Request for Approval for a Nonsubstantive Change:

NATIONAL HOSPITAL CARE SURVEY

OMB No. 0920-0212
(Expires March 31, 2022)

Contact Information
Carol DeFrances
Deputy Director
Division of Health Care Statistics
National Center for Health Statistics/CDC
3311 Toledo Rd
Hyattsville MD 20782
301-458-4440
301-458-4032 (fax)
cdefrances@cdc.gov

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NATIONAL HOSPITAL CARE SURVEY

Nonsubstantive Change Request

A1. Circumstances Making the Special Project Collection of Information Necessary

This request is for a nonsubstantive change to an approved data collection (OMB No. 0920-0212, Exp. Date 03/31/2022). On March 5, 2019, the National Center for Health Statistics (NCHS) was approved for the National Hospital Care Survey (NHCS) to collect data for 3 years – 2020, 2021, and 2022 – from emergency department, inpatient, and outpatient settings. In fiscal year 2018 (FY18), NCHS was awarded funding through the Patient Centered Outcomes Research Trust Fund (PCORTF) for a project to develop enhanced methods that make use of all available structured and unstructured data in the electronic health record (EHR) to identify opioid use in linked hospital and mortality data. In fiscal year 2019 (FY19), NCHS was awarded additional PCORTF funding for a capstone project to modify these methods to build a new set of algorithms to identify co-occurring disorders among opioid users.

The opioid use (FY18) algorithms are designed to identify the manner of a patient's opioid use (i.e., used as directed, misused in a manner contrary to prescriber's instructions, used intentionally to become intoxicated or for the purpose of self-harm, taken accidentally, etc.) and the specific licit or illicit opioid taken. The co-occurring disorders algorithms (funded in FY19) are designed to flag evidence of having both a substance use disorder and selected mental health issues (depression or anxiety). Both sets of algorithms search for a combination of standard medical codes that classify diagnoses, procedures, medications, laboratory tests and related keywords, as well as specific mentions and contextual information found in clinical notes using natural language processing (NLP) and machine learning techniques.

One of the objectives of the PCORTF work is to conduct a validation study to assess the performance of opioid use algorithms developed in the FY18 project and co-occurring disorder algorithms developed in the FY19 project. Findings from this study will be used to identify the highest performing iterations of both sets of algorithms. Validated algorithms will then be applied to linked hospital and mortality data to create an enhanced research dataset, which can provide insights on characteristics, patterns of care, and risk factors among opioid users with co-occurring disorders.

Through this nonsubstantive change request, NCHS seeks approval to validate both sets of FY18 and FY19 algorithms.

Validation Study

In 2020, NCHS plans to apply the algorithms developed for the FY18 and FY19 PCORTF projects to the submitted NHCS 2016 and 2019 data to identify a sample of encounters that will be targeted for full medical record abstraction in order to confirm (or deny) opioid use and the presence of co-occurring disorders. The purpose of the study is to validate the enhanced opioid use and co-occurring disorders algorithms by conducting medical record abstraction from a sample of encounters flagged by the algorithms, and preparation of a final data file and summary report.

Approximately 50 hospitals will be contacted by a contractor for the purpose of securing 9 hospitals for the validation study. This expected participation rate (9/50, 18%) is consistent with the participation rate from previous NHCS collection efforts (approximately 20%). These NHCS targeted hospitals will represent diversity in both geographic area and bed size. Field staff are expected to abstract a sample of 100 encounters from each of the 9 participating hospitals during the data collection period. NCHS will provide the contractor with unique identifiers to locate sampled encounters, such as medical record number, encounter start date, patient name and date of birth. The aforementioned unique identifiers have already been approved for collection and will link extracted data submitted to NHCS to abstracted data from the full EHR on the same set of sampled encounters.

A2. Purpose and Use of Information Collection

Validation of Enhanced Algorithms to Identify Opioid Use and Co-Occurring Disorders in the National Hospital Care Survey

One of the objectives of the PCORTF work is to conduct a validation study to assess the performance of opioid use algorithms developed in the FY18 project and co-occurring disorder algorithms developed in the FY19 project. Findings from this study will be used to identify the highest performing iterations of both sets of algorithms. Validated algorithms will then be applied to linked hospital and mortality data to create an enhanced research dataset, which can provide insights on characteristics, patterns of care, and risk factors among opioid users with co-occurring disorders.

For 2020, an abstraction form has been developed and will be used to validate both sets of algorithms (**Attachment A**).

A8. Efforts to Consult Outside the Agency

NCHS intends to provide improved data for use by both governmental and non-governmental policymakers, Federal and state agencies, clinical researchers, health services researchers, commercial institutions, and private citizens. Due to the broad audience and stakeholders for this project, NCHS has conducted an extensive literature review for the validation study.

Additionally, NCHS has solicited input on the study from the following individuals:

- **Assistant Secretary for Planning and Evaluation** (**ASPE**)
  - **Scott Smith**
    Director, Healthcare Quality and Outcome
    Email: Scott.Smith@hhs.gov
  - **Susan Lumsden**
    Program Manager
    Email: Susan.Lumsden@hhs.gov
  - **Mandar Bodas**
    Email: Mandar.Bodas@hhs.gov

- **Food and Drug Administration (FDA)**
  - **Catherine Dormitzer**
    Health Science Administrator
    Regulatory Science Staff (RSS)
    Office of Surveillance and Epidemiology (OSE)
    Center for Drug Evaluation and Research (CDER)
    Email: Catherine.Dormitzer@fda.hhs.gov
  - **Joann Lee**
    Regulatory Health Project Manager
    Center for Drug Evaluation and Research (CDER)
    Email: Joann.Lee@fda.hhs.gov
  - **Jana Mcaninch**
    Physician
    Center for Drug Evaluation and Research (CDER)
    Email: Jana.Mcaninch@fda.hhs.gov
  - **Tamra Meyer**
    Supervisory Health Scientist
    Center for Drug Evaluation and Research (CDER)
    Email: Tamra.Meyer@fda.hhs.gov
  - **Judy Staffa**
    Associate Director for Public Health Initiatives
    Center for Drug Evaluation and Research (CDER)
    Email: Judy.Staffa@fda.hhs.gov

- **Substance Abuse and Mental Health Services Administration (SAMHSA)**
  - **Sean Lynch**
    Social Science Analyst
    Email: Sean.Lynch@samhsa.hhs.gov

- **National Institute of Mental Health (NIMH)**
  - **Michael Schoenbaum**
    Email: schoenbaumm@mail.nih.gov

- **Board of Scientific Counselors (BSC) Drug Work Group**
  - **Gretchen Van Wye, Chair** (New York City Department of Health and Mental Hygiene)
    Assistant Commissioner
    Bureau of Vital Statistics
    New York City Department of Health and Mental Hygiene, Division of Epidemiology

    Email: gvanwye@health.nyc.gov
  - **Linette Scott** (California Department of Health Care Services)
    Chief Medical Information Officer
    California Department of Health Care Services

    Email: Linette.Scott@dhcs.ca.gov
  - **David Gastfriend** (DynamiCare Health)
    Chief Medical Officer and Co-Founder, DynamiCare Health, Inc.
    Senior Research Scientist, Public Health Management Corp. & PI
    The PCORI PATH Integrated Care Study
    Chief Architect, CONTINUUM - The ASAM Criteria Decision Engine™,
    American Society of Addiction Medicine

    Email: gastfriend@gmail.com
  - **Traci Green** (Boston Medical Center / Brown University)
    Deputy Director, Boston Medical Center Injury Prevention Center

    Boston University School of Medicine, Department of Emergency Medicine
    Associate Professor of Emergency Medicine and Epidemiology

    The Warren Alpert School of Medicine of Brown University
    Email: traci.green@bmc.org
  - **Svetla Slavova** (Kentucky Injury Prevention and Research Center, University of Kentucky)
    Associate Professor
    Department of Biostatistics
    Drug Overdose Technical Assistance Core Director
    Kentucky Injury Prevention and Research Center

University of Kentucky
Email: ssslav2@email.uky.edu

A9. Explanation of Any Payments or Gifts to Respondents

In the initial survey collection (OMB No. 0920-0212) NCHS provided a one-time $500 incentive to each sampled hospital to establish the electronic data transmission to participate in the NHCS, and an additional incentive of $500 after a full year of EHR, UB-04 data, or state files are submitted and received by NCHS. Similarly, NCHS will also provide the 9 hospitals participating in the validation study a one-time incentive payment of $1,000 at the conclusion of medical record abstraction. This one-time continued participation payment is to incentivize hospitals to continue voluntary participation in this minor change to data collection. This one-time incentive payment is intended to help hospitals that otherwise would be unwilling to take on the added burden of participating in the validation study. The validation study requires additional burden for participating hospitals since it includes on-site data abstraction. On-site data abstraction is not part of the NCHS and will require additional hospital resources to implement such as finding a secure location where the abstraction can be done, use of a computer terminal to access the hospital's electronic health record (EHR) system and training by hospital staff on how to use the EHR to find the data needed for abstraction study. The payment is intended to encourage and mitigate costs incurred as a result of participation. All sampled hospitals are eligible to participate in this nonsubstantive change. Future payments and gifts are not contingent on this minor change and all sampled hospitals will receive previously approved payments and gifts.

A12. Estimates of Annualized Burden Hours and Cost

The approved data collection (OMB No. 0920-0212, Exp. Date 03/31/2022) has an annualized burden of 7,080 hours **(Table 1)**. This non-substantive change request includes a continued participation telephone call with an added annualized burden of 13 hours and 5 hours for EHR set-up, for a total annualized burden of 18 hours. The total from the approved (7,080) and this minor change (18) result in a total of annualized burden of 7,098 hours.

Through this non-substantive change request, approximately 50 hospitals will be contacted by a contractor for the purpose of securing 9 hospitals for continued participation in the study. Hospital administrators and/or hospital staff who were previously involved in the EHR extraction process will be sought when possible. The continued participation telephone call is expected to take 30 minutes per respondent. During this call, a contractor, will confirm and verify hospital eligibility, including changes to hospital status and the ability to easily locate medical records from the years 2016 and 2019, for continued participation in this NHCS data collection. Additionally, 60 minutes is expected for preparation and set-up for EHR access from health

information management. The information to be obtained by EHR abstraction is detailed in Attachment A. Contractors will conduct the abstraction by utilizing the EHR, thus the burden to the hospital administrator is limited to the confirmation of continued participation, and EHR preparation and set-up. Of the 50 hospitals contacted, 9 are sought to participate in the validation study. The annualized number of respondents is 25 (50 respondents/2 survey years remaining) for the continued participation call and 5 (9 secured respondents/2 survey years remaining) for EHR abstraction. The telephone call is expected to take 30 minutes, with an annualized burden of 13 hours (25 respondents*0.5 hours). The EHR set-up is expected to take 60 minutes, with annualized burden of 5 hours (5 respondents*1.0 hours) (**Table 1**). The total burden hours for the validation study is 18 hours annually. Burden on hospital personnel is reduced, as most of the data are acquired electronically, not involving hospital personnel.

The annual estimated burden cost for the validation study to hospital administrators is $832.02 (**Table 2**). The previous burden cost for the approved data collection (OMB No. 0920-0212, Exp. Date 03/31/2022) was $327,304.20 and added burden cost of $832.02, result in a total of $328,136.22 for each survey year. Adjusting for hourly wage increase from the previously approved National Health Care Surveys Generic Clearance (OMB No. 0920-0212, Exp. Date 03/31/2022), the previous burden cost is reassessed at $387,484.02 and the added burden cost of this nonsubstantive change is $832.02 resulting in a total burden cost of $388,316.04 for each survey year **(Table 2)**. The hourly wage estimates for completing the interviews mentioned above and in the burden cost table are based on the most recent (May 2018) national estimates from the Bureau of Labor Statistics (http://www.bls.gov) and the American Health Information Management Association (2016) web sites (https://www.ahima.org/).

Table 1. Estimate of Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses	Average Burden/ Response (in hours)	Response Burden (in hours)
Hospital DHIM or DHIT	Initial Hospital Intake Questionnaire	150	1	1	150
Hospital CEO/CFO	Recruitment Survey Presentation	150	1	1	150
Hospital DHIM or DHIT	Prepare and transmit UB-04 or State File for Inpatient and Ambulatory (monthly)	399	12	1	4,788

Hospital DHIM or DHIT	Prepare and transmit EHR for Inpatient and Ambulatory (quarterly)	199	4	1	796
Hospital CEO/CFO	Annual Hospital Interview	598	1	2	1,196
Total (previous)					**7,080**
Hospital Administrators	Telephone questionnaire script	25	1	30/60	13
Hospital DHIM or DHIT	Prepare and setup for contractor EHR access	5	1	1	5
Total (change)					**18**
Total (previous + change)					**7,098**

Table 2. Estimate of Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate[1,2,3]	Total Respondent Costs
Hospital Director of health information management	Initial Hospital Intake Questionnaire	150	$46.18[1]	$6,927.00
Hospital CEO/CFO	Recruitment Survey Presentation	150	$91.15[2]	$13,672.50
Hospital Director of health information management	Prepare and transmit UB-04 or State File for Inpatient and Ambulatory	4,788	$46.18[1]	$221,109.84
Hospital	Prepare and transmit EHR for	796	$46.18[1]	$36,759.28

Director of health information management	Inpatient and Ambulatory			
Hospital CEO/CFO	Annual Hospital Interview	1,196	$91.15[2]	$109,015.40
Total (previous)		7,080		**$387,484.02**
Hospital Administrators	Telephone questionnaire script	13	$46.24[3]	$601.12
Hospital DHIM or DHIT	Prepare and setup for contractor EHR access	5	$46.18[1]	$230.90
Total (change)		18		**$832.02**
Total (previous + change)		7,098		**$388,316.04**

[1]The hourly wage estimates for the Director of Health Information Management (DHIM) is based on the American Health Information Management (AHIMA) salary studies [accessed December 16, 2019]. This can be accessed at the following link: http://www.ahima.org/downloads/2016_Salary_Snapshot_FINAL_2.pdf

[2]The hourly wage estimates for hospital administrators is based on the Bureau of Labor Statistics' website [accessed February 4, 2020]. This can be accessed at the following link: https://www.bls.gov/oes/current/oes111011.htm.

[3]The hourly wage estimates for hospital administrators is based on the Bureau of Labor Statistics' website [accessed February 4, 2020]. This can be accessed at the following link: https://www.bls.gov/oes/current/oes113011.htm.

A15. Explanation for Program Changes or Adjustments

Currently the total burden hours associated with the National Hospital Care survey is 7,080. The burden time for the Hospital Continued Participation Interview is 30 minutes. Sixty minutes is expected for preparation and set-up for EHR access from health information management. The contractors will conduct the algorithm validation (confirm or deny) utilizing the electronic medical record, thus the burden to the hospital administrator is limited to confirming continued participation and EHR preparation and set up. Burden on hospital personnel is reduced, as most of the data are acquired electronically, not involving hospital personnel. The additional increase of 18 hours for this non-substantive change will be an annualized total burden of 7,098 hours.

The current annual burden is 7,080 hours. An additional 18 hours will be added to conduct the validation study for a new burden of 7,098 hours annually.