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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-21-21IE; Docket No. CDC-2021-0103]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Understanding Health System Approaches to Chronic Pain Management. The proposed study is designed to evaluate the effects of evidence-based guidelines related to chronic pain management and opioid prescribing.

DATES: CDC must receive written comments on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2021-0103 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.

- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS H21-8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS H21-8, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection

before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses; and
5. Assess information collection costs.

Proposed Project

Understanding Health System Approaches to Chronic Pain Management – New – National Center for Injury Prevention and

Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC requests OMB approval for three years for this new data collection. This study will evaluate the effects of 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.

Since 1999, nearly 841,000 people have died from drug overdose in the United States. Over 70% of drug overdose deaths in 2019 involved an opioid. 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. In response, a range of clinical practice guidelines, policies, and regulations have been released in recent years to address the opioid overdose epidemic, with the goals of supporting safer opioid prescribing, improving diagnosis and treatment of OUD, and reducing overdose deaths in the United States.

To design this evaluation, we previously conducted and completed a "Feasibility Assessment 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. For the purposes of this evaluation, "Chronic pain management policies/guidelines" refers to policies/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.

In early 2020, CDC requested OMB approval for a Feasibility Assessment of Health Systems ("Feedback on the use of the CDC Guideline for Prescribing Opioids for Chronic Pain") through the "Generic Clearance for the Collection of Routine Customer Feedback" (OMB Control No. 0920-1050). This brief eligibility assessment consisting of surveys was sent to approximately 250 health systems to understand the landscape of health systems and the types of guidelines or policies implemented, and what strategies were used to do so. Of 250 health systems contacted, 46 responded and were considered for the following preliminary phase - the evaluability assessment.

The purpose of this data collection effort is to: (1) 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 health systems, (2) describe unintended benefits and consequences to guideline/policy implementation, and (3) identify racial and ethnic disparities in guideline/policy implementation.

This mixed-methods, pre-post evaluation 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.

The total burden is estimated to be 577 hours annually. There are no direct costs to respondents other than their time to participate in the study.

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	667	1	10/60	111
Treatment facility staff (Including primary care clinicians, health system leaders, and other system staff and	Primary Care Clinician Survey	1,313	1	10/60	219
	Invitation/ Follow up Email	1,980	2	3/60	198
	Health System Leaders Group	17	1	1	17

representatives)	Interview Guide				
	Case Study Interview Guide	30	1	30/60	15
	Member Checking (Validation) Sessions Interview Guide	17	1	1	17
TOTAL					577

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