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***SUPPORTING STATEMENT: PART A***

**Comprehensive Evaluation of the Implementation and Uptake of the CDC  
Clinical Practice Guideline for Prescribing Opioids for Pain**

OMB #

**Date:** November 20, 2024

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**Goal of the Study**

To conduct a rigorous and comprehensive evaluation of the dissemination, implementation, and outcomes of the *CDC Clinical Practice Guideline for Prescribing Opioids for Pain – United States, 2022* (2022 CDC Clinical Practice Guideline).

**Intended Use of the Resulting Data**

The CDC will use this information collection to evaluate the dissemination, impact, and implementation of the 2022 CDC Clinical Practice Guideline to ensure that Americans have access to safer, effective ways of managing their pain.

**Methods to be Used to Collect Data**

Primary data collection methods will include (1) national survey; (2) interviews and (3) focus.

**The Subpopulation to be Studied**

The subpopulations that will be studied include patients and caregivers or family members of patients with acute, subacute, and/or chronic pain. Clinicians and dentists who care for patients with acute, subacute, and/or chronic pain, or subacute dental pain. Leaders from health systems that may oversee efforts or policies related to pain management or opioid prescribing; leaders from payers (e.g., Medicaid; Medicare; private health plans providing employer, marketplace, managed care or Medicare Advantage plans) that may oversee policies related to pain management or opioid prescribing; leaders from professional associations (e.g., American Academy of Family Physicians, American Association of Nurse Practitioners, Society for General Internal Medicine), that may have positions or policies related to pain management or opioid prescribing, and leaders from medical boards that set and/or enforce programs or policies related to pain management or opioid prescribing.

**How Data will be Analyzed**

This study will employ a quasi-experimental design. Descriptive statistical tables will be derived from the survey data, including means, medians, and standard deviations and/or confidence intervals. 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 demographics such as geographic region and clinician type. Qualitative data from the interviews and focus groups will be reviewed and coded to identify themes and contextualize the quantitative data, where applicable. All qualitative data will be coded and analyzed using NVivo qualitative analytic software. Codebook development will be iterative and include deductive codes.

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## A.1. Circumstances Making the Collection of Information Necessary

CDC requests Office of Management and Budget (OMB) approval for three years for this new data collection, “Comprehensive Evaluation of the Implementation and Uptake of the CDC Clinical Practice Guideline for Prescribing Opioids for Pain.”

The goal of this research study is to conduct a rigorous, comprehensive evaluation to assess the 2022 CDC Clinical Practice Guideline implementation, uptake, and outcomes. The government will use this information collection to inform CDC efforts and interventions to ensure that Americans have access to safer, effective ways of managing their pain.

Beginning in the 1990s, opioid prescribing rates for pain management steadily increased until 2010, remained steady until 2012, and have declined since then.<sup>1,2,3</sup> The increase in opioid prescribing rates corresponded with increases in opioid-involved overdose deaths, which initially primarily involved prescription opioids (natural and semi-synthetic opioids and methadone).<sup>4</sup> In response to this emerging crisis, CDC issued the *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016* (2016 CDC Guideline).<sup>5</sup> Implementing the 2016 CDC Guideline was associated with reductions in opioid prescribing and increases in use of non-opioid medications for pain.<sup>2,6</sup> At the same time, laws and policies related to prescribing opioids were instituted that misapplied or were inconsistent with the 2016 CDC Guideline, potentially contributing to patient harm.<sup>7</sup> In 2022, CDC released the *CDC Clinical Practice Guideline for Prescribing Opioids for Pain—United States, 2022*, which provided up to date evidence regarding pain management approaches and re-emphasizes the need for prescribers to be focused on patient-centered care to provide effective pain management. CDC is comprehensively evaluating the uptake, implementation, and outcomes of the 2022 CDC Clinical Practice Guideline on evidence-based care for pain management to understand its impact.

To meet CDC’s goal for a rigorous, comprehensive evaluation, we propose a mixed-method quasi-experimental design with the following three aims to evaluate the 2022 CDC Clinical Practice Guideline:

- **Aim 1: Dissemination** – Assess CDC’s efforts in disseminating the 2022 CDC Clinical Practice Guideline.

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<sup>1</sup> Guy Jr GP, Zhang K, Bohm MK, et al. Vital signs: changes in opioid prescribing in the United States, 2006–2015. *MMWR Morbidity and mortality weekly report*. 2017;66(26):697.

<sup>2</sup> Bohnert AS, Guy Jr GP, Losby JL. Opioid prescribing in the United States before and after the Centers for Disease Control and Prevention's 2016 opioid guideline. *Annals of internal medicine*. 2018;169(6):367-375.

<sup>3</sup> Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC clinical practice guideline for prescribing opioids for pain—United States, 2022. *MMWR Recommendations and Reports*. 2022;71(3):1-95. doi:10.15585/mmwr.r7103a1

<sup>4</sup> Centers for Disease Control Prevention. Vital signs: overdoses of prescription opioid pain relievers---United States, 1999--2008. *Morbidity and mortality weekly report*. 2011;60(43):1487-1492.

<sup>5</sup> Dowell D, Haegerich TM, Chou R. CDC guideline for prescribing opioids for chronic pain—United States, 2016. *Journal of the American Medical Association*. 2016;315(15):1624-1645. doi:10.1001/jama.2016.1464

<sup>6</sup> Goldstick JE, Guy GP, Losby JL, Baldwin GT, Myers MG, Bohnert AS. Patterns in nonopioid pain medication prescribing after the release of the 2016 Guideline for Prescribing Opioids for Chronic Pain. *JAMA Network Open*. 2022;5(6):e2216475-e2216475.

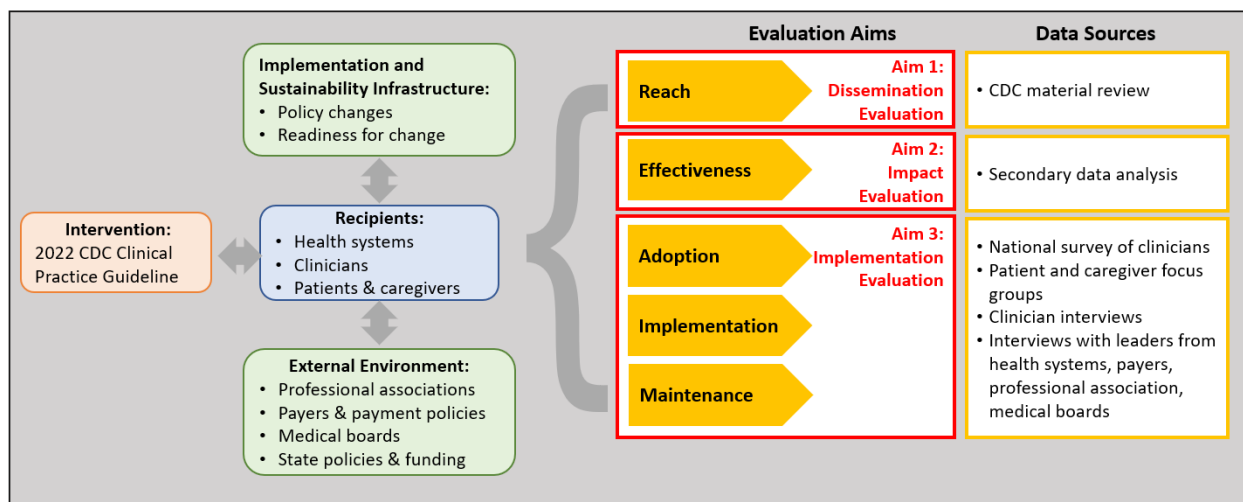
<sup>7</sup> Dowell D, Haegerich T, Chou R. No shortcuts to safer opioid prescribing. *N Engl J Med* 2019;380:2285-2287.

- **Aim 2: Impact** – Evaluate the impact of the 2022 CDC Clinical Practice Guideline through population-wide changes in prescribing practices for opioids and medications for opioid use disorder.
- **Aim 3: Implementation** – Evaluate the implementation of the 2022 CDC Clinical Practice Guideline from perspectives of patients, caregivers, clinicians; and leaders from health systems, payers, professional associations, and medical boards.

To achieve these aims, the project team will use secondary data (i.e., prescription and medical claims data) and primary data collection including implementing a nationally-representative survey of U.S. clinicians and qualitative data collection via focus groups and interviews with various key informants (i.e., clinicians, patients, caregivers; and leaders from health systems, payers, professional associations, and medical boards).

Our evaluation is based on the *Practical, Robust Implementation and Sustainability Model (PRISM)* which expands on the outcome measures of *RE-AIM (reach, effectiveness, adoption, implementation, and maintenance)* to address key contextual factors, including the guideline, partners, implementation and sustainability infrastructure, and external environment. PRISM is specifically designed to examine the dynamic and varied contexts where interventions are implemented. As a determinant and evaluation implementation framework, it is designed to both explain what influences implementation outcomes (determinant frameworks) and evaluate implementation (evaluation frameworks). **Exhibit 1** provides an overview of the framework, aims, methods, and data sources for this evaluation using the PRISM framework.

**Exhibit 1. Overview of Project Framework, Aims, and Methods for the 2022 Guideline Evaluation**



In **Exhibit 1**, we have specified the “intervention” as the release of the 2022 CDC Clinical Practice Guideline, and “recipients” as health systems, clinicians, patients, and caregivers. We have hypothesized potential factors that may affect the implementation and sustainability within a clinical setting, such as changes in health systems or others’ policies and the readiness of clinicians or health systems for change. Finally, we outline examples of contextual factors from the external environment, including engaging leaders from health systems, payers, professional associations, and medical boards; and exploring state policies and funding. The RE-AIM outcome measures map onto the three aims of the evaluation: first, to evaluate the reach of disseminating the 2022 CDC Clinical Practice Guideline; second, to evaluate its effectiveness in

terms of measurable impacts; and third, to measure its adoption, implementation, and maintenance. **Exhibit 1** also includes proposed data sources that the project team will use to examine the evaluation aims.

The project will use a mixed-methods quasi-experimental design to evaluate the 2022 CDC Clinical Practice Guideline dissemination (Aim 1), impact (Aim 2), and implementation (Aim 3). **Exhibit 2** provides the research questions the project seeks to answer.

**Exhibit 2. Evaluation Aims and Specific Research Questions**

Evaluation Aim	Evaluation Questions
<p><b>Aim 1: Evaluate CDC’s efforts in disseminating the 2022 CDC Clinical Practice Guideline</b> <i>(Dissemination Evaluation)</i></p>	<ul style="list-style-type: none"> <li>• How did clinicians and leaders from health systems, payers, professional associations, and medical boards learn about the 2022 CDC Clinical Practice Guideline?</li> <li>• What were successes and challenges of the CDC’s communication and dissemination approaches as viewed by external partners and clinicians?</li> </ul>
<p><b>Aim 2: Evaluate the impact of the 2022 CDC Clinical Practice Guideline through changes in opioid prescribing practices, including medications for opioid use disorder (MOUD).</b> <i>(Impact Evaluation)</i></p>	<p>Based on available secondary data, have any the following outcomes changed since the release of the 2022 CDC Clinical Practice Guideline: (pre-post release comparison)</p> <ul style="list-style-type: none"> <li>• Opioid prescribing rates for acute, subacute, and/or chronic pain conditions</li> <li>• Prescribing rates for immediate-release opioids for acute pain conditions</li> <li>• Prescribing rates for extended-release/long-acting for acute, subacute, and/or chronic pain conditions</li> <li>• Average days’ supply per opioid prescription for acute pain conditions</li> <li>• Average daily dosage of opioids in morphine milligram equivalents (MMEs)</li> <li>• Frequency of opioid/benzodiazepine co-prescribing</li> <li>• Non-opioid medication prescribing rates for acute, subacute, and/or chronic pain conditions</li> <li>• Non-pharmacologic therapies (e.g., physical therapy, behavioral health)</li> <li>• Prescribing rates for naloxone among patients prescribed opioids</li> <li>• Medications for opioid use disorder (MOUD) prescribing rates for patients with acute, subacute or chronic pain and OUD</li> <li>• Continuous MOUD treatment (&gt; 180 days) for patients with pain and OUD</li> <li>• Medical services/treatment utilization which may indicate serious opioid-related adverse drug events (e.g., opioid-related hospitalizations, opioid-related ED visits)</li> <li>• Escalation from low dosage opioids (low MMEs) to high dosage opioids (high MMEs)</li> <li>• Tapering from high MMEs to low MMEs for patients on long-term opioid therapy</li> <li>• Transitions from opioid prescriptions for acute pain to long-term opioid therapy</li> </ul> <p>Sub-analyses will explore heterogeneity in impacts by clinician type, specific pain conditions, and available demographic data (ZIP code).</p>
<p><b>Aim 3: Evaluate the implementation of the 2022 CDC Clinical Practice Guideline from the perspective of patients, caregivers, clinicians; and leaders from health systems, payers, professional associations, and medical boards.</b> <i>(Implementation Evaluation)</i></p>	<ul style="list-style-type: none"> <li>• How are systems operationalizing the 2022 CDC Clinical Practice Guideline in clinical practice? What is the context and through what mechanism(s)?</li> <li>• How have payer/insurer policies changed with respect to opioid prescribing limits and/or coverage of non-opioid therapies?</li> <li>• What were the facilitators and barriers that influenced the 2022 CDC Clinical Practice Guideline’s implementation?</li> <li>• To what extent do patients and caregivers experience a difference in care, specifically pain management, since the implementation of the 2022 CDC Clinical Practice Guideline?</li> <li>• To what extent are there unintended consequences for patients and caregivers</li> </ul>

	<p>related to the 2022 CDC Clinical Practice Guideline?</p> <ul style="list-style-type: none"> <li>• To what extent are there unintended consequences for clinicians related to the 2022 CDC Clinical Practice Guideline?</li> <li>• How has the 2022 CDC Clinical Practice Guideline positively or negatively impacted health equity? Where are the positive impacts? What are the negative impacts and how are they being addressed?</li> <li>• Where is the 2022 CDC Clinical Practice Guideline being successfully implemented and what are the contributing factors? Is the 2022 CDC Clinical Practice Guideline being misapplied, and if so, in what way or with which patient populations?</li> </ul>
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## Logic Model

**Exhibit 3** provides a logic model for the evaluation of the 2022 CDC Clinical Practice Guideline reflected in this ICR. The logic model includes the inputs, activities, outputs, short and intermediate outcomes, and long-term outcomes.

**Exhibit 3. Logic Model for the Evaluation of the 2022 CDC Clinical Practice Guideline**

Inputs	Activities/ Implementation	Outputs	Short or Intermediate-Term Outcomes	Long Term Outcomes
Release of 2022 CDC Clinical Practice Guideline	Use broad-reaching dissemination strategy, including clinician education and training, partnerships with patients, health systems and payers, and multiple clinical tools and fact sheets	<ul style="list-style-type: none"> <li>% of clinicians aware of the Guideline</li> <li>% of clinicians reporting use of Guideline</li> <li>% of clinicians with self-efficacy to implement the Guideline</li> <li>Synthesis of health systems, payers, associations, and medical boards reported implementation of Guideline recommendations</li> <li>Synthesis of patients and caregivers reported changes in care for pain care since November 2022</li> </ul>	<ul style="list-style-type: none"> <li>Increased prescribing concordance with 2022 CDC Clinical Practice Guideline</li> <li>Increased prescribing of non-opioids</li> <li>Increased provision of non-pharmacological therapies</li> <li>Increased provision of naloxone for patients taking opioids</li> <li>Decreased concurrent prescribing of opioids and benzodiazepines</li> <li>Increased prescribing of MOUD</li> </ul>	<ul style="list-style-type: none"> <li>Continuous MOUD treatment for patients with pain and OUD</li> <li>Decreased opioid-related adverse events</li> <li>Decreased number of escalations to high opioid dosages</li> <li>Decreased number of transitions from opioid prescriptions for acute pain to long-term opioid therapy</li> </ul>

This data collection effort is authorized under Section 301 of the Public Health Service Act (42 U.S.C. 241) 280-1a and is necessary and unique (Attachment A). 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.<sup>8</sup> This work fits into CDC’s six principles and five strategic priorities to address the opioid crisis by supporting clinicians, health systems, payers, and employers.<sup>9</sup> Finally, this study helps to meet the goals of the US Department of Health and

<sup>8</sup> United States Congress – 116<sup>th</sup> Congress – Committee on Health, Education, Labor and Pensions. Managing Pain During the Opioid Crisis. February 12, 2019.

<sup>9</sup> Centers for Disease Control and Prevention. 2024. Overdose Prevention. <https://www.cdc.gov/drugoverdose/prevention/index.html>

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Human Services Overdose Prevention Strategy focused on primary prevention, including to “support development of and promote evidence-based treatments to effectively manage pain.”<sup>10</sup>

## A2. Purpose and Use of the Information Collection

Guided by overall project Aims 1-3, the purpose and use of the information collection (**Exhibit 4**) is as follows:

### ***Aim 1 (Dissemination Evaluation)***

The purpose of the dissemination evaluation (Aim 1) is to evaluate CDC’s efforts in disseminating the 2022 CDC Clinical Practice Guideline, with a specific focus on awareness of the 2022 CDC Clinical Practice Guideline among clinicians. Data to support this evaluation aim will be produced from:

- Interviews with clinicians, and leaders from health systems, payers, professional associations, and medical boards to understand how they learned of the updated 2022 CDC Clinical Practice Guideline and the degree to which CDC’s strategies to disseminate the guideline reached these interested parties; and
- Review of CDC-provided dissemination materials and activities to understand dissemination strategy and targeted literature searches in the gray and published literature to investigate how the 2022 CDC Clinical Practice Guideline was received.

The project team will triangulate and synthesize the findings from interviews with interested parties, CDC-provided dissemination activities and resources (e.g., trainings, information sheets, email blasts, etc.), and the gray and published literature search to answer the complex and interdependent research questions provided in **Exhibit** .

### ***Aim 2 (Impact Evaluation)***

The goal of Aim 2 is to evaluate the impact of the 2022 CDC Clinical Practice Guideline on changes in prescribing practices for opioids and medications for opioid use disorder. We will estimate the impact of the 2022 CDC Clinical Practice Guideline on several different outcomes using commercial claims data (Merative MarketScan) on patients’ diagnoses, medical care, and treatments, including prescriptions before and after the release of the 2022 CDC Clinical Practice Guideline. We will use patient level diagnosis and procedure codes reported in the claims data to exclude patients with cancer, sickle cell disease, and those receiving palliative or end-of-life care. We will use patients’ history of diagnosis codes to classify patients with acute, subacute, and/or chronic pain.

### ***Aim 3 (Implementation Evaluation)***

The aim of this evaluation is to evaluate the implementation of the 2022 CDC Clinical Practice Guideline from the perspective of patients, caregivers, clinicians, and leaders from health systems, payers, professional associations, and medical boards. Using the overarching framing of the PRISM implementation science framework (**Error: Reference source not found**), we will examine the contextual factors influencing the implementation of the 2022 CDC Clinical Practice Guideline,

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<sup>10</sup> U.S. Department of Health and Human Services. 2024. Overdose Prevention Strategy - Primary Prevention. <https://www.hhs.gov/overdose-prevention/primary-prevention>



focusing specifically on facilitators and barriers to implementation, lessons learned, unintended positive or negative consequences, and application/misapplication of the guideline. The analysis of Aim 3 will combine data from the national survey of clinicians; interviews with clinicians (including dentists),<sup>11</sup> and leaders from health systems, payers, professional associations, and medical boards; focus groups with patients and caregivers; and the environmental scan of payer policies.

**Environmental Scan, Gray, and Published Literature Search**

To explore the context and ongoing narrative about the 2022 CDC Clinical Practice Guideline implementation, we will conduct targeted literature searches (gray and published) and internet searches to collect reactions to the 2022 CDC Clinical Practice Guideline, including comments and opinion pieces on how effectively the 2022 CDC Clinical Practice Guideline achieves its aim of promoting safer and effective pain management, or the degree to which there are unintended consequences or other negative impacts. We will follow standard strategies for literature and internet searches, including identifying keywords and tracking responses. We may incorporate databases such as Altmetric, Scopus, and BMJ analytics to support the search. We will document the results and thoroughly review key themes.

**Payer Analysis**

We propose conducting an analysis of changes in public and private payers’ policies—e.g., those governing Medicaid, Medicare, private health plans—since late 2022 when the CDC released the Clinical Practice Guideline. While not a goal of the 2022 CDC Guideline, published guidelines often inform public policy and clinical practices. We will conduct an analysis of federal laws and associated regulations that relate to or impact the prescribing or insurance coverage of different pain treatments and modalities as an indication of reach or uptake of the guideline; a brief environmental scan of federal guidance documents and other resources on federal websites or pain management advocacy organization websites, as well as drug formularies and any state or local prescribing regulations; and an analysis of available state Essential Health Benefit Benchmark Plans to summarize the current coverage landscape and any changes implemented since the publication of the 2022 CDC Clinical Practice Guideline.

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

Method	# Collected	Sample Size	Primary Aim(s)
Primary Data			
Clinician Survey	600	3,000 invitations (upper bound is 3,000 clinicians with an estimated 20%)	<ul style="list-style-type: none"> <li>• Approach to managing pain and prescribing opioids</li> <li>• Shared decision-making</li> <li>• Confidence in providing care and treatment for patients with acute, subacute, or chronic pain</li> </ul>

<sup>11</sup> Dentists are included as a separate group from clinicians because the research design includes a separate sampling approach and interview guide specific to dentists.

Method	# Collected	Sample Size	Primary Aim(s)
		response rate)	<ul style="list-style-type: none"> <li>• Changes to clinical practice</li> <li>• Awareness of the 2022 CDC Clinical Practice Guideline</li> <li>• Training about the 2022 CDC Clinical Practice Guideline received</li> <li>• Perceptions of 2022 CDC Clinical Practice Guideline</li> <li>• Practice level policies and changes since 2022 CDC Clinical Practice Guideline published</li> <li>• Facilitators/Barriers</li> <li>• Practice and Clinician Characteristics.</li> </ul>
Clinician Interview	30	Invitations to participate solicited from clinicians responding to survey invitation, estimating 600 respondents	<ul style="list-style-type: none"> <li>• Approach to managing pain and prescribing opioids</li> <li>• Practice level policies and changes since 2022 CDC Clinical Practice Guideline published</li> <li>• Supports/services to help patients manage pain</li> <li>• Awareness of the 2022 CDC Clinical Practice Guideline</li> <li>• Changes in practices since the 2022 CDC Clinical Practice Guideline</li> <li>• Benefits/challenges for patients</li> <li>• Unintended consequences</li> <li>• Perceived patient/caregiver reactions to 2022 CDC Clinical Practice Guideline</li> <li>• Improvements in shared decision-making and person-centered care, equity in management of pain</li> <li>• Facilitators/Barriers</li> <li>• Lessons learned</li> </ul>
Dentist Interview	5	Invitations to 25 dentists to participate  Generated from list of dentists referred by the American Dental Association	<ul style="list-style-type: none"> <li>• Approach to managing pain and prescribing opioids</li> <li>• Practice level policies and changes since 2022 CDC Clinical Practice Guideline published (Practice Policies)</li> <li>• Supports/services to help patients manage pain</li> <li>• Awareness of the 2022 CDC Clinical Practice Guideline</li> <li>• Changes in practices since the 2022 CDC Clinical Practice Guideline</li> <li>• Unintended consequences</li> <li>• Benefits/challenges for patients</li> <li>• Perceived patient/caregiver reactions to 2022 CDC Clinical Practice Guideline</li> <li>• Improvements in shared decision-making and person-centered care, equity in management of pain</li> <li>• Facilitators/Barriers</li> <li>• Lessons learned</li> </ul>
Interviews with Leaders from Health Systems	10	TBD	<ul style="list-style-type: none"> <li>• Role of organization in setting policies/regulations about pain management, opioids, or MOUD</li> <li>• Awareness of the 2022 CDC Clinical Practice Guideline</li> <li>• Changes in policies/regulations/mandates/positions related to pain management, opioid prescribing, or OUD</li> <li>• Strategies to increase implementation/adoption of the 2022 CDC Clinical Practice Guideline</li> <li>• Perception of the 2022 CDC Clinical Practice Guideline broadly</li> </ul>

Method	# Collected	Sample Size	Primary Aim(s)
			<ul style="list-style-type: none"> <li>Dissemination campaigns/support</li> <li>Implementation successes/challenges, unintended consequences</li> <li>Improvements in shared decision-making and person-centered care, equity in management of pain</li> <li>Facilitators/Barriers</li> <li>Unintended consequences</li> <li>Lessons learned</li> </ul>
Interviews with Payers	10	TBD	<ul style="list-style-type: none"> <li>Role of organization in setting coverage/formularies</li> <li>Formulary management strategies related to pain management/opioids/MOUD</li> <li>Updated guidance provided by payers (experience/perspective)</li> <li>Awareness of the 2022 CDC Clinical Practice Guideline</li> <li>Changes in payer policies and coverage for pain treatments, including opioids (e.g., limits on days' supply, prior authorizations, coverage of non-opioid &amp; non-pharmacologic therapies)</li> <li>Communication campaigns conducted</li> <li>Changes in payer policies for MOUD</li> <li>Implementation successes/challenges, unintended consequences</li> <li>Facilitators/Barriers</li> </ul>
Interviews with leaders from professional associations (e.g., American Association of Family Practitioners, National Association of Community Health Centers, Society for General Internal Medicine, American Dental Association)	10	TBD	<ul style="list-style-type: none"> <li>Awareness of the 2022 CDC Clinical Practice Guideline</li> <li>Updated guidance provided by association (experience/perspective)</li> <li>Perception of implementation</li> <li>Uptake by clinicians, practices, or health systems</li> <li>Facilitators/Barriers</li> <li>Improvements in shared decision-making and person-centered care, equity in management of pain</li> <li>Equity in management of pain</li> <li>Changes in clinical practice</li> <li>Lessons learned</li> </ul>
Interviews with Leaders from Medical Boards	10	TBD	<ul style="list-style-type: none"> <li>Role of organization in setting policies/regulations about pain management, opioids, or MOUD</li> <li>Awareness of the 2022 CDC Clinical Practice Guideline</li> <li>Changes in policies/regulations/mandates/positions related to pain management, opioid prescribing, or OUD</li> <li>Dissemination efforts</li> <li>Facilitators/Barriers of adoption/implementation</li> <li>Improvements in shared decision-making and person-centered care, equity in management of pain</li> <li>Changes in clinical practices perceived, unintended consequences</li> </ul>
Focus Groups with patients	3 focus groups at 3 time	TBD	<ul style="list-style-type: none"> <li>Experience with management of pain, treatment modalities</li> </ul>

Method	# Collected	Sample Size	Primary Aim(s)
	points, each ~15 participants		<ul style="list-style-type: none"> <li>Perceptions of changes in prescribing and treatment of pain after the release of the 2022 Clinical Practice Guideline</li> </ul>
Focus Groups with caregivers	2 focus groups at 3 time points, each ~15 participants	TBD	<ul style="list-style-type: none"> <li>Experience with management of pain, treatment modalities</li> <li>Perceptions of changes in prescribing and treatment of pain after the release of the 2022 Clinical Practice Guideline</li> </ul>
<b>Secondary Data</b>			
Secondary data populated from a commercial claims database (Merative LRx and Dx medical claims data)	1 Dataset	Private insurance medical claims data (anonymized) for 5 million individuals from 2020 through 2023 from commercial data vendor	<ul style="list-style-type: none"> <li>Changes in prescribing patterns and practices, based on medical claims and prescribing data</li> </ul>
<b>Internet and Literature Search</b>			
Environmental Scan/Literature Review	N/A	N/A	<ul style="list-style-type: none"> <li>Perception in medical community</li> <li>Changes in policies/protocols because of the 2022 Clinical Practice Guideline</li> <li>Unintended consequences</li> <li>Facilitators/Barriers</li> </ul>
Environmental Scan of Payer Policies	N/A	N/A	<ul style="list-style-type: none"> <li>Changes in payer policies and coverage for continuum of pain therapies</li> </ul>

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

### **Clinician Survey (Attachment C and N)**

We will conduct a survey of 600 outpatient clinicians who are able to prescribe opioids to their patients with acute, subacute, and/or chronic pain (**Exhibit 5**). Inclusion criteria for practicing clinicians include that the clinicians: 1) practice in an ambulatory, outpatient and/or emergency department at least once a week; 2) primarily treat adults (aged  $\geq 18$  years); 3) treat patients with acute, subacute, and/or chronic pain other than pain management related to sickle cell disease, cancer-related pain treatment, palliative care, and/or end of life care; 4) practice in the following care areas: family medicine, internal medicine, emergency medicine, surgery, occupational medicine, physical medicine and rehabilitation medicine, neurology, obstetrics and gynecology. The survey design will be cross-sectional, conducted at a single point in time, and web based. The survey is expected to take 10 minutes to complete.

We will use a random sample for the survey comprising 3,000 clinicians. We will use IQVIA's national database of clinicians. IQVIA's dataset includes a diverse set of clinicians with respect to their specialty, geographic region, and practice type, and which characteristics are associated with differences in opioid prescribing practices. The IQVIA medical professionals database continues to expand, but it is based on commercial claims data and other sources.<sup>12</sup> We will

<sup>12</sup> See the IQVIA's healthcare provider database sources here: <https://www.onekeydata.com/databases>

request a sample from IQVIA that includes clinicians (including physicians, nurse practitioners, and physician assistants) who practice in the following care areas: family medicine, internal medicine, emergency medicine, surgery, occupational medicine, physical medicine and rehabilitation medicine, neurology, obstetrics and gynecology. In addition, clinicians whose primary practice is in the US Department of Veterans Affairs (VA) will be excluded from the sample, as the VA has developed and follows an Opioid Prescribing Guideline that is independent from the 2022 CDC Clinical Practice Guideline. Dentists will also be excluded from the sample due to the fact that IQVIA includes dentists in a separate database than the database from which this sample will be drawn. The survey contains several eligibility questions to ensure we are sampling respondents who align with the intended audience of the 2022 CDC Clinical Practice Guideline.

### Exhibit 5. Survey Domains and Potential Scales, Items, Sources

Domain	Sample Survey Items / Sources
Awareness, use, and attitude as determinant of use toward the 2022 CDC Clinical Practice Guideline	<ul style="list-style-type: none"> <li>✓ Adapted from the Clinician Guideline Determinants Questionnaire (Gagliardi et al. 2019)<sup>13</sup></li> <li>✓ Items used in previous projects surveying clinicians</li> <li>✓ Items developed <i>de novo</i></li> </ul>
Clinician reported prescribing practices	✓ Developed items based on Guideline recommendations and asking for clinicians to report prescribing practices
Clinician confidence items	✓ Items used in prior AHRQ project cited below
Shared decision-making	✓ Items are adapted from the 9-item Shared Decision-Making Questionnaire (SDM-Q-Doc, physician version) <sup>14</sup>
Clinic-level policies and practices related to opioids	✓ Adapted from prior AHRQ opioid project cited below
Facilitators / barriers to implementation	<ul style="list-style-type: none"> <li>✓ Clinician Guideline Determinants Questionnaire (Gagliardi et al. 2019).<sup>9</sup></li> <li>✓ AHRQ Opioids in Older Adults National Survey</li> </ul>
Clinician characteristics	<ul style="list-style-type: none"> <li>✓ Clinician type (MD, DO, NP, PA) and specialty</li> <li>✓ Years practicing medicine</li> <li>✓ Patient characteristics</li> </ul>
Practice characteristics	✓ Practice location and practice setting (e.g., ownership, affiliation, FQHC)

### Survey Administration

The survey will be administered using a central data collection platform once OMB approval is secured. Our survey administration system, Conformat, guarantees high availability, business continuity, data integrity and durability, and scalable high-speed performance from any location. It optimizes surveys for mobile devices and provides a unique URL survey link, so respondents need not enter a user ID and password. In addition, our team tests its web surveys on several types of mobile devices and web browsers to ensure consistent user experiences. Survey administration will follow the schedule in **Exhibit 6**. Conformat also allows for seamless

<sup>13</sup> Gagliardi AR, Armstrong MJ, Bernhardsson S, et al. The Clinician Guideline Determinants Questionnaire was developed and validated to support tailored implementation planning. *Journal of Clinical Epidemiology*. 2019;113:129-136.

<sup>14</sup> Kriston L, Scholl I, Hölzel L, Simon D, Loh A, Härter M. The 9-item Shared Decision Making Questionnaire (SDM-Q-9). Development and psychometric properties in a primary care sample. *Patient education and counseling*. 2010;80(1):94-99.

integration for the virtual incentive payouts. To encourage participation, we will provide respondents with a \$25 incentive for survey completion. We believe a 20% response rate is achievable, which comports with other web-based clinician survey response rates. Assuming a 20% response rate, we anticipate approximately 600 survey responses.

**Exhibit 6. Survey administration timeline**

Survey activity	Timeline
Advance survey notification email sent to all clinicians with an email address	3 business days before survey launch
Initial survey invitation containing URL link sent to all clinicians with email addresses	Day 0 (survey launch)
Reminder email 1 sent to all non-respondents with an email address	Day 14
Reminder email 2 sent to all non-respondents with an email address	Day 28
Survey closes	Day 42

**Interview with Clinicians (Attachment D)**

We will conduct interviews with 30 outpatient clinicians who treat patients for acute, subacute, and chronic pain. This sample will be drawn from the individuals who completed the clinician survey (described in above section) and agreed to be contacted for a follow-up interview. We plan to conduct interviews shortly after the survey closes to allow for respondents to remember the survey and that they agreed to be contacted, with the aim of increasing interest in participation. We will stratify our sample based on categories of interest, such as practice type, reported changes to practice or policies because of the 2022 CDC Clinical Practice Guideline, and others to be determined. We will compile a list of approximately 30 clinicians and collaborate with the CDC COR to select participants. The one-time interviews will be conducted via Microsoft Teams and will last approximately 60 minutes. Participants will receive a \$100 incentive in the form of a virtual gift card.

**Interview with Dentists (Attachment E)**

We will conduct interviews with 5 dentists. We will work with the American Dental Association to seek referrals for potential interview participants. The interviews will be conducted via Microsoft Teams and will last approximately 60 minutes. Participants will receive a \$100 incentive in the form of a virtual gift card. The interviews with dentists will be at approximately the same time as the interviews with clinicians to explore comparative experiences across clinician type.

**Interviews with Leaders from Health Systems (Attachment F)**

We will conduct up to 10 interviews with leaders from health systems to understand their experience implementing the 2022 CDC Clinical Practice Guideline. We will identify and recruit participants through CDC and the project team’s networks as well as through Internet searches. Potential respondents include: chief medical officer (CMO), VP of Quality and Safety, VP for Primary Care. We will conduct interviews with up to 10 individuals at two time periods, approximately two years apart to provide time for evolution in policy and practice. Interviews will be conducted via Microsoft Teams and will last approximately 60 minutes. Participants will receive a \$100 incentive in the form of a virtual gift card.

**Interview with Payers (Attachment G)**

We will conduct up to 10 interviews with individuals that represent public and private payers (i.e., Medicaid, Medicare, private health plans providing employer, marketplace, managed care

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or Medicare Advantage plans) to understand their experience implementing the 2022 CDC Clinical Practice Guideline. We will identify and recruit participants through CDC and the project team's networks as well as through Internet searches. We will conduct interviews with up to 10 individuals at two time periods, approximately two years apart. Interviews will be conducted via Microsoft Teams and will last approximately 60 minutes. Participants will receive a \$100 incentive in the form of a virtual gift card.

#### **Interviews with Leaders from Professional Associations (Attachment H)**

We will conduct up to 10 interviews with leaders from professional associations, such as the American Association of Family Practitioners, National Association of Community Health Centers, Society for General Internal Medicine, to understand their experience implementing the 2022 CDC Clinical Practice Guideline. We will identify and recruit participants through CDC and the project team's networks as well as through Internet searches. We will conduct interviews with up to 10 individuals at two time periods, approximately two years apart to provide time for evolution in policy. Interviews will be conducted via Microsoft Teams and will last approximately 60 minutes. Participants will receive a \$100 incentive in the form of a virtual gift card.

#### **Interviews with Leaders from Medical Boards (Attachment I)**

We will conduct up to 10 interviews with individuals from state medical boards to understand their experience implementing the 2022 CDC Clinical Practice Guideline. We will identify and recruit participants through CDC and the project team's networks as well as through Internet searches. We will conduct interviews with up to 10 individuals at two time periods, approximately two years apart to provide time for evolution in policy. Interviews will be conducted via Microsoft Teams and will last approximately 60 minutes. Participants will receive a \$100 incentive in the form of a virtual gift card.

#### **Patient Focus Groups (Attachment J)**

Focus groups with patients provide an in-depth understanding of experiences with pain management in their real-world contexts. Examining the experiences of patients can provide a deeper understanding of real-world behavior within a specific healthcare context to elucidate perceptions of whether and/or how changes occurred in overall treatment and/or pain management, including opioid prescribing. Focus groups will be conducted via Microsoft Teams and will last approximately 60 minutes. Participants will receive a \$75 incentive in the form of a virtual gift card. We will conduct three focus groups with patients at three time points, each containing 15 participants for a total of 135 patients, to allow for an understanding of how experiences may evolve after the 2022 CDC Clinical Practice Guideline was introduced.

#### **Caregiver Focus Groups (Attachment K)**

Focus groups with caregivers provide an in-depth understanding of experiences with pain management in their real-world contexts. Examining the experiences of caregivers can provide a deeper understanding of real-world behavior within a specific healthcare context to elucidate perceptions of whether and/or how changes occurred in overall treatment and/or pain management, including opioid prescribing. Focus groups will be conducted via Microsoft Teams and will last approximately 60 minutes. Participants will receive a \$75 incentive in the form of a virtual gift card. We will conduct two focus groups of caregivers at three time points, each

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containing 15 participants for a total of up to 90 caregivers, to allow for an understanding of how experiences may evolve after the 2022 CDC Clinical Practice Guideline was introduced.

### **Abstraction of Secondary Data**

To complement the primary data collection efforts described above, a single secondary dataset will be used to estimate the impact of the 2022 CDC Clinical Practice Guideline on several different outcomes using commercial claims data on patients' diagnoses, treatment codes, and prescriptions dispensed before and after the release of the 2022 CDC Clinical Practice Guideline.

### **A3. Use of Improved Information Technology and Burden Reduction**

To minimize respondent burden and to permit the electronic submission of survey responses, the clinician surveys will be web-based and deployed using a well-designed, low burden, and respondent-friendly survey administration process and instruments. We will collect email addresses from and send emails to potential respondents with a unique 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 receive a second reminder email 4 weeks after the initial email is sent. The survey will close on day 42. (Attachment C, C1 and C2).

### **A4. Efforts to Identify Duplication and Use of Similar Information**

This research study will be the first CDC-funded comprehensive evaluation of the implementation and uptake of the 2022 CDC Clinical Practice Guideline for Prescribing Opioids for Pain.

This project builds upon previous efforts by CDC to understand more about pain and pain management through engagement with three different groups: patients with acute, subacute, 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 evaluation is unique in that it seeks to assess the dissemination, implementation, and impact of the 2022 CDC Clinical Practice Guideline across multiple partners including patients, caregivers, clinicians, health system leaders, payers, professional association leaders, and medical board leaders.

CDC has previously supported projects studying various interventions related to implementation of its 2016 CDC Guideline. 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 1onic 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



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Quality Improvement Collaborative, CDC developed quality improvement measures that mapped the 12 recommendations in the 2016 CDC Guideline 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. Overall, research methods proposed within this current evaluation differ substantially in that they will expand upon methods developed in previous investigations and apply them to an evaluation of the new 2022 CDC Clinical Practice Guideline.

#### 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 data collection described in this document will occur over a period of three years with patients, caregivers, clinicians (including dentists), and leaders from health systems, payers, professional associations, and medical boards. Not collecting the data at all or shortening the data collection period (either by decreasing the study duration or number of participants) places us at risk of not obtaining adequate information to ascertain how effectively the 2022 CDC Clinical Practice Guideline was disseminated and implemented or the full extent of its impact on clinical practice. This could limit the ability of the findings to inform future activities related to clinician, dentist, and other partner engagement.

#### 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. Because data related to race/ethnicity would not be a focus of the analysis, it was determined that only the minimum data elements for race/ethnicity would need to be collected. Inclusion of racial and ethnic subgroups as responses to the demographic question would be considered confusing and would serve to increase the burden on respondents.

#### 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 October 1, 2024, vol. 89, No. 190, pp. 79925 (Attachment B). CDC responded to the two public comments to this

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notice (Attachment B1). The public comments received did not have specific suggestions that impact any evaluation instruments; therefore, no changes were made to the instruments.

### **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 on this project include GDIT and Abt Global. Contractors consulted included researchers, statisticians, clinicians, and pharmacists with expertise in evaluation research and survey methodology, as well as opioid prescribing.

Finally, primary data collection materials were reviewed and approved by the Abt Global's 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 clinician survey respondents, as well as key informant interviewees and focus group participants.

We intend to offer, as tokens of appreciation, \$25 to clinicians who complete the survey and \$75 to patients or caregivers for participating in focus groups. A \$100 incentive will be provided to clinicians (including dentists), leaders from health systems, payers, professional associations, and medical boards for participating in interviews. We have constructed this study's incentive structure to be in line with incentives approved by OMB on similar surveys and supported by the literature when surveys are conducted with clinicians and healthcare leaders. 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.<sup>15</sup> 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.<sup>16</sup> Research suggests that even small tokens of appreciation may increase response rates of hard-to-reach populations, such as

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<sup>15</sup> Edwards P, Roberts I, Clarke M, DiGuseppi C, Pratap S, Wentz R, Kwan I. Increasing response rates to postal questionnaires: Systematic review. *British Medical Journal*. 2002;324:1183.

<sup>16</sup> 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>.

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respondents from racial/ethnic minority backgrounds,<sup>17, 18</sup> which in turn may help to avoid non-response bias.

#### 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 participants at the individual level. All personally identifiable information (PII) will be removed from the files prior to uploading using Cerberus/FT, 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 M).

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

##### **Institutional Review Board (IRB)**

This project involves human subject research in which CDC is not engaged. CDC has received IRB approval for this formative research involving human subjects through Abt Global IRB (Attachment L). The Abt Global 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 Global holds a current Federal-Wide Assurance (FWA) for the Protection of Human Subjects from the U.S. Department of Health and 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.

#### A12. Estimates of Annualized Burden Hours and Costs

Time estimates are based on prior experiences and what can reasonably be requested of participating clinicians (including dentists), patients, and health care system leaders. The number of respondents listed in the table below reflects a projected 20% response rate for data collection efforts.

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<sup>17</sup> Beebe, T. J., Davern, M. E., McAlpine, D. D., Call, K. T., Rockwood, T. H. (2005). Increasing response rates in a survey of Medicaid enrollees: the effect of a prepaid monetary incentive and mixed modes (mail and telephone). *Medical Care*, 43, 411-414.

<sup>18</sup> Dykema, J., Stevenson, J., Kniss, C., et al. (2012). Use of monetary and nonmonetary incentives to increase response rates among African Americans in the Wisconsin Pregnancy Risk Assessment Monitoring System. *Maternal Child Health Journal*, 16, 785-791.

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**Clinician Survey (Attachment C and N).** A brief survey will be emailed to all outpatient clinicians who are eligible and treat patients for acute, subacute, and chronic pain. Non-respondents will be contacted with two additional emails after two weeks to increase response rates. A total of 3,000 licensed clinicians will be contacted (Attachment C1 and C2); 600 (assuming a 20% response rate) are expected to respond. The Clinician Survey is expected to take 10 minutes to complete based on pilot testing and experience with similar data collection efforts.

**Interviews with Clinicians (Attachment D).** In-depth interviews will occur with 30 clinicians drawn from clinician survey participants that agreed to participate in an interview. The team will conduct these interviews, each lasting up to 60 minutes. The burden estimate is based on experience with similar data collection efforts.

**Interviews with Dentists (Attachment E).** In-depth interviews will occur with five dentists drawn from referrals from the American Dental Association who agreed to participate in an interview. The team will conduct these interviews, each lasting up to 60 minutes. The burden estimate is based on experience with similar data collection efforts.

**Interviews with Leaders from Health Systems (Attachment F).** In-depth interviews will occur with up to 10 leaders from health systems at two time periods. The team will conduct these interviews, each lasting up to 60 minutes. The burden estimate is based on experience with similar data collection efforts.

**Interview with Payers (Attachment G).** In-depth interviews will occur with up to 10 public or private payers at two time periods. The team will conduct these interviews, each lasting up to 60 minutes. The burden estimate is based on experience with similar data collection efforts.

**Interviews with Leaders from Professional Associations (Attachment H).** In-depth interviews will occur with up to 10 leaders from professional associations at two time periods. The team will conduct these interviews, each lasting up to 60 minutes. The burden estimate is based on experience with similar data collection efforts.

**Interviews with Leaders from Medical Boards (Attachment I).** In-depth interviews will occur with up to 10 leaders from medical boards at two time periods. The team will conduct these interviews, each lasting up to 60 minutes. The burden estimate is based on experience with similar data collection efforts.

**Patient Focus Groups (Attachment J).** To learn more about patient journeys, focus groups will be conducted with patients and caregivers. For patients, we will conduct three focus groups at three time points, each containing 15 participants. The team will conduct these focus groups, each lasting approximately 60 minutes. The burden estimate is based on experience with similar data collection efforts.

**Caregiver Focus Groups (Attachment K).** To learn more about patient journeys, focus groups will be conducted with patients and caregivers. For caregivers, we will conduct two focus groups at three time points, each containing 15 participants. The team will conduct these focus groups,

each lasting approximately 60 minutes. The burden estimate is based on experience with similar data collection efforts.

The table below (**Exhibit 7**) represent the estimated annualized burden, which shows each data collection activity divided by the three project years.

**Exhibit 7. 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)
Clinicians	Clinician Survey (Att. C)	200	1	10/60	33
	Invitation (Att. C1)	1000	1	5/60	83
	Follow up Emails (Att. C2)	1000	1	5/60	83
	Clinician Interview (Att. D)	10	1	1	10
Dentists	Dentist Interview (Att. E)	2	1	1	2
Health System Leaders	Health System Leaders Interview (Att. F)	3	2	1	6
Payers	Payer Interview (Att. G)	3	2	1	6
Professional Association Leaders	Professional Association Leaders Interview (Att. H)	3	2	1	6
Medical Board Leaders	Medical Board Leaders Interview (Att. I)	3	2	1	6
Patients	Patient Focus Groups (Att. J)	15	3	1	45
Caregivers	Caregiver Focus Groups (Att. K)	15	2	1	30
				<b>TOTAL</b>	<b>310</b>

The table below (**Exhibit 8**) present the estimated annualized cost burden associated with the respondents’ time to participate in this research. The total annual cost burden is estimated to be \$51,732, while the annual burden is estimated to be 310 hours. There are no direct costs to respondents other than their time to participate in the study.

**Exhibit 8. Estimated Annualized Burden Cost**

Type of Respondent	Form Name	Total Burden (in hours)	Hourly Wage Rate (in USD)	Total Cost
Clinicians	Clinician Survey	33	\$215.82	\$7,122
Clinicians	Invitation	83	\$215.82	\$17,913
Clinicians	Follow up Email	83	\$215.82	\$17,913
Clinicians	Clinician Interview	10	\$215.82	\$2,158
Dentists	Dentist Interview	2	\$165.66	\$331
Health System Leaders	Health System Leaders Interview	6	\$123.06	\$738
Payers	Payer Interview	6	\$123.06	\$738
Professional Association Leaders	Professional Association Leaders Interview	6	\$123.06	\$738
Medical Board Leaders	Medical Board Leaders Interview	6	\$123.06	\$738
Patients	Patient Focus Groups	45	\$44.58	\$2,006
Caregivers	Caregiver Focus Groups	30	\$44.58	\$1,337

			<b>TOTAL</b>	<b>\$51,732</b>
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Mean hourly wage rates for these groups of occupations were obtained from the Bureau of Labor & Statistics on “Occupational Employment and Wages, May 2022” found at the following URL: [http://www.bls.gov/oes/current/oes\\_nat.htm#b29-0000.htm](http://www.bls.gov/oes/current/oes_nat.htm#b29-0000.htm)

The average hourly rate of \$215.82 for the primary care clinician survey and interviews was calculated based on the 2022 mean hourly wage rate for family medicine physician, \$107.91 (occupation code 29-1215), doubled to account for employer overhead and fringe benefits.

The average hourly rate of \$165.66 for the dentist interview was calculated based on the 2022 mean hourly wage rate for dentist - general, \$82.83 (occupation code 29-1021), doubled to account for employer overhead and fringe benefits.

The average hourly rate of \$123.06 for leaders from health systems, payers, professional associations, and medical boards were calculated based on the 2022 mean hourly wage rate for medical and health services managers, \$61.53 (occupation code 11-9111), doubled to account for employer overhead and fringe benefits.

The average hourly rate of \$44.58 for patients was calculated based on the 2022 mean hourly wage rate for construction laborers, \$22.29 (occupation code 47-2061), doubled to account for employer overhead and fringe benefits.

#### 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 research study will take place over a 4-year period. The total cost of this research study to the Federal Government will be \$3,983,443.38. The government costs include personnel costs for one federal employee providing project planning and oversight at 15% FTE.

Exhibit 9 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 9. Annualized Cost to the Government

Type of Cost	Description of Services	Annual Cost
Contractor	Data collection, data analysis, project management	\$995,860.85
Technical monitor at 15% FTE (CDC)	Study planning and project oversight	\$28,239.90
Total Annual Estimated Government Costs		\$1,024,100.75

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## A15. Explanation for Program Changes or Adjustments

This is a new information collection.

## A16. Plans for Tabulation and Publication and Project Time Schedule

Analysts will clean the dataset and prepare it for analysis once the survey closes; this cleaning may incorporate back-coding to ensure consistency of responses where possible; this may result in dropping some respondents from analyses if inconsistent responses cannot be harmonized. We will analyze the survey data to describe clinicians' awareness of, use of, and facilitators or barriers to implementation of the 2022 CDC Clinical Practice Guideline. We will report descriptive statistics, including the mean, median, and standard deviation and/or confidence intervals of continuous variables and frequencies and proportions for categorical variables, in tables and visualized in figures and graphics.

All qualitative data will be coded and analyzed using NVivo qualitative analytic software. Codebook development will be iterative and include deductive codes (established *a priori* from the evaluation questions and PRISM framework) and inductive codes (those that emerge from the data). Codebook development process will begin with the *a priori* codes and will conduct thematic coding and iteratively expand the codebook, especially where we do not have an existing framework. Research team members will independently read selected excerpts of data sources (interview and focus group transcripts) to link to *a priori* codes and develop potential new codes. We will discuss codes, definitions, and inclusion and exclusion criteria to develop an initial codebook and use the initial codebook to code new transcripts. We will continue to refine the codebook until the codebook is sufficiently detailed to capture meaningful insight and to use the codebook for coding all materials. We will document the themes that emerge from each type of data and across data sources, synthesize themes, determine findings, and extract actionable recommendations. Quality assurance procedures will include training coders, periodically checking inter-rater reliability, and frequent debriefs on findings and coding.

All qualitative data will be analyzed based on the codes developed and previously described. The qualitative analysis and synthesis will take several forms to serve the 2022 CDC Clinical Practice Guideline evaluation aims. The following are some of the key analytic approaches and/or expected syntheses we may present:

- **Comparative analysis of different perspectives on the 2022 CDC Clinical Practice Guideline.** The project team will present a comparative qualitative analysis of the perspectives of different interested parties, for example: 1) What were the **similarities and differences** in clinicians, patients and caregivers' perspectives on the patient-centeredness, shared decision-making, tapering, health equity, positive outcomes, unintended consequences, and trends in potential misapplication? 2) What was the **readiness for implementation and policy changes** related to the 2022 CDC Clinical Practice Guideline by various groups of interested parties, and what may be the driving factors for any differences?
- **What is the context and through what mechanisms or strategies are health systems and clinicians implementing the 2022 CDC Clinical Practice Guideline?** Implementation strategies are methods or techniques used to enhance the adoption, implementation, and sustainability of a clinical program or practice. In this case, these are the strategies to implement the clinical recommendations within guidelines or policies within health systems to address

opioid prescribing, pain management, or provision of MOUD. Based on surveys and interviews with clinicians and health systems leaders, we will characterize the type and nature of discrete implementation strategies used to implement the 2022 CDC Clinical Practice Guideline.

- **What were the facilitators and barriers to implementing the 2022 CDC Clinical Practice Guideline?** What were the external environmental factors that have and/or may play a key role in the implementation and impact of the 2022 CDC Clinical Practice Guideline? The qualitative data from focus groups and interviews will be synthesized to understand implementation experiences including determinants of success or facilitators and challenges or barriers to implementation. The project team will use the determinants highlighted in the PRISM framework, including factors related to: 1) the Intervention (the 2022 CDC Clinical Practice Guideline), 2) the Recipients (health systems, prescribers, patients and caregivers), 3) the Implementation and Sustainability Infrastructure (policy changes, readiness for change for the updated guideline) and 4) the External Environment (how professional associations and medical boards have changed practices; payment policy changes by payers).
- **How have payer/insurer policies changed with respect to opioid prescribing limits and/or coverage of non-opioid therapies?** We will present a synthesis of the findings from the payer analysis and interviews with payers.

### Mixed-Methods Triangulation

Mixed-methods approaches are recognized as useful for rigorous investigations in primary care, and, as such, a range of mixed-methods approaches are anticipated. We anticipate leveraging *triangulation* and *explanatory* designs. For example, we will *triangulate* data from the survey and interviews of health system leaders, professional associations leaders, medical board leaders, and clinicians to understand prescribing practices. We will seek to use interviews with various interested parties to *explain* or *interpret* unexpected findings in the national survey of clinicians or in the impact evaluation. We will ultimately use the collected qualitative and quantitative data to the extent possible to answer the research questions. The mixed-methods approach will involve holding regular team meetings to discuss what the qualitative and quantitative data are revealing in the analysis using the commercial claims data, survey data, and qualitative data to understanding the implementation of the 2022 CDC Clinical Practice Guideline and to describe its effects, as well as to use qualitative data to contextualize findings.

### Exhibit 10. Project Time Schedule

Activity	Time Schedule
Administration of clinician surveys	Ongoing after OMB approval
Administration of patient/caregiver focus groups	Ongoing after OMB approval
Administration of clinician and dentist interviews	Ongoing after OMB approval
Administration of key informant interviews (health system leaders, payers, professional association leaders, medical board leaders)	Ongoing after OMB approval
Administration of patient/caregiver focus groups	Ongoing after OMB approval
Administration of key informant interviews (health system leaders, payers, professional association leaders, medical board leaders)	Ongoing after OMB approval
Administration of patient/caregiver focus groups	Ongoing after OMB approval
Qualitative data analysis	Ongoing after OMB approval



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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.