the development of policy analysis, research, and evidence-building in support of the five priority areas. Specific methods include trend analysis of program data over time, including stratification to examine disparities in trends; portfolio analysis; bibliometric analysis; stakeholder interviews; small area analysis; differential equation simulation modeling; and logistic regression, among others. When required, sampling schemes will be developed to draw representative samples from datasets or populations of interest.

Additional details on the methods for all evidence- building activities are provided in the appendix in the section titled “Study Design or Approach”. For each activity, the information in this section describes the study design or approach used for the analysis.

Challenges and Mitigation Strategies

Challenges

Protecting the health and safety of Americans requires the coordination and engagement of divisions across HHS and the federal government, utilizing the full range of health and human service activities. It can be challenging to isolate the role of a specific program or policy, as well as to determine how programs or policies interact to produce outcomes. Additionally, the American healthcare and human services systems are complex and vast, involving federal, state, local, and tribal governments, private payers, and hundreds of thousands of providers. This complexity requires a high level of engagement and coordination in order to reduce the challenges caused by silos or service disruptions.

To conduct analyses, resources may be required to purchase key data sources and contractor support.

Given the expansive data resources and tools across HHS, it is challenging to identify all appropriate data sources and tools for evaluative and assessment purposes. Data quality issues may be difficult to identify given that some data sources may be completely new. In many cases, the primary use of the data and the reason for its creation were not for evaluative purposes, making it challenging to know whether the data is truly appropriate to address the question. Developing data use agreements to govern the exchange of data for analyses can cause significant delays. Data management can be another challenge. Depending on the topic, database development, maintenance, and dissemination require a complex infrastructure including technical, logistical, and legal support and protections. Furthermore, data are subject to a range of quality issues including completeness, accuracy, and timeliness, which can delay or complicate analyses. Self-reported data, as intended to be use for some activities, are subject to additional concerns arising from reporting bias and recall bias. Many projects will compile data from different states, which may have different laws and regulations governing the collection of data,

introducing challenges related to comparability. HHS requires highly expert, experienced, and specialized staff both to oversee the collection and creation of databases and to use and analyze data to develop information that is useful and accessible to decision makers. Additional challenges described in the Appendix include time lags with regard to data availability, setting realistic expectations for project timelines, and the availability of data on certain populations of interest.

As this plan is under development, the country is still in the midst of responding to the COVID-19 pandemic. The rapidly changing nature of the science, the economy, and the combined federal response to the pandemic created a number of new challenges related to how HHS builds and uses evidence. For example, interventions or policies that were successful when there were fewer risks of communicable disease may no longer produce the same results. Data collection for surveys may have been interrupted or halted altogether, disrupting trend lines. Healthcare visits dropped or switched to virtual appointments. HHS staff were deployed or temporarily reassigned from their regular daily duties to assist with the response.

Mitigation Strategies

Mitigating challenges will require a coordinated, transparent, collaborative process with relevant stakeholders. Given the potential complications related to the scope of these priority areas, analyses and recommendations will focus on data resources, tools, and needs that are likely to be of most benefit widely across HHS. Additionally, because these priority areas are in line with the Strategic Plan, HHS leadership will be actively engaged on a regular basis in understanding any progress, barriers, and facilitators to the work.

Mitigation of challenges related to data resources may include offering multiple ways to submit data, offering training and technical assistance to facilitate data collection, or relaxing deadlines for data submission. Data quality can be improved with clear communication, training for those collecting data, and review and validation processes. Some projects plan to initiate steps to acquire data and develop methodology early in the study process to mitigate likely delays. The use of mixed methods approaches are in themselves mitigation strategies – utilizing different sources and types of information with distinct strengths and weaknesses in complementary ways. The inclusion of “research and evidence” as a priority demonstrates the significant support and commitment from HHS leadership to address challenges in data collection and use.

Mitigation and response to challenges related to the COVID-19 pandemic include adoption of tools to maintain continuity of operations while many HHS employees work remotely (i.e., virtual meeting platforms), revisiting policies to best meet the evolving work environment, and developing contingency plans for future emergency situations minimize disruption to HHS services and operations, including evidence-building activities. Some analysis plans will be revised to accommodate delays in data collection caused by the pandemic.

Additional information about anticipated challenges and mitigation strategies for each evidence-building activity is included in the section titled “Anticipated Challenges and Mitigation Strategies”.

Stakeholder Engagement

During the COVID-19 Pandemic to avoid placing additional burden on state and local governments, and representatives of non-governmental research, HHS engaged a range of stakeholders with various expertise across the Department, utilizing existing communication channels and bodies, such as the HHS Evidence and Evaluation Council. This Council includes representatives from all HHS Operating and several Staff Divisions. The Evidence and Evaluation Council, and specifically the Evaluation and Evidence-Building Plans subcommittee, supported development of the plan, cross-department coordination, and identification of stakeholders to be engaged. The Council has and will continue to be an integral body for Evidence Act implementation, given that Council members provide division-level insights and guidance for a cross—HHS implementation approach.

Specific HHS stakeholders are listed below:

- HHS leadership
- Operating and staff divisions
- Evaluation Officer (EO), Laina Bush
- Evidence & Evaluation Council members
- Evidence-Building Plan and Evaluation Plan Subcommittee
- HHS Division of Strategic Planning
- The HHS Office of the Assistant Secretary for Financial Resources

The HHS Strategic Planning community, especially the HHS Division of Strategic Planning in ASPE, has been a key stakeholder and partner for the development of this plan. The HHS Evidence-Building Plan and Strategic Plan are complimentary plans, which requires a high level of communication and coordination for alignment of strategic planning and evidence-building activities. ASPE's Division of Evidence, Evaluation and Data Policy will work closely with the Division of Strategic Planning to coordinate stakeholder engagement efforts throughout the effective periods for both plans. These activities will be described in annual Plan updates.

Beyond the Department, HHS coordinates with other Federal Evaluation Officers, agency Evidence Act leadership, evaluation and evidence-building staff, the Office of Management & Budget, and others. Federal agencies vary greatly in mission, scope, capacity, size, and organizational structure. For those reasons, implementation approaches have differed greatly based on unique agency needs and context.

HHS is committed to engaging external stakeholders through a variety of methods and channels. Stakeholder meetings such as those held by Federal Advisory Committees, including the National Vaccine Advisory Committee and the Advisory Committee on Minority Health, provide opportunity for public engagement. But, the primary approach to external stakeholder engagement is through HHS Divisions and program offices which foster a wide range of two-way exchanges with diverse stakeholder groups and the results of which were incorporated into their contributions to this plan. These exchanges include Federal Register Notices, the use of Communities of Practice and panels of subject matter experts, publishing Division-specific Evidence-Building Plans¹, and presentations regarding Evidence-

¹ For example, the [ACF plan](#) and the [ACL plan](#).

Building and evaluation activities². The information gathered through these activities is used to inform their evidence building activities and is reflected in this document.

Commitment to Scientific Integrity

OMB's standards for program evaluations notes that Federal evaluations must produce findings that Federal agencies and their stakeholders can confidently rely upon, while providing clear explanations of limitations: they are to be conducted 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 memorandum and guidance are providing 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. This memorandum, together with OMB guidance and HHS policies, affirm that evaluations are scientific activities and as such, require the use of appropriate methods which can include a broad range of approaches, independence from undue influence, and processes that ensure integrity and quality. These recent requirements will contribute to improved evaluation and evidence-building activities in HHS and will guide the development and conduct of evaluations in accordance with the principles and foundations for scientific integrity.

Further demonstrating the Department's commitment to scientific integrity, Chief Data Officer, Evaluation Officer, and Statistical Official of the U.S. Department of Health and Human Services (HHS), are developing a joint statement of commitment to scientific integrity in support of HHS's work and fulfillment of the HHS mission to enhance the health and well-being of all Americans, by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services.

² An example of a presentation is available at <https://mathematica.org/publications/hhs-aspe-webinar-series-developing-using-learning-agenda-approach-to-evidence-building-video-1>.

APPENDIX: Evidence-Building Activities

Contributing Division: ACF

Activity Title: Research and Evaluation for Underserved Communities in Child Welfare

HHS Priority Questions: 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? How can HHS optimize investments in the research enterprise to maintain leadership in the development of innovations that broaden our understanding of disease, health care, public health, and human services resulting in more effective interventions, treatments, and programs?

Activity Description/Research Questions: This project will explore how child welfare agencies and their community partners currently support underserved communities. The project also aims to gain insights on the extent to which data are being used to determine service delivery gaps for underserved communities, identify problematic practices and structures, and support child welfare agency staff and partners to address these gaps. Further, the project will develop a research agenda and designs to better understand and build the capacity for child welfare agencies and their partners to serve children and families in these communities. It will address the following research questions: How do child welfare agencies and their community partners currently support underserved communities? What research is needed to better understand and build the capacity for child welfare agencies and their partners to serve children and families in underserved communities?

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

Existing Data Sources Held by the Division: TBD

Existing Data from Other Sources: TBD

New Data Collection: TBD

Study Design or Approach: TBD

Anticipated Challenges and Mitigation Strategies: TBD

Contributing Division: ACF

Activity Title: African American Child and Family Research Center

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

Activity Description/Research Questions: This research center will lead and support research on the needs of African American populations served by ACF and promising approaches to promote social and economic well-being among low-income African American populations. The center will provide leadership on culturally competent research that can inform policies concerning low-income African

American populations and will foster significant scholarship regarding the needs and experiences of the diverse African American population throughout the nation. The research questions are: What are the needs of African American populations served by ACF? What are promising approaches to promote social and economic well-being among low-income African American populations?

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

Existing Data Sources Held by the Division: TBD

Existing Data from Other Sources: TBD

New Data Collection: TBD

Study Design or Approach: The research center will bring together a diverse, inclusive, culturally sensitive, and interdisciplinary team of academic and organizational partners to undertake research, capacity building, and communication activities. The Center will develop research products, resources, and a comprehensive communication plan that aims to build research capacity in the field and improve understanding of African American populations in order to inform policy development and programmatic responses.

Anticipated Challenges and Mitigation Strategies: Traditionally, research that has informed predominate views of underrepresented groups, including African American populations, has not been community engaged, culturally rigorous, or informed by consideration of structural inequities. Moreover, such research has relied heavily on a comparative research framework in which the behaviors, experiences, and outcomes of White Americans are used as the standard or reference point against which the behaviors, experiences, and outcomes of underrepresented populations are assessed. Often this research approach fails to acknowledge how aspects of research design and measurement can bias findings and fails to acknowledge important historical and cultural contexts that differ across groups. This research approach has contributed to the inherent assumption that the behaviors, experiences, and outcomes of underrepresented groups that differ from White Americans represent deficits and must be addressed to promote their economic and social well-being. We aim to support research that is contextualized by a thorough understanding of historical and contemporary inequitable social structures and systems as well as the diverse cultural practices of African American populations.

Contributing Division: ACF

Activity Title: ACF Evidence Capacity Support

HHS Priority Questions: How can HHS programs and policies improve 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?

Activity Description/Research Questions: This project will support ACF's efforts to build and strengthen programmatic and operational evidence capacity by conducting foundational evidence activities with ACF programs including systematic needs assessments and administrative data analysis. The research

questions are: How can ACF continuously improve the effectiveness and efficiency of its programs? How can ACF continue to develop and improve its evidence infrastructure and culture?

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

Existing Data Sources Held by the Division: ACF program administrative data

Existing Data from Other Sources: TBD

New Data Collection: Semi-structured interviews, focus groups, and brief surveys of internal and/or external stakeholders

Study Design or Approach: Project activities will include systematic needs assessments that will collect and analyze information on program learning priorities; and administrative data analysis to assess the suitability of ACF administrative data to address learning priorities.

Anticipated Challenges and Mitigation Strategies: Challenges may include setting realistic expectations for project timelines; limited ACF SME time; and timely execution of data sharing agreements for access to administrative data sources. To address these issues, the team has instituted a continuous quality improvement approach, incorporating lessons learned into the design and execution of future engagements.

Contributing Division: ACL

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

HHS 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?

Activity Description/Research Questions: Research questions are:

How and to what extent does the National Paralysis Resource Center (NPRC):

1. improve the health and quality of life of individuals living with paralysis of all ages, their families, and their support system?
2. raise awareness of members of the target populations about paralysis?
3. increase access of members of the target populations to services relevant to individuals with paralysis
4. increase the empowerment, confidence, and independence of individuals living with paralysis
5. strengthen support networks for individuals living with paralysis
6. improve or increase opportunities for individuals living with paralysis for community living

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

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

Existing Data from Other Sources: N/A

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 impact of the NPRC services on individuals living with paralysis of all ages, their families, and their support system.

Anticipated Challenges and Mitigation Strategies: None

Contributing Division: AHRQ

Activity Title: TAKEheart Initiative

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

Activity Description/Research Questions: An important goal of AHRQ is to facilitate implementation of findings from patient centered outcomes research (PCOR) into health care practice. Accordingly, to help improve cardiac rehabilitation rates, the American Association of Cardiovascular and Pulmonary Rehabilitation/Million Hearts® Cardiac Rehabilitation Collaborative has developed a Cardiac Rehabilitation Change Package (CRCP) and established a national goal of 70% participation in CR (up from 20-30%) by 2022 for eligible patients. AHRQ's TAKEheart initiative is designed to broadly disseminate and implement the strategies described in the CRCP to hospitals nationwide to help achieve this goal. The research question is: How can AHRQ help disseminate evidence-based practices and foster their implementation within care delivery settings?

Time Period for the Activity (estimated start and end dates): March 2019-March 2023

Existing Data Sources Held by the Division: N/A

Existing Data from Other Sources: TAKEheart project leaders are collecting data from Partner Hospitals and Learning Community hospitals.

New Data Collection: N/A

Study Design or Approach: A public TAKEheart Website has been created to (a) increase awareness of the challenges of increasing patient participation in CR nationwide and (b) provide educational resources and training materials (e.g., web-based training modules and implementation guides) for hospitals wishing to adopt evidence-based strategies for meeting these challenges. In addition, a group

of TAKEheart Partner Hospitals (PHs) recruited from across the US is currently participating in monthly web-based training sessions and receiving individual coaching in developing and implementing individualized hospital action plans for putting these evidence-based strategies into practice. These PHs exchange insights with their peers through monthly meetings of Peer Action Groups. Finally, a larger group of hospitals will be invited to join Learning Community Affinity Groups to share knowledge about ways to address challenges to and disparities in patient participation in CR. Since the Learning Community was launched in March 2020, the first set of Affinity Groups focused on strategies for adapting CR to the COVID-19 pandemic (e.g., providing in-person CR under restricted conditions and in using remote phone and other remote technologies to provide CR training at home).

Anticipated Challenges and Mitigation Strategies: The monthly trainings of the first of two cohorts of Partner Hospitals were halted in March 2020 due to the pandemic and were resumed in May 2021. Some of the hospitals enrolled in the first cohort had to drop out and were replaced with hospitals that had applied to be in a second cohort. Additional recruitment is now underway for this second cohort (that will begin training in Fall 2021), but it is unlikely that the target of an additional 50 hospitals for the second cohort will be met.

Contributing Division: ASPE

Activity Title: Long term effects of COVID on vulnerable patients

HHS Priority Questions: How effective are HHS programs and policies at protecting individuals, families, and communities against communicable, and infectious disease through effective, innovative, readily available and equitable delivery of treatments, therapeutics, medical devices, and vaccines?

Activity Description/Research Questions: Two studies will examine downstream effects of COVID on vulnerable populations. The first will examine the long term health effects of a COVID diagnosis, the second the long term health effects of medical care services foregone due to the pandemic. The research question is: How can we prepare to meet the long term needs of patients affected directly or indirectly by COVID 19?

Time Period for the Activity (estimated start and end dates): Ongoing through FY 2023

Existing Data Sources Held by the Division: Core components database used for HSP contracted research completed in FY 21 (this aggregates findings from evaluations of youth programs)

Existing Data from Other Sources: TBD; data from previous evaluations could be used to take a meta-analytic approach to determining core components of a particular type of program focused on specific outcomes

New Data Collection: TBD; new data could be generated by requiring certain federally funded evaluations to use a core components approach

Study Design or Approach: Study 1 is a cohort analysis comparing outcomes for patient diagnosed with COVID to a matched set of patients without a COVID diagnosis. Study 2 will compare potential

downstream health consequences of key services not provided during March through May of 2020. **Anticipated Challenges and Mitigation Strategies:** The core studies will use Medicare data. We are examining the challenges that will arise due to the issues of completeness, privacy, and continuity of data that arise with TMSIS and private data sources.

Contributing Division: ASPE

Activity Title: Increasing Use of Core Components in HHS Evidence Building and Application

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

Activity Description/Research Questions: HHS will work with a leading expert in the field to establish a federal working group on using component-based research for evidence-based policymaking, to establish common interagency understandings about the potential of evidence generated with core components research, and provide tools and support for using this evidence. This working group will help federal staff put this approach into action for ongoing program improvement and increased, equitable policy and program impact. The research question is: How can the federal government apply a core components approach to improve outcomes by increasing uptake of evidence-based practices?

Time Period for the Activity (estimated start and end dates): August 2021 – August 2024

Existing Data Sources Held by the Division: N/A

Existing Data from Other Sources: N/A

New Data Collection: N/A

Study Design or Approach: To move the evidence base beyond identification of “model programs,” which do not often achieve widespread uptake in the field because they are expensive, difficult to adapt, or don’t meet the community’s needs. ASPE and other research finds that the core components of effective programs can be identified and disseminated to program administrators. This builds on previous work that used meta-analyses to identify core components (program, participant, and implementation features) that were empirically related to specific positive outcomes across youth programs represented in the database used. The working group, to be established in FY 22, will gather additional examples of core components approaches from across the government and develop tools to expand the use of such approaches.

Anticipated Challenges and Mitigation Strategies: HHS agencies and other federal agencies are not at the same point of pursuing core components approaches and may need time and support to work toward a common language and understanding.

Contributing Division: ASPE

Activity Title: COVID-19 Vaccine Hesitancy and Confidence

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

Activity Description/Research Questions: Evidence-building activity: This policy analysis utilizes data on COVID-19 vaccination and intent to vaccinate. The analysis examines demographic and geographic factors associated with vaccine hesitancy, including reasons for not vaccinating. The analysis also develops predictions of vaccine hesitancy, and vaccination at state, county and sub-state levels. The research questions are: How can HHS improve the comprehensiveness and applicability of vaccine confidence and related data available for stakeholders and policymakers? How can HHS programs be utilized to build confidence in COVID-19 vaccines?

Time Period for the Activity (estimated start and end dates): 02/2021-ongoing

Existing Data Sources Held by the Division: N/A

Existing Data from Other Sources: U.S. Census Household Pulse Survey; American Community Survey; CDC Vaccine Administration Tracker; CDC Social Vulnerability Index; Surgo COVID-19 Vaccine Coverage Index

New Data Collection: N/A

Study Design or Approach: The statistical analysis utilizes a logistic regression to analyze predictors of the outcome of interest (e.g., vaccination, vaccine hesitancy) that include sociodemographic and geographic information. The estimates are then used to make predictions for other geographic areas. Our approach also discusses the relevant literature or other information to complement the findings from the statistical approach.

Anticipated Challenges and Mitigation Strategies: Data for certain groups or areas may not be available and may need to be supplemented with information from the literature or case studies.

Contributing Division: ASPR

Activity Title: National Healthcare Preparedness Program (NHPP) Evaluation

HHS Priority Questions: How can HHS improve capabilities to predict, prepare for, and respond to public health emergencies and threats in the nation and across the globe?

Activity Description/Research Questions: NHPP Evaluation activities use performance measure data across programs (including the Hospital Preparedness Program Cooperative Agreement, the Hospital Association Cooperative Agreement, and funding to the Regional National Special Pathogen System) to assess progress toward program goals, successes, challenges, and gaps in health care preparedness. The

research question is: How have NHPP's cooperative agreement activities improved and addressed gaps in health care preparedness?

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

Existing Data Sources Held by the Division: HPP Cooperative Agreement End-of-Year data; Hospital Association Cooperative Agreement End-of-Year data

Existing Data from Other Sources: N/A

New Data Collection: Annual Hospital Preparedness Program Cooperative Agreement End-of-Year data; Annual Hospital Association Cooperative Agreement End-of-Year data; COVID-19 Supplemental Funding Data

Study Design or Approach: Annual Hospital Preparedness Program Cooperative Agreement End-of-Year data; Annual Hospital Association Cooperative Agreement End-of-Year data; COVID-19 Supplemental Funding Data.

Anticipated Challenges and Mitigation Strategies: A challenge is the self-reported nature of the data. Clear communications, training for recipients, and validation processes are conducted to mitigate this challenge and to seek to enhance the quality and completeness of the data.

Contributing Division: ASPR

Activity Title: Biomedical Advanced Research and Development Authority (BARDA) Portfolio Review

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

Activity Description/Research Questions: BARDA will continue to evaluate alignment of medical countermeasure investments to the forthcoming BARDA Strategic Plan, MCM requirements and policies, and relevant authorizing legislation. As these investments generate data and new advancements are made in life sciences, the opportunity to calibrate these investments will be undertaken. The research question is: How can BARDA optimize investments in medical countermeasure (MCM) development and procurement to protect Americans from national health security threats?

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

Existing Data Sources Held by the Division: Data showing how well the existing portfolio aligns with identified threats, forthcoming BARDA Strategic Plan, and MCM requirements and policies will be regularly evaluated.

Existing Data from Other Sources: Data from contract performers is regularly conveyed to the BARDA as part of the reporting process spelled out in the agreements. The outside data will include preclinical toxicology and efficacy and clinical safety & efficacy. Other programs that are not specific to a single

MCM, will utilize data relevant to the performance or advancement of a technology, capability or platform.

New Data Collection: Data from contract performers is regularly conveyed to the BARDA as part of the reporting process spelled out in the agreements. The outside data will include preclinical toxicology and efficacy and clinical safety & efficacy. Other programs that are not specific to a single MCM, will utilize data relevant to the performance or advancement of a technology, capability or platform.

Study Design or Approach: The design of the portfolio analysis is to:

1. Evaluate alignment of current BARDA portfolio to identified threats, forthcoming BARDA Strategic Plan, and MCM requirements and policies
2. Account for the ongoing costs for the advancement and procurement of MCMs in the portfolio
3. Analyze the current and prospective future investments to enhance the preparedness posture
4. Inform budget formulation process

The Portfolio Review process will initiate in January 2022 and continue on an annual basis thereafter. The Portfolio Review will build on focused Program Reviews BARDA conducted in 2021.

Anticipated Challenges and Mitigation Strategies: **Uncertainty:** An enormous amount of emerging data regarding the performance of MCMs for COVID-19 in real-time will guide how BARDA should invest. A clear understanding of the multiyear COVID-19 funding will be a prerequisite to any/all choices made about ongoing development or procurement of vaccines, therapeutics, and diagnostics. Wherever transitions for financial obligations to other agencies or institutions can be articulated, the scope of data BARDA should collect or maintain will be simplified. **Operational:** Collecting the detailed data to support Portfolio Analysis will require systematic and centralized capture of MCM level information from within each BARDA Contract. The data structure and systems to manage this are nearing completion within BARDA.

Contributing Division: ASPR

Activity Title: Supply Chain Control Tower (SCCT)

HHS Priority Questions: How can HHS improve capabilities to predict, prepare for, and respond to public health emergencies and threats in the nation and across the globe?

Activity Description/Research Questions: Identify medical supplies of interest in support of various types of incident responses to add to the SCCT that would be of use for ASPR and Strategic National Stockpile situational awareness. As part of the distributor sustainment plan and updated data user agreements, identify and prioritize new data feeds for enhanced medical supply visibility. The research question is: How have the types of supply chain data feeds into the SCCT been expanded and enhanced in support of ASPR's all-hazards response beyond COVID?

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

Existing Data Sources Held by the Division: PPE, pharmaceutical, testing, and select needles and syringe data feeds that identify product distribution from private distributors, manufacturers, USG stockpiles, and State stockpile inventory

Existing Data from Other Sources: Private medical supply distributors, state stockpiles, and non-HHS federal supplies (such as FEMA)

New Data Collection: With new product identification, request current SCCT participants to expand their data feeds to include the new products as it relates to SNS needs in addition, identifying new partners to participate in SCCT to enhance the end to end visibility for these new product additions

Study Design or Approach: A complete review of relevant medical supply products will need to be performed and mapped to types of responses that have medical impacts that ASPR responds to. That mapping will demonstrate which supplies are used for multiple types of incidents and would be considered as a higher priority supply to include in the SCCT data feeds.

Anticipated Challenges and Mitigation Strategies: Encouraging new participants to contribute data, justification for importance of data needs, establishing DUAs for new participants, and updating current DUAs. All these things take time and legal review.

Contributing Division: ASPR

Activity Title: emPOWER At-risk Population and Healthcare System Resilience Monitoring and Evaluation

HHS Priority Questions: How effective are HHS programs and policies at protecting individuals, families, and communities against communicable, and infectious disease through effective, innovative, readily available and equitable delivery of treatments, therapeutics, medical devices, and vaccines? How can HHS programs and policies improve 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?

Activity Description/Research Questions: The HHS emPOWER Program and healthcare system monitoring project seeks to identify gaps and translate evidence based findings into translational federal-to-community level innovative data, mapping, and artificial intelligence tools, as well as training and resources, to help communities nationwide protect the health of at-risk populations prior to, during, and after a disaster. For example, prior studies identified gaps in assistance for electricity and healthcare service dependent at-risk populations living independently in communities. These findings were translated into mitigation tools via the HHS emPOWER Program that is currently helping communities prepare for over 4.2 million individuals who live independently and rely on electricity-dependent durable medical and assistive equipment and devices, and or essential health care services. Research questions are: How can HHS programs, policies, and data identify gaps and inform federal to community

based mitigation tools to protect at-risk populations prior to, during and after a public health emergency or disaster? How can HHS programs, policies, and data provide critical information to reduce disparities and advance community readiness to address at-risk needs prior to, during, and after a disaster? How can HHS programs, policies, and data help communities identify opportunities to strengthen healthcare system readiness and delivery from inpatient to home and community-based models of care and reduce adverse outcomes in at-risk populations? How can HHS programs, policies, and data help communities understand gaps in access to healthcare coverage and services to advance health equity?

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

Existing Data Sources Held by the Division: ASPR, in partnership with the Centers for Medicare and Medicaid Services Center for Medicare, evaluate Medicare and Medicaid administrative claims data

Existing Data from Other Sources: Federal hazard and other available data sources as needed (e.g., weather and other climate, housing, power outage, etc.).

New Data Collection: Monthly updated Medicare, and as available Medicaid, administrative claims data obtain from CMS standard operations

Study Design or Approach: N/A

Anticipated Challenges and Mitigation Strategies: The studies will not represent 100% of the at-risk population as studies will use Medicare and Medicaid claims data. However, studies and their peer-reviewed publications have identified critical findings for addressing needs and may be similarly applied across at-risk populations even though they may not be fully represented by Medicare and Medicaid data. Additionally, publishing methods for these studies allows researchers who may have access to other data sources the ability to expand analyses and findings as well.

Contributing Division: CDC

Activity Title: Rigorous Evaluations of Telehealth Strategies to Address Hypertension Management and Control

HHS Priority Questions: To what extent do HHS programs and policies reduce costs and improve quality of health care services? How do HHS policies and programs promote healthy lifestyle choices to reduce occurrence and disparities in preventable injury, illness, and death?

Activity Description/Research Questions: Telehealth is one avenue that may increase access to healthcare for underserved populations, and this project will focus on identifying implications and recommendations for the use of telehealth among populations who experience disproportionate risk of hypertension and barriers to healthcare access. The project will use a stepwise approach, using an understanding of the context and policies related to telehealth, to develop an evaluation plan which will evaluate the implementation of telehealth at three health systems. The evaluations will assess telehealth implementation, cardiovascular disease outcomes over time, compare differences in outcomes among patients receiving telehealth services versus those receiving in-person medical care,

cost-effectiveness, and the sustainability of telehealth strategies including the policy context for long term implementation of telehealth.

Time Period for the Activity (estimated start and end dates): September 2021 – November 2023

Existing Data Sources Held by the Division: N/A

Existing Data from Other Sources: • Secondary data analysis using data extracted from health system site data systems (i.e., EHRs) • Secondary data analysis of Federal and state telehealth statutes, legislation, and regulations • Secondary data analysis of published and grey literature for the use of telehealth to address cardiovascular disease and address health disparities

New Data Collection: Qualitative Interviews

Study Design or Approach: Overall, evaluation methods will include a retrospective analysis of adult patients with hypertension, hypercholesterolemia, or other cardiovascular disease who received telehealth services at three separate health systems over the past year or more. The evaluation design will use quasi-experimental methods that includes a comparison group to assess the contribution of telehealth implementation to relevant outcomes including hypertension. A policy analysis will include a systematic assessment of Federal and state policies, statutes, and regulations that facilitate and limit telehealth.

Anticipated Challenges and Mitigation Strategies: This effort aims to build practice-based evidence within a national context of rapidly changing of healthcare delivery, largely driven by the ongoing COVID-19 pandemic. These challenges also present unique opportunities for evidence-building. The evaluation design seeks to demonstrate effectiveness of telehealth strategies to address cardiovascular disease and health disparities, while proactively considering how current policies and regulations affect telehealth implementation and reimbursement of services, and the role of the COVID-19 pandemic in catalyzing broad health system implementation of telehealth.

Contributing Division: CDC

Activity Title: Disease Reporting Legal Epidemiological Studies

HHS Priority Questions: How can HHS further strengthen surveillance, epidemiology, and laboratory capacity to understand and equitably address diseases and conditions? How can HHS programs and policies improve 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?

Activity Description/Research Questions: PHLP attorneys analyze state laws that require healthcare providers, laboratories, and other entities to report findings of certain diseases and conditions to state or local public health authorities. Attorneys use legal epidemiology to build datasets that allow researchers to view trends and variations across jurisdictions related to identified factors such as

diseases and conditions required to be reported, the manner in which reporting must take place, and the information required to be reported. Compilation of these data can be used to (1) help health care providers and laboratories achieve compliance with reporting laws; (2) study the reporting of demographic information, and (3) inform public health professionals about the scope of disease reporting requirements by jurisdiction. The research question is: How do state disease reporting laws factor into state, tribal, local, and territorial public health authorities with disease surveillance and presentation?

Time Period for the Activity (estimated start and end dates): August 2020 – September 2023

Existing Data Sources Held by the Division: CSTLTS/OPHLS currently holds preliminary datasets on state disease reporting laws in the Public Health Law Information Portal.

Existing Data from Other Sources: The datasets on state disease reporting laws held by the CSTLTS/OPHLS were constructed based on searches and data extraction from the following secondary data sources: Westlaw (for statutes and regulations) and health department websites (for disease lists and procedures).

New Data Collection: This activity involves ongoing search and data extraction from the aforementioned secondary data sources. New data will be collected as the dataset is updated following legislative sessions each year. Additional data elements may be added as need requires.

Study Design or Approach: Attorneys use legal epidemiology to build datasets that will allow researchers to view trends and variations across jurisdictions related to identified factors such as diseases and conditions required to be reported, the manner in which reporting must take place, and the information required to be reported. These legal epidemiology methods include the collection of legal text (state statutes, regulations, and policies), coding and qualitative analysis of legal text for the presence or absence of previously identified legal attributes. This portfolio is expected to grow and evolve over time.

Anticipated Challenges and Mitigation Strategies: There are several challenges with this project: (1) states use various legal and policy mechanisms to promulgate these requirements – statutes, regulations, health department websites – so ensuring a complete collection is challenging; (2) there are a tremendous number of laws in this domain – across at least fifty-one jurisdictions and covering over 485 reportable diseases and conditions; (3) designing a coding scheme that applies consistently across the wide array of mechanisms and jurisdictions; (4) designing a coding scheme that works applies across the hundreds of diseases and conditions covered by these laws. To address these challenges, researchers will make improvements to the coding scheme(s) through the systematic application of coding questions to sample states, strategically selected to represent the diversity of laws and jurisdictions. PHLP will also continue to engage with subject matter experts at CDC and STLT health departments and in healthcare settings.

Contributing Division: CMS

Activity Title: Maternal Opioid Misuse (MOM) Model Evaluation

HHS Priority Questions: 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?

Activity Description/Research Questions: MOM is a program for pregnant/postpartum Medicaid and CHIP participants with opioid use disorder (OUD). The MOM Model evaluation seeks to determine if evidenced-based, integrated care that includes access to medication assisted treatment (MAT) can improve outcomes and reduce costs for pregnant and postpartum women with opioid disorder and their infants. The evaluation seeks to build the evidence base for what works best for treating pregnant women with OUD, especially in light of multiple co-morbidity often present (particularly other substance abuse and behavioral health disorders). The evaluation also seeks to assess the effects of integrated care (including data sharing) among provider and social service entities. The research questions are: To what extent does implementing a coordinated care model for pregnant and postpartum women with OUD improve quality and reduce the costs associated with treating pregnant and postpartum women and infants affected by OUD? What are specific best practices for serving this population?

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

Existing Data Sources Held by the Division: Medicaid T-MSIS data for MOM Model awardees and potential comparison States (yet to be determined), including demographic and eligibility data, inpatient data, other services data, pharmacy data, and other T-MSIS data files

Existing Data from Other Sources: Vital records data provided by MOM Model awardees; Mother-infant dyad identifiers provided by MOM Model awardees; Ongoing literature reviews and environmental scans, including any new documents provided by MOM Model awardees; MOM Model awardee-reported, participant-level data on demographic characteristics, mental and physical health characteristics, substance abuse, social determinants of health data, service use type and frequency, and outcomes.

New Data Collection: 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: The evaluation will produce annual reports of model outcomes beginning with an evaluation of the model pre-implementation period (through June 20, 2021). The evaluation uses a theoretically guided, integrated mixed methods design. As such, each aspect of the evaluation continuously informs the others. Participant level data includes program-based quality measures and information on participants provided by care delivery partners. The qualitative analysis includes in-person and virtual site visits that involve environmental scans, interviews, focus groups, and innovative participant-directed methods. The quantitative analysis of claims and vital records (birth and death) will

include impacts analyses with comparison groups as possible. Where an impacts analysis is not possible, the evaluation will consider pre-post analysis and forms of descriptive statistical analysis.

Anticipated Challenges and Mitigation Strategies: An impact analysis may not be possible for all awardees (barriers include small sample sizes, difficulties in establishing appropriate comparison groups, and quality of claims data for this population).

Contributing Division: CMS

Activity Title: Integrated Care for Kids (InCK) Model Evaluation

HHS Priority Questions: To what extent do HHS programs and policies reduce costs and improve quality of health care 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?

Activity Description/Research Questions: The evaluation seeks to determine whether implementation of InCK improves health outcomes and reduces Medicaid costs among beneficiaries in the targeted population. The evaluation employs a mixed methods approach that includes measures for key service areas (clinical and behavioral health, food and housing security), rigorous qualitative case studies, and an impacts analysis of Medicaid claims data using within-state comparison groups. The primary questions for the pre-implementation period are:

What are the characteristics of the InCK population? What are barriers and facilitators to initiating InCK programs, including APM design? How do these barriers and facilitators differ by awardee and by local and state-specific contexts?

The primary evaluation questions for the implementation period are: Does the InCK intervention (including the APM) result in reduced total health care expenditures and improved quality of care, and specifically:

- a reduction in Medicaid and CHIP covered inpatient utilization and Emergency Department (ED) use?
- reductions in cost of care to Medicaid and CHIP?
- reductions in out of home placement (e.g., foster care, prolonged hospitalization)?

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

Existing Data Sources Held by the Division: Unredacted, Final and Preliminary T-MSIS Analytic Research Identifiable Files (TAF RIF) for the years covering 2017-2027; CMS TAF Vital Status Files for the years covering 2017-2027; Model documentation submitted by awardee recipients (ARs) including progress reports, operational plans, standard operating procedures, and applications/NCCs; Clinical and non-clinical performance measure data (to be captured by the Implementation and Monitoring contractor)

Existing Data from Other Sources: Area Health Resource File (<https://data.hrsa.gov/topics/health-workforce/ahrf>); HPSAs (<https://bhw.hrsa.gov/shortage-designation/hpsas>); US Census/American Community Survey (<https://www.census.gov/programs-surveys/acs/data.html>); Rural-Urban Commuting Areas (<https://www.ers.usda.gov/data-products/rural-urban-commuting-area-codes/>); Area Deprivation Index (<https://www.neighborhoodatlas.medicine.wisc.edu/>); COVID-19 data from USAFacts.org (<https://usafacts.org/visualizations/coronavirus-covid-19-spread-map/>); County Health Rankings (<https://www.countyhealthrankings.org/>); Social Determinants of Health (<https://www.ahrq.gov/sdoh/index.html>); Child welfare and foster care data: Data from states' Statewide Automated Child Welfare Information System (SACWIS) or Child Welfare Information Systems (CCWIS) or alternative administrative data system (specifically, data elements that support states' submissions to the Federal Adoption and Foster Care Analysis and Reporting System (AFCARS) and the National Child Abuse and Neglect Data System (NCANDS)); Juvenile justice data: Data from states' juvenile justice agencies, courts, or other sources containing data related to "systems that respond to youth that come into contact with law enforcement and are accused of breaking the law"; Education data: Data from states' education agencies and/or local school districts; Food security data: Data from 1) states' health departments, 2) human services / social services agencies, or 3) education agencies related to eligibility/utilization of food assistance or food-related needs; Cash assistance data: Data from states' health departments or human services / social services agencies related to eligibility/utilization of cash assistance programs; Housing data: Data from federal, state, or local agencies on eligibility/utilization of housing assistance

New Data Collection: Retrospective Attribution Files (collected by ARs); Retrospective Comparison Files (collected by ARs); Service Integration Level (SIL) Checklists (collected by ARs); Aggregate Performance Measures and underlying individual-level admin or EHR data (collected by ARs); Interviews with ARs ; Interviews with State Medicaid Agencies; Interviews with members of the Partnership Council; Interviews/focus groups with providers serving the attributed population and providers serving the comparison group population.; Interviews/focus groups/other TBD data collection with patients and families/caregivers potentially involved with and/or impacted by the InCK model

Study Design or Approach: The evaluation will produce annual reports of model outcomes beginning with an evaluation of model pre-implementation. Milestones are still being negotiated with awardees. The design plan for the implementation design is due in the fall of 2021. The evaluation uses an integrated mixed methods approach. As such, each aspect of the evaluation continuously informs the others. Quality measures and demographic information on participants are provided by awardees. The qualitative analysis includes in-person and virtual site visits that involve environmental scans, interviews, focus groups, and innovative participant-directed methods. The quantitative analysis of Medicaid (and CHIP where applicable) claims will include impacts analyses with comparison groups from non-overlapping areas in the same states where beneficiaries are served.

Anticipated Challenges and Mitigation Strategies: Implementation has not yet begun for this model, and quality of the anticipated data is unclear.

Contributing Division: CMS

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

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

Activity Description/Research Questions: The QIOs 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; and Training. CMS's evaluation strategy aims to understand: 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 impact, in addition to eliminating low-value, low-impact activities. The NQIIC Independent Evaluation Contractor executes a formative evaluation that plans to address the following priority questions: Which contractors are meeting which program targets? What strategies are they using to meet them? What barriers are keeping contractors from meeting targets and how can these be overcome? Annual provider satisfaction surveys will measure: What proportion of targeted providers use QIO contractor resources to improve health care quality? How satisfied are the providers with these resources? What can the QIOs do to improve satisfaction? The impact evaluation will measure: To what extent did the QIO program meet the targets for each quality improvement category? To what extent can we attribute the changes in outcomes associated with the categories to the quality improvement networks and/or other activities supported through the QIO? What are the likely projected and actual ROI for QIO program outcomes (both quantitatively and qualitatively)? How does ROI and impact vary by contractor? For COVID-19 response, what synergies were achieved between the QIOs and other major HHS programs, especially AHRQ's Project Echo?

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; Provider/Physician Performance (Hospital Compare, Nursing Home Compare, Physician Compare); Medicare Current Beneficiary Survey (MCBS); Deliverable Administration Review Repository Tool (DARRT) data

Existing Data from Other Sources: 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); National Healthcare Safety Network (NHSN); Tiberius data (HHS); Nursing Home Minimum Data set;

New Data Collection: QIN-QIO real-time collected data (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. 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: No challenges identified at this time.

Contributing Division: CMS

Activity Title: Section 2001 of the SUPPORT Act: Impact of Telehealth Amendments on Healthcare Utilization and Outcomes related to SUD

HHS Priority Questions: 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?

Activity Description/Research Questions: The SUPPORT for Patients and Communities Act provisions allow expanded telehealth reimbursement for individuals receiving treatment for SUD and co-occurring MH disorders; therefore, changes in telehealth use for these services is of interest. For our analysis, we will select individuals with a SUD diagnosis, and measure any telehealth use for SUD or MH treatment among this population. We will ask whether the use of telehealth for these services increased after enactment of the SUPPORT for Patients and Communities Act, compared to the year prior to enactment, by examining metrics associated with the following areas: SUD/MH treatment utilization; Emergency Department Visits Related to SUD; Follow-up After ED Visit; Overdoses; 2.1.2.5 Hospital Utilization Related to SUD; Treatment Lag; and Costs. Questions to Be Addressed in the Quantitative Analysis: 1) What is the impact of SUPPORT for Patients and Communities Act implementation on telehealth use for treatment of OUD and SUD and co-occurring MH disorders? 2) What is the impact of SUPPORT for Patients and Communities Act implementation on the following healthcare utilization outcomes? Emergency department (ED) visits related to SUD; Follow-up after an ED visit related to SUD; Hospitalization related to SUD; Treatment lag (i.e., time between diagnosis and treatment); Costs related to SUD and MH treatment reimbursement. 3) What is the impact of implementation of SUPPORT for Patients and Communities Act on the following health outcomes? Rate of overdoses, Rate of overdose deaths. Questions to Be Addressed in the Qualitative Analysis: 1) What, if any, are the key facilitators to implementation that have resulted in positive outcomes (clinical or non-clinical)? 2) What, if any, are the key barriers/challenges preventing effective and efficient implementation? 3) What, if any, are the unintended consequences associated with implementation?

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

Existing Data Sources Held by the Division: Medicare FFS Part A, Part B and Part D claims

Existing Data from Other Sources: Explore the use of social and geographic covariates, such as the Area Deprivation Index (ADI), other census block variables, or variables from the Health Resources and Services Administration (HRSA) Area Health Resources Files (AHRF). This evaluation will also look at

National Death Index (NDI) data, which is included in the Chronic Conditions Data Warehouse (CCW) for the years through 2016. The NDI is a compendium of death record information on file in state vital statistics offices and is maintained by the National Center for Health Statistics (NCHS) and the Centers for Disease Control and Prevention (CDC).

New Data Collection: Qualitative data collection will be conducted.

Study Design or Approach: The Health Federally Funded Research and Development Center (FFRDC) will first conduct descriptive analyses examining crude differences and rates of telehealth use and other, related outcomes across the three time periods (baseline; SUPPORT act implementation; COVID waivers), as well as by key demographic characteristics including (but not necessarily limited to) age, sex, race/ethnicity, disability status, comorbidities, urban or rural residence, urban or rural provider location, facility type, and other geographic and socioeconomic indicators. Telehealth use and outcomes may also be examined stratified by substance(s) used and by MH condition. We will also conduct descriptive analyses of OUD and SUD prevalence, deaths, overdoses, and related healthcare utilization, such as ED visits. Based on results from the descriptive analyses, we will construct analytic models that seek to determine changes in trends of telehealth use and other outcomes between the three time periods. We propose using regression discontinuity in time (RDIT), a regression-based analysis approach that tests for differences in outcomes between the different time periods, controlling for variables shown to be associated with each outcome. The primary goal of this analysis is to examine whether the SUPPORT for Patients and Communities Act telehealth policy change was associated with an overall difference in the rates of the various measured outcomes. In addition to the RDIT analysis, we propose conducting case-control analysis to address whether outcomes differ between individuals with SUD who received telehealth treatment compared to those who received treatment in-person only. For this analysis, we examine differences only among beneficiaries with SUD who received any form of SUD or MH treatment during the three time periods. Cases will be defined as those receiving any form of SUD or MH treatment via telehealth. Controls will be selected from those who received in-person only treatment and will be matched to cases based on propensity scores. Propensity scores will be generated using an artificial intelligence machine learning algorithm based on patient demographic, clinical (e.g., type of substance), and geographic characteristics. The goal of this analysis is to examine whether receiving these services via telehealth versus in-person only was associated with differences in the risk of experiencing various utilization and health outcomes, including emergency department visits and overdoses.

Anticipated Challenges and Mitigation Strategies: No challenges identified at this time.

Contributing Division: CMS

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

HHS Priority Questions: To what extent do HHS programs and policies reduce costs and improve quality of health care services?

Activity Description/Research Questions: The VBID Model allows Medicare Advantage organizations (MAOs) to further target benefit design to enrollees based on chronic condition and/or socioeconomic characteristics and/or incentivize the use of Part D prescription drug benefits through rewards and incentives. MAOs may also offer the Medicare hospice benefit to its enrollees as part of the VBID Model. Additionally, the VBID model requires that all participating plans 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 to Medicare. Research Questions:

Impact of the VBID Model (including Hospice component):

1) Eligibility and Enrollment:

Do participating plans enroll more or fewer enrollees over the course of the model test, and why?

2) Utilization and health outcomes:

Does the model result in targeted enrollees consuming fewer high-intensity services, such as emergency department visits and inpatient admissions?

Does the model improve targeted enrollees' overall health status and specific conditions? What, if any, impact does the model have on enrollees' risk scores?

How does the hospice benefit component of the model impact the decision to elect hospice, and the timing of hospice election, by enrollees?

How does the model affect enrollee hospice experience, as measured by visits in the last week of life, likelihood of live discharge/transfer/revocation, among others? Where relevant, how do these utilization patterns differ between hospice patients in MA vs FFS?

3) Cost:

What is the model's impact on plans' cost (both medical and drug benefit)?

What is the model's effect on plans' bids, for Parts C and D?

What is the model's impact (if any) on targeted enrollees' and non-targeted enrollees' overall cost-sharing, premiums and the availability of supplemental benefits for non-targeted enrollees in participating plans?

What factors or variables are driving any increases or decreases in plan's costs and bids?

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

Existing Data Sources Held by the Division: Medicare Advantage plan enrollment/disenrollment files, Fee-for-Service claims, Medicare Advantage Organizations encounter, Bid Pricing Tool, Provider of

Service, Hospice Item Set, Prescription Drug Event, Star ratings, risk scores, Reusable Framework monitoring data (submitted by VBID plans)

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

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 in 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 will 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 will estimate how MAOs' participation in the VBID model test affected outcomes. For most analyses, we will 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 will characterize the experience of beneficiaries, providers, and MAOs with VBID through a series of semi-structured telephone interviews.

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

Contributing Division: FDA

Activity Title: Modeling the evolution of the U.S. opioid crisis for national policy development

HHS Priority Questions: How do HHS policies and programs promote healthy lifestyle choices to reduce occurrence and disparities in preventable injury, illness, and death?

Activity Description/Research Questions: This is a modeling activity with a systems approach to capture major dynamics in the opioid crisis, to be able to assess short term and long term, intended and unintended consequences of potential policies

Time Period for the Activity (estimated start and end dates): 2019 - Ongoing

Existing Data Sources Held by the Division: N/A

Existing Data from Other Sources: IQVIA, NSSATS, NFLIS, TEDS-A, NVSS, NBER, Symphony Health, NSDUH

New Data Collection: N/A

Study Design or Approach: The model has been built using System Dynamics methodology, which is a differential equation simulation modeling technique. Additional data science techniques and methods have been used to prepare and utilize the data for this model.

Anticipated Challenges and Mitigation Strategies: Data scarcity in this arena remains the biggest challenge (i.e., we lack true longitudinal, national level drug use data). Other challenges include lack of comprehensive understanding on some of the underlying behavioral dynamics.

Contributing Division: FDA

Activity Title: Outcome Measures Integration Workgroup/Food Safety Dashboard

HHS Priority Questions: How can HHS programs and policies improve the promotion of effective enterprise governance to ensure programmatic goals are met equitably and transparently across all management practices?

Activity Description/Research Questions: The OMI workgroup is responsible for implementing measures to track the progress of the Food Safety Modernization Act (FSMA). The Workgroup utilizes the Food Safety Dashboard to monitor progress and performance towards achieving key outcomes over time. The research Question is: How can HHS programs and policies best protect the food and medical supply chains?

Time Period for the Activity (estimated start and end dates): 2016 - Ongoing **Existing Data Sources Held by the Division:** Domestic and Foreign PCHF Inspections (including classifications); Domestic and Imported Recall Events (Class I and II); Foreign Supplier Verification Program (FSVP) Inspections

Existing Data from Other Sources: N/A

New Data Collection: N/A

Study Design or Approach: The FDA has finalized seven major rules to implement FSMA, recognizing that ensuring the safety of both the human and animal food supply is a shared responsibility among many different parties at various points in the global supply chain. The FSMA rules outline specific

actions the food industry must take at each of these points to prevent contamination. For each rule, the FDA has identified measures that will help to evaluate how well the regulations are being implemented and where there could be room for improvement. The agency anticipates these performance measures will evolve and improve over time as the agency and its partners continue to implement FSMA and collect more and better-quality data. FDA will update the Food Safety Dashboard on a quarterly basis.

Anticipated Challenges and Mitigation Strategies: The compliance dates for the FSMA rules were staggered over time, largely based on business size, and some entities still have not reached certain compliance dates. Routine inspections for others may only just be starting. This means that the early data collected based on these performance measures will reflect the current status of implementation. Depending on the measure, it may take several years to establish baselines and identify meaningful trends in FSMA implementation.

Contributing Division: HRSA

Activity Title: Healthy Start (HS) Evaluation & Capacity Building Support

HHS Priority Questions: 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?

Activity Description/Research Questions: 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. The research question is: To what extent are HHS programs associated with improved health status among participants served, and how effective are HHS programs in addressing maternal and infant health disparities?

Time Period for the Activity (estimated start and end dates): Sept 2021 - Sept 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: CDC Pregnancy Risk Assessment Monitoring System (PRAMS)

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 impact 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.

Contributing Division: HRSA

Activity Title: Collaborative Health Equity Measurement (CHEM) Project in Maternal and Child Health

HHS Priority Questions: 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? How can HHS programs and policies improve 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?

Activity Description/Research Questions: This is an evidence-building effort to support development of common measures for health equity in maternal and child health (MCH) and expand the capacity and use of meaningful and practical health equity measures to track the impact of MCH programs on health equity, for two main audiences: (1) states and communities nationwide and, (2) HRSA Maternal and Child Health Bureau grantee programs. The activity will support measuring the baseline of health equity in MCH populations and monitor the trend. The research question is: How can HHS health and social services policies and programs improve equity for the Maternal and Child (MC) population in the US? How can HHS policies and programs address upstream social determinants of health to improve overall health status and disease burden in MC population?

Time Period for the Activity (estimated start and end dates): July 1, 2022 – January 1, 2024

Existing Data Sources Held by the Division: MCHB Health Equity Performance Measures and data reported within the Child & Adolescent Health Measurement Initiative; MCHB data collection systems for discretionary and non-discretionary grant programs; Title V Block Grant reporting related to equity

Existing Data from Other Sources:

New Data Collection: Public datasets that measure health equity and social determinants of health at the national, state, and local level

Study Design or Approach: Direct estimation and/or small area analysis (SAE) to measure health equity among MCH populations at the national, state, and local-level; data tables that contain national, state, and local-level estimates for the health equity measures; stratified data to be incorporated into the MCHB data warehouse.

Anticipated Challenges and Mitigation Strategies: The methodology for the SAE may take time to develop which may delay the progress of the project. To prevent it from happening, OER staff will identify the needed datasets and the methodology while developing the contract SOW, and invite SAE methodology experts to be on the expert panel.

Contributing Division: NIH

Activity Title: Impact Assessment – Opioid and Chronic Pain Pathways to Prevention Workshop

HHS Priority Questions: 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? How can HHS programs and policies improve 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?

Activity Description/Research Questions: The NIH Office of Disease Prevention is currently conducting an impact assessment of the recommendations that resulted from the 2014 Pathways to Prevention (P2P) Workshop- The Role of Opioids in the Treatment of Chronic Pain. The workshop addressed four key areas, including the long-term effectiveness of opioids; the safety and harms of opioids in patients with chronic pain; the effects of different opioid management strategies; and the effectiveness of risk mitigation strategies for opioid treatment. The workshop was designed to identify future research needs and priorities to improve the treatment of pain with opioids. Results of the impact assessment will inform how well this workshop influenced future funding in this area as well as how to improve the design of future P2P workshops.

Time Period for the Activity (estimated start and end dates): Fall 2021 – Fall 2022

Existing Data Sources Held by the Division: iSearch – Grants (including the Portfolio tool) iSearch – Publications; iCite; RCDC

Existing Data from Other Sources: Almetric

New Data Collection: N/A

Study Design or Approach: Three products were produced as a result of the P2P workshop which outlined key research gaps and recommendations to address these gaps. The impact assessment will include three components:

- (1) portfolio analysis – assess NIH grant portfolio of funding announcements and research funding post-workshop.
- (2) bibliometric analysis – use citation data to assess the impact of publication of systematic evidence review and recommendation by external panel.
- (3) key leader and stakeholder interview – anecdotal insight regarding the key activities and collaborations that resulted from the workshop proceedings and recommendations.

Anticipated Challenges and Mitigation Strategies: It may be difficult to provide a causal link between the recommendations and the resulting funding opportunity announcements and grants that don't specifically cite the P2P workshop. NIH will complement the quantitative analyses with key leader and stakeholder interviews who provided subject matter expertise during the workshop process and oversaw/guided the resulting activities and collaborations.

Contributing Division: NIH

Activity Title: Cancer Moonshot Assessment

HHS Priority Questions: How can HHS programs and policies improve 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?

Activity Description/Research Questions: The Cancer Moonshot is an exceptional opportunity to accelerate progress in cancer prevention, diagnosis, treatment, and care. The 21st Century Cures Act provided 7 years of funding for the initiative from FY 2017 through FY 2023. The National Cancer Institute (NCI) is conducting a data-driven overall assessment to look at cross-Moonshot trends that will complement ongoing and planned evaluations of a subset of individual initiatives that are occurring throughout NCI. The overall assessment focuses on the overarching goals of the Moonshot: generating new knowledge, fostering collaboration, and improving data sharing.

Time Period for the Activity (estimated start and end dates): 2019 - 2027

Existing Data Sources Held by the Division: NIH administrative funding data – grants, cooperative agreements, contracts, and intramural research project data; Publication and clinical trials data

Existing Data from Other Sources: US patent data; Dimensions Database

New Data Collection: Data associated with data sharing metrics

Study Design or Approach: Impacts and outcomes of scientific funding typically become apparent years after the investment. As a result, the assessment will be divided into two phases – phase 1 (Data Collection, Monitoring, and Interim Reporting) is the development of an evidence base that both supports annual reporting and will be used as an input for phase 2, the final assessment. The evidence base will include both quantitative data and qualitative data collected through automated and manual methods. Portfolio analysis will be conducted to understand the Cancer Moonshot investment, the workforce funded by the Cancer Moonshot, and the outputs and achievements from the Cancer Moonshot funds.

Anticipated Challenges and Mitigation Strategies: In general, a challenge of this type of assessment is the lag time between investment in research and notable societal benefit. In addition, societal benefit of a particular investment often cannot be directly measured. This can be compensated for by the use of surrogate measures of impact. Specific to this assessment, challenges exist in ways to measure data sharing. A number of possible methods and metrics for this are being explored, and NIH anticipates that new methods may be developed by the research community as there is increased use of shared data sets.

Contributing Division: NIH

Activity Title: Analyzing the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Data Science portfolio and Developing Plans for NIDDK implementation of the New NIH Data Management and Data Sharing Policies

HHS Priority Questions: How can HHS programs and policies improve 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?

Activity Description/Research Questions: NIDDK has embarked on an evidence-based approach to: a) evaluate current data science activities to plan for future data science needs, and b) assess the types of data NIDDK-supported investigators generate.

Time Period for the Activity (estimated start and end dates): January 2021 – January 2023

Existing Data Sources Held by the Division: NIH Information for Management Planning, Analysis, and Coordination (IMPAC II); NIDDK Data Repository; NIDDK Intramural investigators; NIH Intramural Databases

Existing Data from Other Sources: N/A

New Data Collection: N/A

Study Design or Approach: NIDDK is developing a sampling algorithm that seeks to target about 20% of all new NIDDK awards from the past five years. It will develop the algorithm to ensure that it includes a representative sampling with respect to institution type, science type, and discipline. A data science

contractor will evaluate the dataset and then answer a set of questions developed by NIDDK about the awards.

Anticipated Challenges and Mitigation Strategies: One challenge is balancing cost/level of effort and informativeness. NIDDK prefers a sampling algorithm that provides the smallest set of data that is sufficiently representative of the Institute's entire portfolio given the logistical constraints. A second challenge is in developing a set of questions that can adequately inform both policy decisions and strategic planning for future data science needs.

Contributing Division: ONC

Activity Title: ONC Certification Program Evidence Building

HHS Priority Questions: How can HHS programs and policies improve 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?

Activity Description/Research Questions: The key goal of this project is to identify the impacts of the ONC Health IT Certification Program on health IT. This will be an ongoing analysis of the Program through data collection from multiple sources. The results of this analysis will be used to assess the progress of the Program as well as inform future policy making. The research Question is: In what ways is certification of health IT improving the access, exchange, and use of electronic health information for patient care?

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

Existing Data Sources Held by the Division: Data from the Certified Health IT Products List; Centralized Feedback System

Existing Data from Other Sources: Health IT Surveys (e.g., AHA, NEHRS, HINTS, LOINC); CMS Promoting Interoperability Program data

New Data Collection: Real World Testing data; EHR Reporting Program data; New Surveys

Study Design or Approach: ONC will primarily be conducting quantitative analyses, looking at progress in key areas over time. ONC measures interoperability through healthcare providers' ability to query, send, receive, and integrate electronic health information into their systems. In addition to exchange of patient health records, this analysis will explore the impacts on improving exchange of health information in areas of public health, SDOH, patient access, and other areas related to the HHS Federal Health IT Strategic Plan.

Anticipated Challenges and Mitigation Strategies: In order to get a clearer picture of what is happening in health IT interoperability, ONC will attempt to collect real world data. ONC expects challenges in the diversity and quality of such data. Thus, ONC is working with subject matter experts to best determine the requirements for collecting this data.

Contributing Division: SAMHSA

Activity Title: Internal Formative Evaluation of the Projects for Assistance in Transition from Homelessness (PATH)I

HHS 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?

Activity Description/Research Questions: 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 research question is: How can HHS health and social services programs increase access to those experiencing homelessness?

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

Existing Data Sources Held by the Division: PDX

Existing Data from Other Sources: Web-based survey

New Data Collection: N/A

Study Design or Approach: Mixed method approach

Anticipated Challenges and Mitigation Strategies: Delay in data collection

Contributing Division: SAMHSA

Activity Title: SAMHSA's Report to Congress on Garrett Lee Smith (GLS) Youth Suicide Prevention and Early Intervention Program.

HHS Priority Questions: How do HHS policies and programs promote healthy lifestyle choices to reduce occurrence and disparities in preventable injury, illness, and death?

Activity Description/Research Questions: Performance measurement and outcome evaluation to evaluation how HHS programs can reduce suicidal ideation leading to reductions in mortality and morbidity among youth across the country

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

Existing Data Sources Held by the Division: SAMHSA's Performance and Accountability Reporting System (SPARS), Infrastructure Development, Prevention and Mental Health Promotion (IPP) measures

Existing Data from Other Sources: N/A

New Data Collection: N/A

Study Design or Approach: Examination of program data over time and with particular emphasis on priority and high risk populations

Anticipated Challenges and Mitigation Strategies: Delay in data collection

Contributing Division: SAMHSA

Activity Title: Performance Measurement of SAMHSA's discretionary grants (40-50 Program Profiles)

HHS Priority Questions: How can HHS programs and policies improve 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?

Activity Description/Research Questions: Performance measurement, portfolio analysis, and data dissemination to understand how the ongoing assessment of clients' demographic and associated early outcomes data can help HHS leaders to make data-driven decisions.

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

Existing Data Sources Held by the Division: SPARS

Existing Data from Other Sources: N/A

New Data Collection: N/A

Study Design or Approach: The profiles share descriptive data, frequencies and formative evaluation data including short term outcomes

Anticipated Challenges and Mitigation Strategies: Delay in data collection due to COVID-19 pandemic