

# Building the Data Capacity for Patient-Centered Outcomes Research:

## The 2019 Annual Report Executive Summary

Office of Health Policy  
Assistant Secretary for Planning and Evaluation  
U.S. Department of Health and Human Services



## Introduction

Since 2010, the Office of Health Policy of the Office of the Assistant Secretary for Planning and Evaluation (ASPE) has funded and supported a portfolio of approximately 70 individual projects aimed at building data infrastructure capacity for patient-centered outcomes research (PCOR). The Office of the Secretary Patient-Centered Outcomes Research Trust Fund (OS-PCORTF) has funded a rich portfolio of projects to meet emerging U.S. Department of Health and Human Services (HHS) policy priorities and fill gaps in data infrastructure to enhance capabilities to collect, link, and analyze data for patient-centered research. The OS-PCORTF portfolio includes projects that are developing and testing standards that improve data interoperability, piloting novel approaches to patient-provided data collection, using real-world data (RWD) in evidence generation, and addressing challenges to data linkages.

This annual report provides a synopsis of the 27 OS-PCORTF projects that were active in Fiscal Year (FY) 2019. The topics of these projects simultaneously respond to the Secretary's priorities, address major federal legislation, and individual agency data strategies and evolving patient-centered research needs. This report also contains a synthesis of the work of six projects that concluded activities in FY 2019; an analysis of how active FY 2019 projects are meeting key HHS policy priorities; and individual project profiles for each active project in 2019 that describe the project goals, objectives, major accomplishments, and disseminated products.

## 2019 Major Accomplishments

Six OS-PCORTF projects that concluded in 2019 offered meaningful, usable solutions that build data infrastructure that researchers and/or clinicians can use for patient-centered outcomes research and patient care. These accomplishments occur in the following areas:

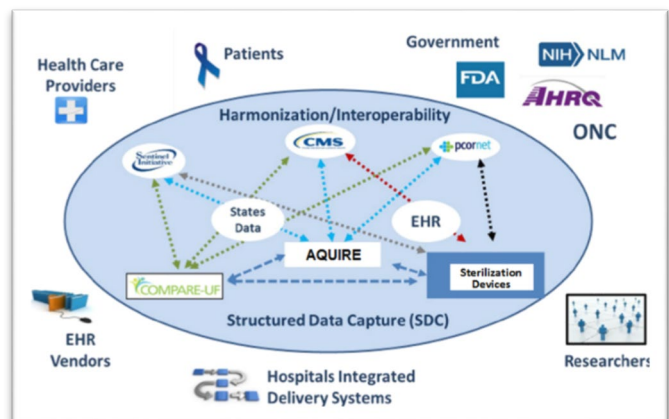
- 1. Tools for Enhancing Patient Participation in Research and Access to Patient-Reported Outcomes (PROs).** To better integrate patient perspectives into health care research and care delivery, PROs must be captured in standardized ways and incorporated into the patient's electronic health record (EHR). To address the issue, the Agency for Healthcare Research and Quality (AHRQ) and the Office of the National Coordinator for Health IT (ONC) collaborated on a project called *Advancing the Collection and Use of PROs through Health IT*. The project modified an existing application used to collect PROs and developing a new app to capture and integrate PRO data into electronic health record (EHR) systems in a user-friendly way. The apps allow patients to easily report health information outside of the health care setting, enabling providers to view that information in their EHR systems alongside other clinical data, to guide future discussions and clinical decision-making.
- 2. Tools for Linking Data across Databases and Research Registries.** Data related to certain health treatments and outcomes are often captured in a variety of databases and registries whose data are not necessarily complete, standardized, and shareable among the larger research community. Lack of

standardized data from diverse sources means that robust research is difficult and creates gaps in evidence-based guidance for specific health issues. To address this issue in women’s health, the Food and Drug Administration (FDA), National Institutes of Health (NIH)/National Library of Medicine (NLM), and ONC collaborated on a project, *Developing a Strategically Coordinated Registry Network (CRN) to Support Research on Women’s Health Technologies*. This project created the Women’s Health Technologies Coordinated Registry Network (WHT-CRN). WHT-CRN consists of four data sources (registries, claims, EHR data, and PROs) totaling over 550,000 records with detailed data and statistics for each, describing population demographics, disease presentation, device exposure, follow-up duration, and relevant clinical outcomes.<sup>1</sup> The project identified data elements commonly captured across four women’s health issues and then harmonized them so that registries can capture these data in a standardized way, enabling research around the safety of devices that address these conditions.



- Tools to Standardize Data for Analysis across Networks.** Using diverse data sources benefits research by allowing studies to take in data that is more representative of a greater number of patients. However, researchers often find the data difficult to compare across sources because the information is collected and coded in different ways. There is a need for standardization across clinical areas and data sources (e.g., EHRs, administrative claims data, registries). Two portfolio projects targeted the need to build bridges across networks and databases, so that information captured in each source can be combined and used for research. The first project, *Harmonization of Various Common Data Models and Open Standards for Evidence Generation*, was a collaboration between the FDA, ONC, and NIH that sought to harmonize the data available in four major research networks to make it easier to conduct research across the networks. The second project, FDA’s *Standardization and Querying of Data Quality Metrics and Characteristics for Electronic Health Data*, created an online platform and toolkit to help researchers identify high quality “real-world data” sources that can be incorporated into their studies.

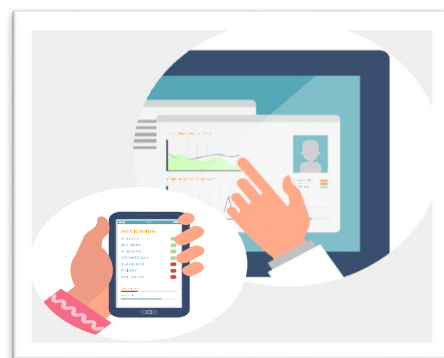
- Methods for Converting Narrative Text into Data That Can Be More Easily Analyzed for Public Health.** Narrative text data, such as a doctor’s description of a medication plan, is common in clinical reports and EHRs and serves as a rich source of information. However, unstructured text is difficult for researchers to extract and analyze. To create better tools for standardizing narrative data, the



Centers for Disease Control and Prevention (CDC) and FDA conducted a project for the *Development of a Natural Language Processing (NLP) Web Service for Public Health Use*. The team built the Clinical Language Engineering Workbench (CLEW) platform, which uses natural language processing (NLP) to help researchers convert unstructured, open-text clinical information into structured, standardized coded data that can be easily analyzed for research. The CLEW provides free access to vetted, open-source NLP and machine learning tools to assist engineers to develop new NLP applications that address specific domain needs.

5. **Tools for Supporting Research through Patient-Donated**

**Data.** The *All of Us* Research Program is a national, large-scale research enterprise designed to support discoveries that increase the health system’s ability to better treat and prevent disease. Achieving this goal will involve enrolling 1 million or more volunteers who are willing to donate their health data for research and analysis. The NIH and the Centers for Medicare & Medicaid Services (CMS) project, *Technologies for Donating Medicare Beneficiary Claims Data to Research Studies*, was designed to increase patient



engagement in the *All of Us* Research Program and other research by creating an easy process for data donation. The project collaborated with multiple EHR vendors to build secure mechanisms (e.g., patient portals, apps, and application programming interfaces [APIs]) to allow Medicare beneficiaries to donate their medical and prescription drug claims data (i.e., Medicare Parts A, B, and D claims data) to research studies in which they choose to participate. Lessons from this project are applicable to future efforts to enable patients to donate their health data to support a wide range of health care studies.

## Portfolio Contributions to Key HHS Policy Priorities

Over the years the OS-PCORTF portfolio has evolved to support the data infrastructure needs of HHS policy priorities. This has included promoting inter-agency collaboration around linking data sets and making data more accessible for research, testing new tools and services for data linkage and de-duplication, and supporting the development of innovative data resources and analytic approaches.<sup>2</sup>

This report highlights four key policy areas in which current OS-PCORTF projects are working to develop solutions:

### Increase the Use of Real-World Data for Evidence Generation

The FDA’s Real-World Evidence Framework seeks to encourage real-world or clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of RWD, which can come from a range of sources including EHRs, claims data, registries, and patient-generated health data (PGHD).<sup>3</sup> These data are often difficult to access because of a lack of data standardization,



cost, patient privacy, or other legal and intellectual property restrictions. Further, due to a variety of interoperability issues, it is often difficult to bring data together from different RWD sources. As HHS agencies consider how to leverage RWD to inform key decisions, standardized approaches for evaluating these data and curating processes to ensure their fitness for the intended use are necessary.<sup>4</sup> Several OS-PCORTF projects are working to address gaps in the accessibility and use of RWD sources by standardizing and building linkages across RWD sources:

- The FDA's 2016 project, ***Standardization and Querying of Data Quality Metrics and Characteristics for Electronic Health Data***, helps researchers incorporate real-world data into their studies. The project has created an online platform with an open-source toolkit that contains visualization and analytic tools, and a data quality model to help researchers compare, contextualize, and assess the quality and appropriateness of data sources for their research questions, regardless of the different common data models (CDMs) involved.
- The FDA's 2018 project, ***Source Data Capture from Electronic Health Records: Using Standardized Clinical Research Data***, created a platform (OneSource) with tools and methods to automate the flow of structured clinical EHR data into systems that support clinical trials. Removing manual processes improved the speed and efficiency of data transfer, reduced costs and burden for healthcare providers and research staff, and improved the data quality.
- The FDA's 2019 project on ***Bridging the PCOR Infrastructure and Technology Innovation through Coordinated Registry Networks (CRN) Community of Practice (COP)*** builds upon the work of a previous OS-PCORTF project that created a women's health CRN. The team is strengthening the CRN by harmonizing their core minimum data sets, including device identification numbers, adding patient-generated data, and building Communities of Practice (COPs) across 12 clinical conditions to connect and use diverse data sources for research (i.e., clinical, claims, registries).
- The NIH's 2016 project, ***Use of the ADAPTABLE Trial to Strengthen Methods to Collect and Integrate Patient-Reported Information with Other Data Sets and Assess Its Validity***, the team developed, piloted, and evaluated methods to validate and integrate patient-reported information with EHR data. The project team developed a Patient-Reported Data Assessment Tool that allows investigators to evaluate the quality of their own patient-reported data by comparing it to EHR data using a menu-driven query tool.
- The CDC's FY 2018 ***Childhood Obesity Data Initiative (CODI): Integrated Data for Patient-Centered Outcomes Research Project*** is developing and testing an expanded common data model including pediatric obesity-related information, patient linkage and de-duplication tools, and data query services to bring together data stored across different organizations to create an individual-level, linked longitudinal record that includes individual and community-level risk factors, weight management interventions delivered in clinical and community settings, and clinical outcomes across health information systems. The AHRQ and the Office of the Assistant Secretary for Preparedness and Response (ASPR) FY 2018 project ***Assessing and Predicting Medical Needs in a Disaster*** is working to build a data platform to analyze an expanded Healthcare Cost and Utilization Project (HCUP) data set (used to identify, track, and analyze national trends in health care utilization, access, charges, quality, and outcomes) to include quarterly emergency department and inpatient data.

- Finally, the FY 2019 CDC project, ***Making Electronic Health Record (EHR) Data More Available for Research and Public Health***, is focused on building greater interoperability across EHR systems by developing an application that can extract data from multiple clinical organizations using multiple EHR platforms. This data will be mapped to a common data model (CDM), the technical building blocks that will make data compatible across different systems.

## **Improve Women and Maternal Health Outcomes by Establishing and Enhancing the Data Infrastructure Needed to Support Women’s Health Research**

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Women’s and maternal health outcomes data are often captured across multiple, disparate platforms using unique data elements that limit researchers’ ability to view and analyze these data in aggregate. OS-PCORTF projects are working to establish and enhance the data infrastructure needed to support surveillance for women’s health research in several ways:

- One project, ***Developing a Strategically Coordinated Registry Network (CRN) for Women’s Health Technology*** (or, WHT-CRN), is a collaboration between the FDA, NLM, and ONC that began in FY 2017, developed an infrastructure to evaluate medical devices in three clinical areas unique to women’s health: uterine fibroid treatments, pelvic organ prolapse treatments, and elective female sterilization therapies. The WHT-CRN supports use of diverse registry data sources and standardized data elements for post-market surveillance of therapies and evidence generation to the development of innovative therapies for women’s health. The project has produced a publicly available Fast Healthcare Interoperability Resources (FHIR®) Implementation Guide to describe the technical requirements needed for others to use the data sources and standardized data elements created by the project to exchange women’s health data.
- The CDC, in partnership with NIH, the Substance Abuse and Mental Health Services Administration (SAMHSA), and CMS, are tackling the challenge of a lack of national-level data on maternal health outcomes through an FY 2019 project establishing the ***MAT-LINK: MATernaL and Infant Network to Understand Outcomes Associated with Treatment for Opioid Use Disorder during Pregnancy***. Specifically, the MAT-LINK network is working to enhance the data infrastructure for surveillance of maternal (as well as infant and child) health outcomes associated with medication-assisted treatment (MAT) for opioid use disorder (OUD) during pregnancy.

## **Address the Opioids Epidemic through Better Data and Data Infrastructure for PCOR**

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HHS has led the federal response to the opioid crisis through its 5-Point Strategy to Combat the Opioid Crisis, which includes the need for “better data” or data collection efforts that are timely and specific to inform real-time public health responses.<sup>5</sup> In 2019, eight OS-PCORTF projects across HHS agencies were working to expand data capacity or data infrastructure for patient-centered outcomes research on opioids.

One area of focus is around building linkages across data sources to better address comorbidities:

- The CDC, in partnership with SAMHSA, FDA, the NIH/National Institute on Drug Abuse (NIDA), and the NIH/National Institute of Mental Health (NIMH), has been working on a project around ***Identifying Co-Occurring Mental Health Disorders among Opioid Users Using Linked Hospital Care and Mortality Data*** to address the lack of data on health outcomes of opioid users with co-occurring substance use and mental health issues. The purpose of this project is to build an enhanced, linked data set using National Center for Health Statistics (NCHS) National Health Care Survey/National Death Index (NDI)/National Vital Statistics System's restricted-use mortality files on drug overdose death (NVSS-M-DO) as well as additional information on co-occurring disorders.
- ASPE's and the Administration for Children and Families' (ACF's) ***Linking State Medicaid and Child Welfare Data for Outcomes Research on Treatment for Opioid Use Disorder (OUD)*** project is working to address comorbidities related to OUD through a pilot-testing linkage between state Medicaid records with records for parents and children involved in the child welfare system. This will allow identification of parents with children in the child welfare system to enable researchers to better understand their needs.

A second area of focus is around building capacity for the collection of PROs related to OUD:

- In FY 2018, NIDA initiated the ***Emergency Medicine Opioid Data Infrastructure: Key Venue to Address Opioid Morbidity and Mortality*** project, which seeks to standardize data to track patients presenting in the emergency department, a main point of entry into the health care system for many OUD patients. The work will improve interoperability across EHRs, research networks and registries to enable researchers to aggregate opioid relevant data elements, including PROs.
- In FY 2019, NIDA initiated ***AMNET: An Addiction Medicine Network to Address the Opioid Epidemic in the United States***. Through this project, NIDA is working to establish a new practice-based research network and an electronic patient registry to gather standardized data on patients' characteristics, treatments, and outcomes for patients treated with buprenorphine and naltrexone in office-based practices.

## Support Value-Based Care Transformation by Promoting Interoperability and Care Coordination

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The transformation of the U.S health care system to a value-based care (VBC) system has been an incremental process supported by legislation such as MACRA, as well as numerous agency programs intended to incentivize performance rather than volume.<sup>6</sup> The quality, safety, and patient outcomes goals underlying VBC require building greater interoperability across data systems to maximize care coordination and enable organizational efficiencies. OS-PCORTF projects are working to support VBC transformation in a variety of ways:

- AHRQ and the NIH/National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) initiated an FY 2019 project on Data Capacity for Patient-Centered Outcomes Research through Creation of an Electronic Care Plan for People with Multiple Chronic Conditions. The project team is working to build data capacity to improve the continuum of care for people with multiple chronic

conditions (MCCs) by developing an interoperable, accessible electronic care (eCare) plan that extracts data from EHRs to facilitate aggregation and sharing of critical patient-centered data across home-, community-, clinic-, and research-based settings.

- Under VBC programs, EHR data are frequently used for quality reporting through electronic clinical quality measures. ASPE, AHRQ, and CDC are collaborating on an FY 2019 project around ***Validating and Expanding Claims-based Algorithms of Frailty and Functional Disability for Value-based Care and Payment***. The project seeks to refine and validate claims-based algorithms around frailty and functional disabilities using EHR databases. The project began working to identify patients with frailty and functional disabilities across payer and patient populations (Medicare, Medicaid, dual) to create indicators of frailty and functional disability, which can be used to assess quality of care in VBC programs.
- Addressing social determinants of health (SDOH) provides clinicians with a greater understanding of patient needs in order to increase the quality and lower the cost of care. Under the FY 2019 project ***Enhancing Patient-Centered Outcomes Research (PCOR): Creating a National Small-Area Social Determinants of Health Data Platform***, AHRQ and CDC are working to develop a consolidated set of national standardized databases on valid and reliable SDOH factors at the small-area and other geographic levels, building on existing federal databases. The project will make this longitudinal data set of SDOH variables for use by researchers working to better understand the impact of value-based care at a small-area level.

## Overview of New FY19 Projects

There were 27 projects active in FY 2019, of which 13 were new additions to the portfolio in 2019 (Exhibit 1). New projects in 2019 demonstrate the range of data capacity-building projects and the breadth of the portfolio to address emerging policy areas, including substance abuse and mental health, value-based care, patient empowerment and interoperability, data innovation, and—most recently—a focus on expanding data capacity or infrastructure for current policy priorities including the opioids epidemic, reducing the prevalence of childhood obesity, and improving emergency preparedness and response.

**Exhibit 1.** OS-PCORTF FY 2019 New Projects

Active Project	Project Description
<b>Agency for Healthcare Research and Quality (AHRQ)</b>	
<p><i>Enhancing Patient-Centered Outcomes Research (PCOR): Creating a National Small-Area Social Determinants of Health (SDOH) Data Platform</i></p>	<ul style="list-style-type: none"> <li>■ Develop a consolidated set of national standardized databases on valid and reliable SDOH factors at the small-area and other geographic levels to increase longitudinal data on SDOH available for patient-centered health services research.</li> </ul>



Active Project	Project Description
<b>Centers for Disease Control and Prevention (CDC)</b>	
<i>Augmenting the National Hospital Care Survey (NHCS) Data through Linkages with Administrative Records: A Project</i>	<ul style="list-style-type: none"> <li>■ Link the 2016 NHCS with Medicare Fee-for-Service claims data and federal housing assistance program data collected from the U.S. Department of Housing and Urban Development (HUD). The linked data will allow researchers to examine the role of federal social support programs in health outcomes and treatment efficacy for persons with stable housing and will feature the ability to focus on specific subpopulations, including persons with substance use disorders.</li> </ul>
<i>Identifying Co-Occurring Disorders among Opioid Users Using Linked Hospital Care and Mortality Data: Capstone to an Existing FY18 PCORTF Project</i>	<ul style="list-style-type: none"> <li>■ Develop a new set of algorithms using the linked NHCS, NDI, and NVSS-M-DO to identify patients with an opioid event and co-occurring mental health disorders.</li> </ul>
<i>Making Electronic Health Record (EHR) Data More Available for Research and Public Health</i>	<ul style="list-style-type: none"> <li>■ Develop and test an application to support the real-time data extraction and exchange of data between EHRs and public health systems.</li> </ul>
<i>MAT-LINK: MATernaL and Infant Network to Understand Outcomes Associated with Treatment for Opioid Use Disorder during Pregnancy</i>	<ul style="list-style-type: none"> <li>■ Establish a surveillance network to monitor maternal, infant, and child health outcomes following treatment for OUD during pregnancy to inform patient-centered care for pregnant women with OUD and for infants and children with prenatal opioid exposure.</li> </ul>
<b>Food and Drug Administration (FDA)</b>	
<i>Bridging the PCOR Infrastructure and Technology Innovation through Coordinated Registry Networks (CRN) Community of Practice (COP)</i>	<ul style="list-style-type: none"> <li>■ Strengthen the CRNs as a RWD source for high quality, relevant, reliable, timely and actionable evidence to improve patient outcomes of medical devices, specifically for technologies affecting women's health. The CRN CoP will promote registries maturity through harmonization of their minimum core data sets, commitment to incorporation of device identification, patient engagement throughout and by facilitating the linking of registries to other data sources.</li> </ul>
<i>SHIELD—Standardization of Lab Data to Enhance Patient-Centered Outcomes Research and Value-Based Care</i>	<ul style="list-style-type: none"> <li>■ Improve the quality and semantic interoperability of laboratory data within and between institutions so that diagnostic information can be pulled from different sources or shared between institutions to help illuminate clinical management and understand health outcomes.</li> </ul>
<b>National Institutes of Health (NIH)</b>	
<i>NIDA's AMNET: An Addiction Medicine Network to Address the United States Opioid Crisis</i>	<ul style="list-style-type: none"> <li>■ Establish a new practice-based research network and electronic patient registry to improve the study of medication-assisted drug therapy in office-based practices.</li> </ul>
<b>Office of the Assistant Secretary for Planning and Evaluation (ASPE)</b>	
<i>Linking State Medicaid and Child Welfare Data for Outcomes Research on Treatment for Opioid Use Disorder</i>	<ul style="list-style-type: none"> <li>■ Develop a linked data set of state Medicaid and child welfare data systems to study substance use disorder diagnoses and treatment outcomes of parents with children in the welfare system.</li> </ul>

Active Project	Project Description
<b>Office of the National Coordinator for Health Information Technology (ONC)</b>	
<i>A Synthetic Health Data Generation Engine to Accelerate Patient-Centered Outcomes Research</i>	<ul style="list-style-type: none"> <li>Enhance Synthea by developing or updating data generation modules for opioid, pediatric, and complex care use cases to increase the number and diversity of synthetic patient health records to meet PCOR needs.</li> </ul>
<b>Cross-Agency-Funded Projects</b>	
<i>Data Capacity for Patient-Centered Outcomes Research through Creation of an Electronic Care Plan for People with Multiple Chronic Conditions</i>	<ul style="list-style-type: none"> <li>Develop and pilot an interoperable longitudinal electronic care (eCare) plan to facilitate data aggregation and exchange of critical patient-centered data across home-, community-, clinic-, and research-based settings. The pilot eCare Plan tool will be designed for use with patients who have chronic kidney disease (CKD), cardiovascular disease (CVD), diabetes, and/or pain with OUD.</li> </ul> <p><i>Agencies: AHRQ and NIH/NIDDK</i></p>
<i>Training Data for Machine Learning to Enhance Patient-Centered Outcomes Research (PCOR) Data Infrastructure</i>	<ul style="list-style-type: none"> <li>Develop high-quality training data sets used to develop, train, and improve machine learning algorithm performance.</li> </ul> <p><i>Agencies: NLM, ONC</i></p>
<i>Validating and Expanding Claims-based Algorithms of Frailty and Functional Disability for Value-based Care and Payment</i>	<ul style="list-style-type: none"> <li>Validate Medicare and Medicaid claims-based algorithms used to identify a person's risk for physical and cognitive decline and impairment to support more robust risk adjustments and case identification and assess quality in VBC programs.</li> </ul> <p><i>Agencies: ASPE, AHRQ, CDC</i></p>

<sup>1</sup> HL7 FHIR. Women's Health Technologies (WHT) Coordinated Registry Network (CRN) FHIR Implementation Guide. <http://hl7.org/fhir/us/womens-health-registries/2019May/>

<sup>2</sup> Dhopeswarkar, R., Dullabh, P., Dungan, R., Gonzales, A., Hovey, L., Isaacson, A., Heaney-Huls, K., Lumsden, S., Moriarty, E., Sanders, E., Smith, S., and Trevino, M. (2019). Building Data Capacity for Patient-Centered Outcomes Research Portfolio Highlights (2016–2019): Impact, Opportunities, and Case Studies.

<sup>3</sup> Food and Drug Administration (FDA). (December 2018). Framework for FDA's Real-World Evidence Program.

<sup>4</sup> Carino, T. and McClellan, M.B. (September 19, 2019). Accelerating the Shift Toward Person-Generated Real-World Evidence. Health Affairs Blog.

<https://www.healthaffairs.org/doi/10.1377/hblog20190918.730735/full/>

<sup>5</sup> U.S. Department of Health and Human Services (HHS). 5-Point Strategy to Combat the Opioid Crisis. <https://www.hhs.gov/opioids/about-the-epidemic/hhs-response/index.html>

<sup>6</sup> Centers for Medicare and Medicaid Services (CMS). What are the value-based programs? <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/Value-Based-Programs>