SUPPORTING STATEMENT: *PART A*

Understanding Health System Approaches to Chronic Pain Management

OMB #

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A. JUSTIFICATION

Summary Table

Goal of the Study
The goal of this formative research study is to obtain an enhanced understanding of the effects of policies and evidence-based guidelines related to chronic pain management and opioid prescribing, including access to medications for opioid use disorder (MOUD), for patients and clinicians in primary care settings among a diverse sample of health systems.

Intended Use of the Resulting Data
The government will use this information collection to inform efforts to enhance safety of opioid prescribing by: (1) obtaining an enhanced understanding of facilitators and barriers to guideline-concordant management of chronic pain and opioid prescribing (including access to MOUD) at the health system level, in order to improve patient outcomes while maximizing patient safety and to facilitate uptake by clinicians and health systems, (2) describing unintended benefits and consequences to guideline/policy implementation, and (3) identifying racial and ethnic disparities in guideline/policy implementation.

Methods to be Used to Collect Data
Primary data collection methods will include qualitative data from (1) surveys of primary care clinicians and patients, (2) interviews with health system leaders, (3) group interviews with patients, caregivers, clinicians, and staff for case studies, and (4) member checking, or validation, sessions with health system leaders, administrators, and staff.

Secondary data from health system electronic health records (EHRs) will provide longitudinal quality improvement (QI) measure data before and after guideline/policy implementation.

The Subpopulation to be Studied
The subpopulation to be studied includes 1) patients age 18 years and older with chronic pain who currently or previously have been prescribed long-term opioid therapy (LTOT), in primary care, outpatient settings (excluding active cancer, palliative, and end of life care situations), and 2) primary care clinicians, staff, and health system leaders affiliated with a diverse sample of participating AMGA (American Medical Group Association) member health systems.

How Data will be Analyzed
Survey Analysis: Univariate statistics across systems will be performed on survey data, including means, medians, and standard deviations. Distributions of continuous variables will be plotted and frequency tables created. We will code responses to open-ended survey questions thematically; describe common themes, along with demonstrative examples of responses of each theme; and stratify analyses by geographic region, clinician type, and system.

Qualitative Synthesis and Analysis: Qualitative data from the process evaluation will be reviewed and coded to identify themes and contextualize the quantitative data. All qualitative data will be coded and analyzed using Nvivo qualitative analytic software. Codebook development will be iterative and include deductive codes.

Secondary EHR Data Analysis: The study will use quantitative methods such as odds ratio to measure health system variation in QI measure change and their significance over time.

A.1.Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) requests Office of Management and Budget (OMB) approval for three years for this New information collection, "Understanding Health System Approaches to Chronic Pain Management."

The goal of this formative research study is to obtain an enhanced understanding of the effects of policies and evidence-based guidelines related to chronic pain management and opioid prescribing including access to medications for opioid use disorder (MOUD), for patients and clinicians in primary care settings among a diverse sample of health systems.

The government will use this information collection to enhance safety of opioid prescribing efforts among similar health systems by:

- (1) obtaining an enhanced understanding of facilitators and barriers to guideline-concordant management of chronic pain and opioid prescribing (including access to MOUD) at the health system level, in order to improve patient outcomes while maximizing patient safety and to facilitate uptake by clinicians and health systems;
- (2) describing unintended benefits and consequences to guideline/policy implementation; and
- (3) identifying racial and ethnic disparities in guideline/policy implementation.

Since 1999, nearly 841,000 people have died from drug overdose in the United States.[1] Over 70% of drug overdose deaths in 2019 involved an opioid.[2] From 1999 to 2019, nearly 247,000 people died in the United States from overdoses involving prescription opioids, with rates of deaths involving prescription opioids more than quadrupling from 1999 to 2019.[3] In response, a range of clinical practice guidelines, policies, and regulations have been released in recent years to address the opioid overdose epidemic (Attachment L).

To design this formative research study, we previously conducted an exploratory work of health systems via surveys to determine the range of policies and guidelines being implemented by health systems, followed by an "evaluability assessment" by means of interviews with leaders of nine health systems. Both projects are described in attachment L. For the purposes of this request, "chronic pain management policies/guidelines" refers to policies and guidelines that may include prescribing of opioid medications, nonpharmacologic therapies, and/or non-opioid medications for chronic pain, as well as OUD assessment and treatment.

This data collection effort is authorized under Section 301 of the Public Health Service Act (42 U.S.C. 241) 280-1a (Attachment K) (Conducting this study is in furtherance of Congressional priorities noted in House, Senate, and Conference appropriations reports to support and provide education to clinicians on safe opioid prescribing, pain management, and patient safety. This

[1] Wide-ranging online data for epidemiologic research (WONDER). Atlanta, GA: CDC, National Center for Health Statistics; 2020. Available at http://wonder.cdc.gov.

[2] Mattson CL, Tanz LJ, Quinn K, Kariisa M, Patel P, Davis NL. Trends and Geographic Patterns in Drug and Synthetic Opioid Overdose Deaths — United States, 2013–2019. MMWR Morb Mortal Wkly Rep 2021;70:202–207.

[3] Wide-ranging online data for epidemiologic research (WONDER). Atlanta, GA: CDC, National Center for Health Statistics; 2020. Available at http://wonder.cdc.gov.

work fits into CDC's five-pillar approach to reduce drug overdose-related harms by supporting providers, health systems, and payers and also sits within agency priorities under CDC's strategic framework to "reduce opioid prescribing by at least 10% by 2025 to prevent harms associated with prescription opioid misuse.[4]" Finally, this study helps to meet the goals of the US Department of Health and Human Services Five Point Strategy to Combat Opioid Abuse, Misuse and Overdose by building the evidence base to "advance the practice of pain management to enable access to high-quality, evidence-based pain care that reduces the burden of pain for individuals, families, and society while also reducing the inappropriate use of opioids and opioid-related harms.[5]"

A2. Purpose and Use of the Information Collection

The purpose of this data collection effort is to:

- (1) conduct formative research to obtain an enhanced understanding of facilitators and barriers to guideline-concordant management of chronic pain and opioid prescribing (including access to MOUD) at the health system level, in order to improve patient outcomes while maximizing patient safety and to facilitate uptake by clinicians and similar health systems,
- (2) describe unintended benefits and consequences to guideline/policy implementation, and
- (3) identify racial and ethnic disparities in guideline/policy implementation.

Exhibit 3 in attachment L outlines the formative research questions, their data source(s), and the intended use of the data obtained from each question.

This assessment of health systems' implementation of chronic pain management and opioid prescribing policies/guidelines and the resultant outcomes requires both primary data collection (such as surveys, key informant interviews, focus groups, etc.) and secondary data collection (such as administrative, EHR, pharmacy dispensing, prescribing data, etc.) efforts to adequately answer the research questions. While secondary data (QI measures) from health system EHRs will provide longitudinal pre-post measures, primary data is needed to understand the characteristics and mechanisms of practice and patient change that can be attributed to the policies and guidelines. This document describes the primary data collection further below.

The primary data collection methods will include surveys of primary care clinicians (Attachment A) and patients (Attachment B), as well as interviews with various leaders within health systems (Attachment C) and interviews for case studies (Attachment D). Qualitative data from surveys of clinicians and patients will be used to understand the reported effects of implemented policies on patient-clinician communication, as well as attitudes and perspectives. Interviews with health system leaders (e.g., chief medical officer, VP of quality and safety, primary care leadership) will be used to characterize and understand the specific policies and guidelines implemented, as

[4] From "CDC Strategic Framework and Priorities," https://www.cdc.gov/about/organization/strategic-framework/index.html, accessed August 31, 2021.

[5] From "U.S. Department of Health and Human Services Strategy to Combat Opioid Abuse, Misuse, and Overdose A Framework Based on the Five Point Strategy," available at https://www.hhs.gov/opioids/sites/default/files/2018-09/opioid-fivepoint-strategy-20180917-508compliant.pdf, accessed August 31, 2021.

well as when and how they were implemented. The interviews will also help to elucidate drivers of success, challenges encountered, and lessons learned in overcoming barriers. Finally, case studies will be conducted to obtain detailed stories about successful cases of clinicians improving the care of patients previously or currently prescribed LTOT, patients being connected to MOUD when indicated, and/or programs addressing racial and ethnic disparities. Finally, to support validation of findings from each system, we will conduct "member checking sessions" (Attachment E), which will review primary findings from the study with administrators and clinicians from each health system, to check for agreement and validation of recommendations generated from data analysis. Additionally, systems will be requested to provide opioid-related QI measures. The data collection methods are summarized in Exhibit 4 and described in detail below.

Exhibit 4. Overview of Data Collection Efforts (maximum sample size)

Method	# Systems	Sample Size (# / system)	Primary Aim(s)
Primary Care Clinician Survey	10	1,182 (upper bound is 3,940 primary care clinicians for all systems with a 30% response rate)	Clinician perspective on implementation, changes in clinician practices, patient-clinician communication
Patient Survey	10	1,000 (100/system, assume 50% response rate)	Patient perspective on implementation, patient-clinician communication
Group Interviews with system leaders	10	50 (5/system)	Understand implementation, its consequences, and barriers/facilitators
Staff Case Study Interviews	10	20 clinicians (2/system) 20 other health care staff (2/system)	Understand successes for clinicians, teams, and patients/caregivers
Patient Case Study Interviews	10	50 patients and/or caregivers (5/system)	Understand successes for patients/caregivers
Member Checking (Validation) Sessions	10	50 (5/system)	Validate individual system's findings

Below, we discuss the specific use of the information collected under each method.

Primary Care Clinician Survey (Attachments A & J)

We will conduct a survey of approximately 1,182 primary care clinicians who are able to prescribe opioids among ten participating health systems that agree to field a survey of their staff to understand the clinician perspective on pain management and opioid prescribing guideline and policy implementation in their health systems, effects on patient outcomes, and patient-clinician communication. The survey is expected to take 10 minutes to complete. The proposed survey domains include:

- Attitudes, knowledge, awareness of, confidence regarding, and perception of guidelines and policies implemented in their health system
- Observed benefits and unintended consequences
- Reported observations of patients
- Clinic-level practices and resources (e.g., policies, support, QI measures and monitoring)
- Implementation (e.g., opioid QI efforts, challenges, barriers)
- Patient-clinician communication
- Clinic environment (e.g., practice capacity, major disruptions)
- Respondent characteristics (e.g., burnout, stress, specialty, years in practice)

The survey will ask primary care clinicians about their awareness of chronic pain management and opioid prescribing policies and guidelines implemented in their health systems; prescribing behaviors before and after implementation; confidence in caring for patients with chronic pain; the impact of guideline/policy implementation on day-to-day work; barriers to care for patients with chronic pain; and prescribing or referring for MOUD.

Patient Survey (Attachments B & J)

Surveys of patients will be critical to obtain an enhanced understanding of specific guideline or policy implementation in health systems to understand the patient perspective of effects of implementation of guidelines/policies, including effects on patient-clinician communication. One hundred patients per health system will complete the Patient Survey, for a total of up to 1,000 patients among up to 10 health systems. All surveys will be designed to be completed in ten minutes. Domains of interest include:

- Attitudes, knowledge, and perception of their health system's guidelines, policies, or regulations
- Unintended consequences reported (e.g., illicit use, inadequate pain control, diminished quality of life, patient abandonment)
- Perceived harms and benefits from implemented policies and guidelines
- Patient-clinician communication (e.g., Consumer Assessment of Healthcare Providers and Systems (CAHPS)[6] items, communications literature)
- Patient characteristics

The survey will ask patients about their chronic pain histories, awareness of health system's implementation of pain management and opioid prescribing policies and guidelines, beneficial and harmful consequences of implementation, and patient-clinician communication.

[6] https://www.ahrq.gov/cahps/index.html

Group Interviews with System Leaders (Attachments C)

We plan to conduct one group interview per health system to include five health system leaders per interview, for a total of up to 50 health system leaders among up to 10 health systems involved in implementation efforts. We will work with the system liaison to identify the appropriate leaders from each health system who should be interviewed to understand the system's implementation across primary care. Potential respondents in the leadership role include: chief medical officer (CMO), VP of Quality and Safety, VP for Primary Care, lead for the opioid improvement effort (if applicable), members of opioid committee (if applicable), IT analytics lead who developed measures and/or EHR tools, or other relevant leaders. Prior to interviews, a copy of health system pain management and opioid prescribing policies and guidelines will be requested to facilitate discussion.

All interviews will be conducted by telephone and are expected to take 60 minutes, depending on the level of respondent involvement in the implementation of the policies or guidelines of interest. All interviews will be recorded with respondents' permission and transcribed. If permission to record the interview is not given, we will rely on the notes taken by a note taker.

Health system leaders will be interviewed on how and why decisions were made to implement guidelines or policies and who made those decisions; benefits and unintended consequences to implementation (such as patients leaving the system due to stricter prescribing behaviors); whether these initiatives have been successful or not; facilitators and strategies to overcome barriers; and lessons learned. Questions about effects of COVID-19 and whether and how systems have addressed racial/ethnic disparities in pain management, opioid prescribing, and treatment of OUD will also be asked.

Case Studies Interviews (Attachment D)

Case studies with patients and caregivers, as well as clinicians and staff, provide an in-depth understanding of a single or small number of cases set in their real-world contexts. Examining the experiences of clinicians, care teams, patients, and caregivers can provide a deeper understanding of real-world behavior within a specific healthcare context to elucidate how or why change occurred for chronic pain management, opioid prescribing, and/or provision of MOUD. These interviews will provide an opportunity to learn more about patient journeys and the strategies and approaches to a health system's implemented guidelines and policies and will complement the analysis of unintended consequences that will occur via the other primary and secondary data collection efforts included in this project.

Interviews will be conducted by telephone and are expected to last approximately 30 minutes. Four staff members (two clinicians and two other care team staff) per health system will be interviewed (for a total of up to 40 staff), as well as five patients and/or caregivers per system for a total of up to fifty patients. Briefly, the interviews may potentially explore:

- The care team's approach to buy-in with safer prescribing or actively engaging in efforts to diagnose and treat patients with OUD
- The care team's approach of working together with planned care visits, huddles, or workflows to improve care of patients with chronic pain

- A clinician's or care team's approach to improve diagnoses and treatment of OUD in racial or ethnic minority populations, or develop specialized clinics to treat chronic pain (e.g., sickle cell disease)
- A patient's and/or caregiver's story of taking LTOT and its effects on pain and functioning, engaging in nonopioid therapies, and/or receiving an OUD diagnosis and starting on MOUD (Note that not all listed examples may be applicable to all patients)

"Member Checking" (Validation) Sessions (Attachment E)

In addition to interviews, we will hold a separate session with each health system, each with five representatives in key roles at participating health system, for a total of 50 representatives to conduct "member checking,"[7,8,9] or validation.

In these group sessions we will review and discuss findings from the mixed-methods findings from the study of each health system's implementation of policies and guidelines[10,11] and we will engage the participants in validating our findings for their system and/or helping to explain unexpected changes in trends or add additional context and insights. Each health system's session will include approximately 4 participants, be conducted via WebEx or Zoom, and will take 60 minutes. Prior to each session, participants will be provided with a list of topics to be discussed in the sessions, so that they may come prepared.

Abstraction of Secondary Data

To complement the primary data collection efforts described above, a variety of secondary data sources will be used to quantitatively describe and evaluate the implementation of specific guidelines and policies and their effects on patients and clinicians' practices.

- A subset of AMGA members contributes EHR and limited adjudicated, deidentified claims data to a common data repository through a partnership with Optum, AMGA's data analytics partner. We will conduct a quantitative patient-level, longitudinal (pre-post) analysis within each of up to 10 health systems of the secondary data in the Optum dataset. We will also consider clinician-level longitudinal analyses for these 10 health systems as an alternative to the patient-level analyses if insufficient data/sample size limitations make the patient-level analyses impractical.

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7 Creswell, J. W., & Miller, D. L. (2000). Getting good qualitative data to improve educational practice, Theory Into Practice, 39(3), 124-130.

8 Candela AG. Exploring the function of member checking. The Qualitative Report. 2019 Mar 1; 24(3):619-28.

9 Cohen DJ, Balasubramanian BA, Gordon L, Marino M, Ono S, Solberg LI, Crabtree BF, Stange KC, Davis M, Miller WL, Damschroder LJ. A national evaluation of a dissemination and implementation initiative to enhance primary care practice capacity and improve cardiovascular disease care: the ESCALATES study protocol. Implementation Science. 2015 Dec; 11(1):86.

10 Lincoln YS, Guba EG. But is it rigorous? Trustworthiness and authenticity in naturalistic evaluation. N Dir Eval. 1986; 1986 (30):73–84.

11 Cohen DJ, Crabtree BF. Evaluative criteria for qualitative research in health care: controversies and recommendations. The Annals of Family Medicine. 2008 Jul 1; 6(4):331-9.

- Additionally, we will examine trends and pre-post changes in quality improvement (QI) measures at each health system, as several health systems have measures they have built and used to monitor implementation of policies or guidelines.

These secondary analyses will provide quantitative estimates of the association between implementation of the policies and guidelines and the patient outcomes of interest separately within each of the 10 health systems (although causal relationships cannot be definitively determined). We will analyze each system separately because each system implemented policies and guidelines in a different manner, and there are many unobserved system-specific factors that may impact patient outcomes. Results from these secondary analyses will add context to the discussions with health system leaders during the member checking sessions described above.

A3. Use of Improved Information Technology and Burden Reduction

In order to minimize respondent burden and to permit the electronic submission of survey responses and data collection forms, the clinician and patient surveys will be web-based and deployed using a well-designed, low burden, and respondent-friendly survey administration process and instruments. 100% of the data will be collected electronically or by telephone. We will collect email addresses from the participating health systems and send emails to potential respondents with a link to the survey. Potential respondents not accessing the link and completing the survey will receive a follow-up email approximately two weeks after the initial email is sent. Potential respondents will not be contacted after the second follow-up email (Attachment I).

Interviews with system leaders, case study interviews and member checking sessions will be conducted by telephone with video conference capability.

A4. Efforts to Identify Duplication and Use of Similar Information

This formative research study will be the first CDC-funded investigation to collect primary data from both clinicians and patients at participating health systems related to opioid prescribing and chronic pain management policies and guidelines.

The data collected as part of this project are unique and will be the first multi-health system study of clinician, patient, and system leader perceptions and patient outcomes across a diverse array of health systems. To our knowledge, there have not been other efforts to obtain program information required to demonstrate impact and improve implementation of these guidelines across clinicians, patients, and health system leaders on a health systems level.

This project builds upon similar efforts by CDC to assess the impact of the 2016 *CDC Guideline for Opioid Prescribing for Chronic Pain* on national opioid prescribing behaviors by using secondary data accessed from the IQVIA transactional data warehouse from 2012 to 2017[12]. However, the objectives of this ICR require the primary data collection of survey and interview

[12] Bohnert ASB, Guy GP Jr, Losby JL. Opioid Prescribing in the United States Before and After the Centers for Disease Control and Prevention's 2016 Opioid Guideline. Ann Intern Med. 2018 Sep 18;169(6):367-375. doi: 10.7326/M18-1243. Epub 2018 Aug 28. PMID: 30167651; PMCID: PMC6176709.

data from clinicians and patients from corresponding health systems, in addition to secondary EHR-sourced outcome measures, providing a more robust and multidimensional picture of the effects of policies and guidelines. CDC also previously sought to understand more about pain and pain management through engagement with three different groups: patients with acute or chronic pain, patients' family members and caregivers, and clinicians who care for patients with pain or conditions that can complicate pain management. This outreach occurred via two pathways through the Federal Register: soliciting written public comment (85 FR 21441) and also conducting individual telephone and video conversations (85 FR 44303), and was approved through the "Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery" (OMB Control Number: 0920-1050, "Stakeholder Engagement and Feedback - Management of Acute and Chronic Pain"). While CDC learned many perspectives and personal stories through those complementary efforts, this ICR is unique and expands upon this prior work in that it will systematically capture data from different perspectives (i.e., patients, caregivers, clinicians, staff, and health system leaders) with relatively large sample sizes from various health systems while also leveraging secondary data sources like electronic health record (EHR) data, claims data, and quality improvement measures to allow CDC to more broadly explore and answer critical research questions about the effect of implementing opioid prescribing and chronic pain management guidelines and policies. Lastly, existing data at other federal agencies such as the National Survey on Drug Use and Health administered by the Substance Abuse and Mental Health Services Administration and projects such as the Agency for Healthcare Research and Quality-led "Evaluating and Implementing the Six Building Blocks Team Approach to Improve Opioid Management in Primary Care" may address some limited aspects of this ICR in that they collect patient data on opioid use and support primary care clinicians who treat patients with chronic pain on LTOT, respectively. However, these efforts differ quite markedly in scope and representation across administrators, staff, clinicians, patients, and caregivers from the same health systems like this ICR.

CDC has previously supported projects studying various interventions related to implementation of its *Guideline for Prescribing Opioids for Chronic Pain.* For example, in CDC's "Opioid Prescribing Guideline Implementation: Clinical Decision Support" project, CDC engaged with health system champions and information technology leaders across four different health systems to develop and evaluate electronic clinical decision support tools to assist clinical care teams in making timely and guideline-informed opioid prescribing and care decisions. Also, through CDC's Opioid Quality Improvement Collaborative, CDC developed quality improvement measures that mapped the 12 recommendations in the *CDC Guideline for Prescribing Opioids for Chronic Pain* and engaged with two separate cohorts of health systems to implement these measures with an accompanying care coordination guide and to monitor progress. For these projects, fewer than nine individual clinicians were contacted to provide insight into how the *CDC Guideline for Prescribing Opioids for Chronic Pain* impacted clinical practice. Also, while both projects involved examination of EHR data from a small number of health systems with a few accompanying interviews to understand health systems' efforts, these data did not involve primary data collection from patients, a key population whose voice will be specifically included in this ICR via two different methods. Also, these previous projects did not include a focused assessment of how known racial and ethnic disparities in chronic pain management, opioid prescribing, and access to MOUD may have been impacted by implemented guidelines/policies, which this ICR proposes to study, and involved an observation period insufficient to observe a

significant change before and after implementation, whereas this ICR specifically seeks to recruit health systems that have implemented policies for years and can thus provide a thorough, nuanced examination of baseline data and several years of post-implementation data to effectively assess impact. Overall, research methods proposed within this ICR differ substantially in that they will expand upon methods developed in previous investigations and deploy them on a significantly larger scale among patients and a larger sample of clinicians to achieve a more representative sample of national opioid prescribing trends.

A5. Impact on Small Businesses or Other Small Entities

Data will not be collected from small entities.

A6. Consequences of Collecting the Information Less Frequently

The one-time data collection described in this document will occur over a period of three years with clinicians, patients, and system leaders at each of the participating health care organizations. Not collecting the data at all or shortening the data collection period (either by decreasing the study duration or number of sites) places us at risk of not obtaining adequate information for the study of chronic pain management, and opioid prescribing, policies and guidelines. Should we shorten the data collection period, we may not identify potential barriers, facilitators or outcomes of existing chronic pain management and opioid prescribing policies and guidelines. This would limit the understanding of the landscape of treatment barriers, which will inform future activities related to clinician engagement, such as enhanced and targeted academic detailing outreach.

A7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request is consistent with the general information collection guidelines of 5 CFR 1320.5(d)(2). No special circumstances apply.

A8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. Federal Register Notice

A 60-day Federal Register Notice was published in the Federal Register on September 27, 2021, vol. 86, No. 184, pp. 53313 (Attachment F). There were no public comments to this notice.

Efforts to Consult Outside the Agency

Efforts were made to consult outside of the agency. The data collection instruments were designed collaboratively by CDC staff and selected contractors. Contractors consulted included researchers, statisticians, clinicians, and pharmacists with expertise in evaluation research and survey methodology, as well as opioid prescribing.

In addition, leadership at the American Medical Group Association (AMGA), from which member health systems will be selected to participate, were consulted extensively to determine the appropriateness of all primary data collection efforts. All surveys and interview guides were

developed in collaboration with contractors and AMGA leadership to consider the burden of primary collection instrument on respondents, content of all primary collection materials, instructions for materials, and relevance of content addressed in each instrument.

Finally, primary data collection materials were also reviewed and approved by the Abt Associates' Institutional Review Board (IRB) for appropriateness of content, burden, clarity, respondents, and data availability. Consultation with the above-mentioned groups will continue throughout the implementation process.

A9. Explanation of Any Payment or Gift to Respondents

This study will offer incentives to patient and clinician survey respondents, as well as health system leader interviewees. Because of stigma and legal implications, recruiting and surveying patients with chronic pain or OUD may pose difficulties. Patients with chronic pain or OUD may not want to identify as receiving treatment due to stigma or legal concerns. Inquiring about opioid use among patients with chronic pain or opioid use disorder, including questions that inquire about use of illicit drugs, are highly sensitive in nature, and thus justify financial incentives for patients. Also, given the short duration of the data collection period of the project (approximately 12 months) and the desired response rate for participants (50% among patients and 80% among clinicians and health system leaders), the use of incentives is necessary to maximize response rates and carry out the study's proposed data collection activities.

We intend to offer, as tokens of appreciation, $25 to primary care clinicians and $5 to patients for taking surveys. A $50 incentive will be provided to health system leaders for participating in interviews. We have constructed this study's incentive structure to be in line with incentives approved by the OMB on similar surveys and supported by the literature. The offering of incentives for these data collection tools is comparable to--and often less than--incentives offered on similar data collections including the National Survey on Drug Use and Health (OMB No. 0930-0110).

The literature supports use of monetary incentives to increase response rates, with a Cochrane Collaboration systematic review showing that a monetary incentive doubled the odds of response rates on postal questionnaires.[13] Another study of patients with chronic low back pain found that, while motivations to participate in research studies were often multilayered, in 19% of cases, financial incentives were an important reason for participation.[14] Research suggests that even small tokens of appreciation may increase response rates of hard-to-reach populations, such as

[13] Edwards P, Roberts I, Clarke M, DiGuiseppi C, Pratap S, Wentz R, Kwan I. Increasing response rates to postal questionnaires: systematic review. *British Medical Journal.* 2002;324:1183.

[14] Ajay D. Wasan, MD, MSc, Simone P. Taubenberger, PhD, Walter M. Robinson, MD, MPH, Reasons for Participation in Pain Research: Can They Indicate a Lack of Informed Consent?, *Pain Medicine*, Volume 10, Issue 1, January 2009, Pages 111–119, https://doi.org/10.1111/j.1526-4637.2008.00481.

respondents from racial/ethnic minority backgrounds[15],[16] which in turn may help to avoid non-response bias.

In addition, the COVID-19 pandemic has placed significant burdens on clinicians and health system leaders. Recognizing this added burden, administrators from the American Medical Group Association have recommended the use of survey incentives among all responding parties, including clinicians and health system leaders. Failure of any of these groups—patients, clinicians, or health system leaders--to participate would jeopardize the quality of survey and interview data.

A10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

This submission has been reviewed by the CIO's Information Systems Security Officer, who determined that the Privacy Act does not apply. Response data will not contain any personally identifiable information (PII) that could be used to identify any participating clinicians and/or patients at the individual level. All personally identifiable information (PII) will be removed from the files prior to uploading using MOVEit, an online platform for data sharing which meets FedRAMP requirements. Abt staff will store files on a FedRAMP-compliant server, on which all de-identified data will be kept. The Privacy Impact Assessment (PIA) for this study is attached (Attachment H).

However, the data collection instruments may provide sufficient information (indirect identifiers) to meet the definition of identifiable, sensitive information (ISI) stated in Section 301(d) of the Public Health Service Act, therefore, qualifying for a Certificate of Confidentiality, discussed further below in Section A11. The Certificate will support the research team in protecting data against compulsory legal demands (e.g., court orders, subpoenas), and indicates that research staff cannot disclose information or documents pertaining to the data collection to anyone who is not connected with the research.

A11. Institutional Review Board (IRB) and Justification for Sensitive Questions

Institutional Review Board (IRB)

This formative research study involves human subjects research. CDC has received IRB approval for this formative research involving human subjects through Abt Associate's IRB (Attachment G). CDC will not be engaged.

The Abt Associates IRB is committed to conducting research in conformity with basic ethical principles, and federal and other regulatory requirements that govern human subjects research and the confidentiality of personal information. Abt Associates holds a current Federal-Wide Assurance (FWA) for the Protection of Human Subjects from the U.S. Department of Health and

[15] Beebe, T. J., Davern, M. E., McAlpine, D. D., Call, K. T., Rockwood, T. H. (2005). Increasing response rates in a survey of Medicaid enrolless: the effect of a prepaid monetary incentive and mixed modes (mail and telephone). *Medical Care, 43*, 411-414.

[16] Dykema, J., Stevenson, J., Kniss, C., et al. (2012). Use of monetary and nonmonetary incentives to increase response rates among African Americans in the Wisconsis Pregnancy Risk Assessment Monitoring System. *Maternal Child Health Journal, 16*, 785-791.

Human Services' Office for Human Research Protections (FWA#00000664) and maintains its own Institutional Review Board (IRB).

Sensitive Questions

The data collection protocols do not contain any questions concerning political affiliations and attitudes; antisocial or demeaning behavior; critical appraisals of other individuals with whom respondents have close relationships; legally privileged relationships; or records describing how an individual exercises First Amendment rights, nor do they contain questions related to sexual behavior and attitudes, religious beliefs, income or proprietary business information.

However, the topics covered by this information collection request include the use and misuse of prescribed and non-prescribed opioid substances, including illicit drug use, as well as opioid use disorder, topics that are commonly considered sensitive and/or private. In addition, our surveys may elicit sensitive information that reflects negatively on staff or health care organization performance related to chronic pain management or opioid prescribing.

Respondents will be explicitly informed that their participation is voluntary, that information they provide is confidential to the extent provided by law, and that they may choose to withdraw from the study or not respond to specific items without penalty. Protections, and limits to protections, provided by the Certificate of Confidentiality will be discussed with all respondents by staff at recruitment, and in the data collection instruments. Staff involved with recruitment will be trained on how the Certificate protects the information collected, and the limitations of the Certificate's protections. We will also remove individual staff and health care organization names from written interview records and reports to maintain respondent confidentiality.

Consistent with Section 301(d) of the Public Health Service Act, a Certificate of Confidentiality (CoC) applies to this research because this research is funded, conducted, or supported by CDC, and the activity constitutes research.

The research involves information about an individual for which there is at least a very small risk that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual. That is, as discussed in Section A10, there may be enough information (indirect identifiers) collected to meet the definition of identifiable, sensitive information (ISI) stated in Section 301(d) of the Public Health Service Act, therefore, qualifying for a Certificate of Confidentiality.

The Certificate will support the research team in protecting data against compulsory legal demands (e.g., court orders, subpoenas), and indicates that research staff cannot disclose information or documents pertaining to the data collection to anyone who is not connected with the research. The Certificate of Confidentiality allows researchers to promise participants' confidentiality and may improve researchers' ability to recruit subjects in research on sensitive topics.

Therefore, CDC and any of its collaborators, contractors, grantees, investigators or collaborating institutions that receive "identifiable, sensitive information" as defined by subsection 301(d) of the Public Health Service Act shall not:

• Disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding "identifiable, sensitive information" that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or

• Disclose "identifiable, sensitive information" (ISI) or provide ISI to any other person not connected with the research.

Disclosure is permitted only when:

• Required by Federal, State, or local laws (e.g., as required by the Food, Drug and Cosmetic Act or required by state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding;

• Made with the consent of the individual to whom the information, document, or biospecimen pertains; or

• Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.
CDC and its collaborators and contractors conducting this research will establish and maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the research is managed in compliance with subsection 301(d) of the Public Health Service Act.

CDC will ensure: 1) that any investigator or institution not funded by CDC who receives a copy of identifiable, sensitive information protected by this Certificate, understands that it is also subject to the requirements of the Certificate; and 2) that any subrecipient that receives CDC funds to carry out part of this research involving a copy of identifiable, sensitive information protected by a Certificate understands that it is subject to subsection 301(d) of the PHS Act. Therefore, all study staff will receive training on the importance of protecting the confidentiality of human research subjects and of personal information acquired.

A12. Estimates of Annualized Burden Hours and Costs

Time estimates are based on prior experiences and what can reasonably be requested of participating clinicians, patients, and health care system leaders. The number of respondents listed in the table below reflects a projected 30 to 50% response rate for data collection efforts.

Primary Care Clinician Survey (Attachment A). A brief survey will be emailed to all primary care clinicians who are able to prescribe opioids in each of the 10 healthcare systems included in the study. Non-respondents will be contacted with one additional email after two weeks to increase response rates.

A total of 3,940 primary care clinicians among all systems will be contacted over 3 years, or 1,313 per year; 1,182 (assuming a 30% response rate) are expected to respond over 3 years, or 394 per year. The Primary Care Clinician Survey is expected to take 10 minutes to complete based on pilot testing and experience with similar data collection efforts.

Patient Survey (Attachment B) A total of 2,000 surveys will be distributed over 3 years. Surveys of up to 1,000 patients (assuming a 50% response rate and 100 patient surveys per health system) will be critical to evaluate specific guideline or policy implementation in health systems. Respondents will be invited to complete the online surveys via REDCap through a suite of available options, including a unique email link, text messaging interface, or the REDCap mobile application. The survey is expected to take 10 minutes to complete based on pilot testing and experience with similar data collection efforts.

Interviews with system leaders (Attachment C). In-depth group interviews will occur with five staff at each health care organization, for a total of up to 50 individuals (10 per health system, up to 10 systems). The team will conduct these interviews, each lasting up to 60 minutes. The burden estimate is based on experience with similar data collection efforts.

Case Study Interviews (Attachment D). To learn more about patient journeys and the strategies and approaches to a health system's implemented guidelines and policies, interviews will be conducted with clinicians, teams, and patients/caregivers. Four staff members (two clinicians and two other health care staff) per health system will be interviewed (for a total of up to 40 staff), as well as five patients and/or caregivers per system for a total of up to fifty patients. The team will conduct these interviews, each lasting approximately 30 minutes. The burden estimate is based on experience with similar data collection efforts.

Member Checking Sessions (Attachment E). To validate individual system findings we will gather five representatives per health system, for a total of up to 50 representatives, among all participating systems for a one hour discussion on findings to obtain insight from health system representatives. The burden estimate is based on experience with similar data collection efforts.

Exhibit 5. Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Patient	Patient Survey (Att. B)	667	1	10/60	111
Treatment facility staff (Including	Primary Care Clinician Survey	1,313	1	10/60	219

primary care clinicians, health system leaders, and other system staff and representatives)	(Att. A)				
	Invitation/ Follow up Email (Att. I)	1,980	2	3/60	198
	Health System Leaders Group Interview Guide (Att. C)	17	1	1	17
	Case Study Interview Guide (Att. D)	30	1	30/60	15
	Member Checking (Validation) Sessions Interview Guide (Att. E)	17	1	1	17
	TOTAL				577

The table below, presents the estimated annualized cost burden associated with the respondents' time to participate in this research. The total cost burden is estimated to be $84,306. There are no direct costs to respondents other than their time to participate in the study.

Exhibit 6. Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Total Burden (in hours)	Hourly Wage Rate (in USD)	Total Cost
Patients	Patient Survey (Att. B)	667	111	$40.12	$4,453
	Invitation/ Follow up Email (Att. I)	667	67	$40.12	$2,688
Primary Care	Invitation/ Follow up	1,313	131	$205.06	$26,863

Clinicians	Email (Att. I)				
Primary Care Clinicians	Primary Care Clinician Survey (Att. A)	1,313	219	$205.06	$44,908
Health Systems Leaders	Health System Leaders Interview (Att. C)	17	17	$110.74	$1,883
Primary Care Clinicians, Healthcare staff, & Patients	Case Study Interview Guide (Att. D)	30	15	$108.53	$1,628
Health System Administrators & Clinicians	Member Checking Session Interview Guide (Att. E)	17	17	$110.74	$1,883
					Total: $84,306

Mean hourly wage rates for these groups of occupations were obtained from the Bureau of Labor & Statistics on "Occupational Employment and Wages, May 2019" found at the following URL: http://www.bls.gov/oes/current/oes_nat.htm#b29-0000.htm

The average hourly rate of $205.06 for the primary care clinician survey was calculated based on the 2019 mean hourly wage rate for family medicine physician, $102.53 (occupation code 29-1215), doubled to account for employer overhead and fringe benefits.

The average hourly rate of $110.74 for systems leaders, interviews, providing the QI measures, and member checking sessions was calculated based on the 2019 mean hourly wage rate for medical and health services managers, $55.37 (occupation code 11-9111), doubled to account for employer overhead and fringe benefits.

The average hourly rate of $40.12 for patients was calculated based on the 2019 mean hourly wage rate for medical and health services managers, $20.06 (occupation code 47-2061), doubled to account for employer overhead and fringe benefits.

The average hourly rate of $80.42 for health care staff was calculated based on the 2019 mean hourly wage rate for healthcare practitioners and technical occupations, $40.21 (occupation code 29-0000), doubled to account for employer overhead and fringe benefits.

The average hourly rate of $108.53 used for the case studies is an average of health care staff, primary care clinicians, and patients.

A13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

No capital or maintenance costs are expected.

A14. Annualized Cost to the Federal Government

This formative research study will take place over a 3-year period. The total cost of this formative research study to the Federal Government will be $2,433,647.70. The government costs include personnel costs for one federal employee providing project planning and oversight at 15% FTE.

The below table describes total annual costs for: contract labor for planning and design, development of study protocols, recruitment, data collection, data preparation, data analysis, report writing, and dissemination of findings; CDC personnel labor for project oversight (15% of a GS-13 medical officer and scientist salary); and total estimated government costs.

Exhibit 7. Annualized Cost to the Government

Type of Cost	Description of Services	Annual Cost
Contractor	Data collection, data analysis, project management	$ 782,976.00
Technical monitor at 15% FTE (CDC)	Study planning and project oversight	$28,239.90
Total Annual Estimated Government Costs		$ 811,215.90

A15. Explanation for Program Changes or Adjustments

This is a new information collection.

A16. Plans for Tabulation and Publication and Project Time Schedule

For the survey results we will run descriptive and univariate statistics by system. We will compute means, medians and standard deviations. We will plot the distributions of continuous variables and create frequency tables and plots for categorical variables.

Exhibit 8. Project Time Schedule

Deliverable	Due Date
Administration of patient and clinician surveys, health system leader interviews, case studies interviews	Ongoing 1-36 months after OMB approval
Abstraction of secondary data from health systems (e.g., EHR and claims data)	Ongoing until 36 months after OMB approval

A17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is appropriate.

A18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.