Supporting Statement A for Request for Clearance:
Physician Pain Management Questionnaire Pilot Study

Generic IC:
Development Studies to Improve the National Health Care Surveys
OMB No. 0920-1030
Expires June 30, 2023

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March 30, 2021

Table of Contents

List of Attachments:

Attachment A – Final Cognitive Report – Draft (PPMQ)
Attachment B – Survey Instrument (PPMQ)
Attachment C – List of Consultants (PPMQ)
Attachment D – Recruitment Materials (PPMQ)
Attachment E – ERB Protocol #2021-04 (PPMQ)

The National Center for Health Statistics (NCHS) requests approval to conduct a developmental, methodological survey study among physicians assessing their knowledge, awareness, and adherence to published clinical guidelines for prescribing opioids for pain. This study would fall under the current National Health Care Surveys Generic Clearance package (OMB No. 0920-1030, Exp. Date 06/30/2023), which currently allows for developmental studies on survey design and data collection activities that are part of the National Health Care Surveys.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Along with the novel coronavirus (COVID-19) pandemic, one of the greatest public health issues currently facing the nation is the opioid epidemic. Between 1999 and 2019, there was an increase in opioid induced overdose deaths occurring across 3 waves. The first wave was associated with prescription opioids (i.e., natural and semi-synthetic opioids and methadone) and began in 1999. Increased mortality involving heroin marked the second wave in 2010, and most recently there has been a third wave starting in 2013 involving synthetic opioids (which in part include the prescribed opioid fentanyl).

The rise in overdose deaths due to prescribed opioids heralded the opioid epidemic and was attributed to increased prescribing of opioids for chronic pain that began in the 1990s. In response, the public health community devised strategies to combat the epidemic. The Department of Health and Human Services (DHHS) deployed a National Pain Strategy in 2011, with safe delivery of pain therapies as one of its goals. In March 2016, the Centers for Disease Control and Prevention (CDC) developed a national guideline for prescribing opioids for chronic pain. Additionally, several professional medical associations, U.S. states and health organizations have developed their own independent guidelines for pain management.

Despite these efforts, overdoses involving prescription opioids accounted for 41 deaths per day in 2018, indicating that prescription opioids continue to play a role in the opioid epidemic. Consequently, it is important to understand physicians' awareness of and use of clinical guidelines when prescribing opioids. Currently, no surveys or data systems exist that collect national data on this topic; therefore, methodological development of a survey that could be implemented for these needs is essential.

As previously mentioned, the National Pain Strategy, an interagency effort, has a focus on implementing safe approaches for treating pain. Within the National Institutes of Health (NIH), the National Center for Complementary and Integrative Health (NCCIH) has been involved in this effort. One of the CDC's role in combatting the opioid epidemic is through supporting healthcare providers with guidance and tools to improve opioid prescribing and patient safety through evidence-based approaches. As such the NCCIH and National Center for Health Statistics (NCHS) entered into an interagency agreement (IAA) to: evaluate survey questions on physician knowledge, awareness and use of prescription opioid guidelines, assess the feasibility of a national physician survey to gain a better understanding of physician opioid prescribing practices for pain management, and conduct a pilot study to collect data on the topic. Through this agreement, NCCIH funded this pilot study to be conducted by the NCHS.

The NCHS has structured its health care surveys into a family of nationally representative surveys of health care providers called the National Health Care Surveys. Among these surveys is the National Ambulatory Medical Care Survey (NAMCS; OMB No. 0920-0234), the nation's premier study on the provision of ambulatory care in the United States. Conducted since 1973, NAMCS uses a nationally representative sample of visits to U.S. non-federal office-based physicians and providers in community health centers. NAMCS is used to inform health policy, medical practice, quality of care research, and education for health professionals.

NCHS has conducted numerous NAMCS supplements on additional sampled physicians to provide data on emerging health topics. Notably, the Electronic Medical Records (EMR) Mail Survey to track the Nation's progress in adopting and using EHR systems was added to NAMCS in 2008 (which in 2012 became the National Electronic Health Records Survey; NEHRS OMB No. 0920-1015), and in 2016 a supplement on National Culturally and Linguistically Appropriate Services in Health and Health Care Standards (i.e., National CLAS Standards; OMB No. 0920-1119) was conducted. These and other supplements have provided timely data on relevant public health topics. Though the proposed pilot study will not be a NAMCS supplement, it will borrow methodological aspects and lessons from NAMCS, and leverage the knowledge gained from the implementation of these NAMCS supplements. If the pilot study is successful, future data collected is anticipated to be as informative as those of previous NAMCS supplement surveys.

The specific data collection objectives of this pilot study are to test the questionnaire's ability to:

- Collect data on physician awareness and adherence to national and other clinical guidelines on opioid prescribing.
- Collect data on physicians' approach to pain management

2. Purpose and Use of Information Collection

The purpose of this study is to test a survey questionnaire that would collect reliable data to assess physicians' awareness of national, local or professional clinical guidelines on prescribing opioids, and the physicians' adherence to these guidelines. Along with other guidelines, this would include the 2016 CDC guideline for prescribing opioids. While these guidelines exist, the level to which they are implemented remains unknown. Since no ongoing surveillance exists on this topic, data collection is imperative to understand the provision of these guidelines.

A draft of the questionnaire was developed collaboratively by NCHS and NCCIH, with input from the National Pain Strategy Implementation Team within DHHS. The initial questionnaire went through rigorous cognitive testing by the NCHS Collaborative Center for Questionnaire Design and Evaluation Research (CCQDER), followed by revision to ensure that the questions perform optimally and collect reliable data. A copy of the NCHS CCQDER cognitive report can be found as **Attachment A**. The questionnaire to be used in this study, which has been updated based on the findings in this cognitive report is provided in **Attachment B**.

Although the questionnaire is intended to primarily collect information on physician knowledge of and adherence to different types of opioid prescribing guidelines, the questions are also designed to collect additional information that can be broadly used. This information includes, but is not limited to: physician specialty, the proportion of patients undergoing pain management for each physician, the physician's clinical approach to pain management and the knowledge and use of alternative (non-pharmaceutical) treatment methods for pain. The survey's ability to collect this type of information is important to both NCCIH and associated stakeholders, who are involved with the development of clinical guidelines for safe and efficacious pharmacologic treatment of pain, and others concerned with planning, monitoring, and managing how healthcare providers prescribe opioids for pain management.

As mentioned earlier, NCCIH is a part of the interagency National Pain Strategy Implementation Team, under the National Pain Strategy, commissioned by DHHS. Along with NCCIH, the Interagency Pain Research Coordinating Committee (IPRCC) and the NIH Pain Consortium have a vested interest in the methodological findings from this study. The IPRCC is a DHHS Federal advisory committee designated to enhance pain research efforts and promote collaboration across government with the goal of advancing the fundamental understanding of pain and improving pain-related treatment strategies. The NIH Pain Consortium promotes collaboration among NIH centers and researchers conducting programs and activities addressing pain. The findings from this study will be used to inform these committees on the feasibility of a larger scale, nationally representative study on physician opioid prescribing patterns and to secure funding.

Furthermore, this information is expected to be beneficial for several research and development purposes such us: understanding how to assess the utility of clinical guidelines for prescribing opioids, determining methods that can best explore the characteristics of physicians that use and don't use established guidelines and most importantly for developing further studies to reliably collect more data on this critical topic. The results could provide valuable information regarding the feasibility for NCHS to use these survey questions to collect data on this topic at a broader scale, whether it be through its own independent survey, or as part of an established survey such as NAMCS. This data collection is for methodological research and development purposes only. Though the data collection is National in scope, National estimates will not be produced.

3. Use of Improved Information Technology and Burden Reduction

The questionnaire used in this study (**Attachment B**) will be administered via mail. In fielding previous physician surveys, NCHS has found tracing of physician addresses effective in ensuring receipt of mailed letters and survey instruments. This tracing is projected to increase the number of physician respondents who are administered the survey through the mail, thereby reducing the number of needed follow-up mailings and increasing response rates. As such, locating updated

physician specialties and contact information (i.e., addresses) will be emphasized and used for follow-up mailings where necessary. Additionally, eligibility determination activities via web-search and databases such as those provided by the Centers for Medicare and Medicaid Services (CMS) will be performed to limit non-response rates and ensure only eligible physicians are included.

Revisions based on the cognitive report reduced both the length and anticipated burden of the survey instrument. Each physician who responds will spend an estimated 15 minutes to read the introductory letter, and complete the 1-page, double-sided questionnaire (possible of 15 total questions). To further reduce burden, the questionnaire employs skip patterns. These patterns use responses to initial survey questions by a respondent to determine if certain proceeding survey questions are applicable, allowing a respondent to only answer relevant items. Incorporation of these skip patterns into the questionnaire design reduces response burden for participating physicians.

4. Efforts to Identify Duplication and Use of Similar Information

There are currently no national surveys that collect information from physicians on their awareness and adherence to clinical practice guidelines on prescribing opioids for pain management. This pilot survey is a one-time research project.

5. Impact on Small Businesses of Other Entities

Several respondents to this pilot study are expected to be physicians in private solo practices or small group practices. To reduce the respondent burden for these and all respondents, the survey procedures select only a sample of physicians to be contacted. Furthermore, the sample drawn for this pilot study will not overlap with samples used for NAMCS, NEHRS, or any other physician supplemental survey data collection in the prior two years. In addition, cognitive testing and revision of the questionnaire ensures that the questions asked will be kept to the minimum necessary for the study, limiting the time taken away from a physician's normal operations to respond.

6. Consequences of Collecting the Information Less Frequently

This is a one-time data collection.

7. Special Circumstances Related to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

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

A. Federal Register Notice

In compliance with 5 CFR 1320.8(d), a 60-day Federal Register Notice was published in the Federal Register on January 23, 2020. No public comments were received as a result of this Notice.

B. Efforts to Consult Outside the Agency

Both NCCIH and NCHS have worked closely on the development of the survey questions used in the pilot study survey. As mentioned above, the National Pain Strategy Implementation Team within the DHHS contributed to development of the survey questions. **Attachment C** includes a list of consultants for this project.

9. Explanation of Any Payment or Gift to Respondents

No payments, gifts, or incentives will be offered to respondents.

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

This submission has been reviewed by the Information Collection Review Office (ICRO), who determined that the Privacy Act does apply. The applicable System of Records Notice (SORN) is 09-20-0167 Health Resources Utilization Statistics. The NCHS Privacy Act Coordinator and the NCHS Confidentiality Officer have also reviewed this package and have determined that the Privacy Act is applicable.

An assurance of confidentiality is provided to all respondents according to section 308(d) of the Public Health Service Act (42 USC 242m(d)) which states:

"*No information, if an establishment or person supplying the information or described in it is identifiable, obtained in the course of activities undertaken or supported under section...306 (NCHS legislation),...may be used for any purpose other than the purpose for which it was supplied unless such establishment or person has consented (as determined under regulations of the Secretary) to its use for such other purpose and (1) in the case of information obtained in the course of health statistical or epidemiological activities under section...306, such information may not be published or released in other form if the particular establishment or person supplying the information or described in it is identifiable unless such establishment or person has consented (as determined under regulations of the Secretary) to its publication or release in other form,[...]"*

The following assurance of confidentiality statement is provided to all respondents:

"We take your privacy very seriously. All information that relates to or describes identifiable characteristics of individuals, a practice, or an establishment will be used only for statistical purposes. NCHS staff, contractors, and agents will not disclose or release responses in identifiable form without the consent of the individual or establishment in accordance with

section 308(d) of the Public Health Service Act (42 U.S.C. 242m) and the Confidential Information Protection and Statistical Efficiency Act (Title III of the Foundations for Evidence-Based Policymaking Act of 2018 (Pub. L. No. 115-435, 132 Stat. 5529 § 302)). In accordance with CIPSEA, every NCHS employee, contractor, and agent has taken an oath and is subject to a jail term of up to five years, a fine of up to $250,000, or both if he or she willfully discloses ANY identifiable information about you."

In addition, legislation covering confidentiality is provided according to the Confidential Information Protection and Statistical Efficiency Act (Title III of Public Law 115-435) which states:

"Whoever, being an officer, employee, or agent of an agency acquiring information for exclusively statistical purposes, having taken and subscribed the oath of office, or having sworn to observe the limitations imposed by section 512, comes into possession of such information by reason of his or her being an officer, employee, or agent and, knowing that the disclosure of the specific information is prohibited under the provisions of this title, willfully discloses the information in any manner to a person or agency not entitled to receive it, shall be guilty of a Class E felony and imprisoned for not more than 5 years, or fined not more than $250,000, or both."

Physicians can review the details of this pilot survey in order to decline or accept participation. Recruitment of respondents is done through an invitation letter that explains the basics of the survey, that participation is completely voluntary, and that the physician will not be penalized for nonparticipation. All other letters sent to respondents during the study period will reiterate this information. All letters can be found in **Attachment D**. Phone numbers for the study coordinator and NCHS' Ethics Review Board (ERB) are also included if physicians have any questions or comments about the study. The package contains detailed instructions on how to decline participation.

The pilot study survey will include a routine set of measures to safeguard confidentiality. First, all staff, including contractors, who have access to confidential information are given instruction by NCHS staff on the requirement to protect the confidentiality, and are required to sign a pledge to maintain confidentiality. Second, only authorized personnel are allowed access to confidential records, strictly for work requirements. Third, confidential information is stored in secure conditions when it is not actively in use. All individually identified information, such as physician name, address, and any other specific information, will be removed prior to analysis. Confidential data are never released to the public.

Much of the data used or collected in this study are not considered personally identifiable, however the data used to draw the sample consists of both personally identifiable information (PII) and information in identifiable form (IIF). A list of PII and IIF data items is highlighted

below. These data items have all received prior approval by the NCHS Ethics Review Board through the NAMCS (OMB No. 0920-0234) data collections, the NEHRS (OMB No. 0920-1015) as well as other physician supplemental survey data collections. None of these data are released to the public or become part of public-use files.

Personally Identifiable Information:

- Physician name
- Physician NPI

Information in Identifiable Form Categories:

- Physician or office mailing address
- Physician or office telephone number
- Physician or office fax number
- Physician gender

Note that the NPI is a unique identifier for healthcare providers. This data element will allow for linkage of physician specialty information to other administrative sources of information to be used primarily for tracing and eligibility assessments.

11. Ethical Review Board (ERB) and Justification for Sensitive Questions

The pilot survey data collection plan has been submitted for approval to the NCHS's ERB (Protocol #2021-04, **Attachment E)** based on 45 CFR 46. A waiver for the documentation of informed consent by physicians has been requested.

There are no sensitive questions included within the data collection instrument.

12. Estimates of Annualized Burden Hours and Costs

A. Burden Hours

The estimated sample size is 1,000. The expected response rate for this pilot survey is approximately 30%, which is based on recent response rates from NEHRS (2017: 36% , 2018: 42.4%). Since the PPMQ resembles NEHRS methodology, a similar response rate is expected. However, due to challenges presented by the COVID-19 pandemic, there has been a notable decrease in survey response rates. Because of this, our expected response rate (30%) is lower than that of NEHRS. To achieve a target response rate of 30%, at least 1,000 physicians need to be sampled. We have calculated the annualized burden hours based on the assumption that all sampled physicians will respond. While we recognize that not all respondents will complete the survey, this method of estimating the burden has been routinely used by many other surveys conducted by NCHS. The time to complete the survey, including reading the letter, is estimated to be 15 minutes for each respondent. This amounts to 250 total burden hours (Table 1).

Table 1. Estimate of Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (Hours)	Total Response Burden (Hours)
Physicians	Physician Pain Management Questionnaire	1,000	1	15/60	250
Total					**250**

B. Burden Cost

The average annual cost for office-based physicians and office staff to participate over the three data collections is estimated to be $26,485.00. The hourly wage estimates for reading the letter and completing the questionnaire are based on information from the Bureau of Labor Statistics website. The "May 2019 National Occupational Employment and Wage Estimates" table for health care practitioners and technical occupations, physicians and surgeons (occupation code 29-0000) was used for this calculation.[1] The hourly wage rate of $105.94 in Table 2 is an average of the mean hourly wages for physicians and surgeons.

Table 2. Estimate of Annualized Burden Costs

Type of Respondent	Form Name	Total Burden (Hours)	Hourly Wage Rate[1] ($ per Hour)	Total Respondent Costs
Physicians	Physician Pain Management Questionnaire	250	$105.94	$26,485.00

[1]Information for hourly wage rate calculations can be found in this link: https://www.bls.gov/oes/current/oes_nat.htm#29-0000

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no additional costs to physicians other than their time to participate in the voluntary self-administered questionnaire.

14. Annualized Cost to the Federal Government

Itemized below are the estimated annual expenses to the government for this pilot study.

Table 3. Annualized Cost to the Federal Government

Item	Cost
Federal employee salaries	$86,355.00
Mailing expenses	$10,110.00
Total Cost	**$96,465.00**

15. Explanation for Program Changes or Adjustments

This is a generic IC. There are no program changes or adjustments.

16. Plans for Tabulation and Publication and Project Time Schedule

This project is designed to assess the feasibility of collecting data on physician awareness and use of opioid guidelines. The cognitive testing (**Attachment A**) provided valuable insight into respondent understanding and comprehension of the questions in relation to designing individual survey items for the questionnaire; however, this approach is unable to provide insight as to how the questionnaire itself may perform during data collection.

To assess its performance in the field, NCHS and NCCIH will collaboratively analyze the data collected in this study using standard analyses for performing a methodological assessment of a survey questionnaire. Techniques used in this assessment may include: examining overall questionnaire response rates and item nonresponse; exploring percentage distributions to assess the ability of survey questions to capture variability across question response categories; examining responses across selected physician characteristics to identify systematic biases (if any); identifying potential patterns of item response error; and assessment of questionnaire skip patterns. The results of such analyses may be made available in publications such as journal articles or reports, and as oral or poster presentations at professional meetings, where only the methodological findings and implications would be discussed.

As a member of the National Pain Strategy Implementation Team, it is important that findings of this pilot study be shared with key stakeholders that may provide input and funding for the fielding of a full survey. As such, NCCIH will be presenting study data and analyses to the IPRCC and the NIH Pain Consortium to help inform the feasibility of using this questionnaire in a broader scale study. During dissemination, it will be emphasized that: the data were not weighted, no national estimates were produced, and that findings are not nationally representative and are to be used strictly for methodological purposes. The following disclaimer will accompany any publication or presentation.

> "***Note:*** *Responses based on* ***n*** *physicians, are unweighted, and not representative of physicians. Percent distribution of responses are shown for methodological purposes only, including the determination of item non-response and the ability to capture variation/distribution."*

Table 4 shows the proposed timetable for key activities for the pilot survey, acknowledging that the actual initiation of these activities is pending all required approvals.

Table 4 Tentative Study Timeline

Action Item	**Schedule**

Recruitment initiated via mailed Invitation letter	Within 6 weeks following OMB approval
1st Survey package (Introductory)	Within 2 months following OMB approval
2nd Survey package sent (1st Follow-up)	Within 3 months following OMB approval
3rd Survey package (2nd Follow-up)	Within 4 months following OMB approval
Data entry and analysis	Within 6 months following OMB approval
Publish results/presentation	Within 9 months following OMB approval

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

The display of the OMB expiration date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submission

There are no exceptions to the certification.