FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF REQUEST FOR DATA TO SUPPORT SOCIAL AND BEHAVIORAL RESEARCH (0910-0847)

TITLE OF INFORMATION COLLECTION: Multistate Pharmacist Survey for Methodologic Advances in Evaluating Abuse Deterrent Opioid Analgesics

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of Need:**

Research teams at the University of Kentucky, the University of North Carolina, in partnership with FDA, via a Broad Agency Announcement (BAA) research grant, will perform research to enhance our understanding of the uptake and use of abuse deterrent opioid product formulations (ADFs) after drug approval. Our research will include ADF's impact on the following: (1) patterns of misuse, abuse, addiction, overdose, and death in communities; (2) improving knowledge about the data systems and methods available to study their impact; and (3) developing new data resources and methods in this area.

2. **Intended Use of Information:**

This survey will provide insight on practice-level decisions that affect how opioids are prescribed and dispensed and focus on motivators of pharmacist behavior surrounding opioids, including ADFs. At the pharmacy, patient selection intersects with practical limitations of health insurance reimbursement and state laws, including an unknown extent of therapeutic substitution of non-ADF opioids for traditional opioids. These structural factors determine the nature of population exposure to ADFs; understanding the pathways and barriers to ADF utilization are important for comparator selection as well as policy development.

Research teams at the University of Kentucky and the University of North Carolina will compile the research results in a white paper and send them to stakeholders as well as make the research results available for download on the project website (https://www.opioiddata.org). In addition, research teams will present research results at relevant state association conferences and disseminate them through presentations at national conferences. For secondary data analysis, research teams will provide to other researchers the data collection instruments, raw data sets, and codebook.

A joint working group including members from the University of Kentucky, the University of North Carolina, and FDA was established. The working group and other relevant FDA units reviewed the survey questions to identify any duplication of research efforts.

3. **Description of Respondents:**

Licensed pharmacists in Maryland are respondents to this information collection. We have already received PRA approval to administer this survey to pharmacists in North Carolina and Florida (ICR REFERENCE NUMBER: 201910-0910-010; OMB CONTROL NUMBER: 0910-0847).

4. **Date(s) to Be Conducted:**

a. Multistate Pharmacist Survey Administration – Complete by August 2021

b. Multistate Pharmacist Survey Analysis – Complete by October 2021

c. Multistate Pharmacist Survey Outputs – Complete by December 2021

5. How the Information Is Being Collected:

The research team at the University of Kentucky will electronically administer survey questionnaires using REDCap, a secure web application for building and managing online surveys and databases (https://www.project-redcap.org/).

Data Collection Procedures:

On behalf of the research team at the University of Kentucky, the Maryland Pharmacist Association will send to its pharmacist members an email containing a cover letter with an explanation of the study and a link to the electronic survey (Appendix 1). No identifying information or linkages to either respondent email addresses or IP addresses will be recorded with survey responses. The Maryland Pharmacist Association will send reminder emails 1 week and 2 weeks following the initial survey to convert non-responders (those who do not respond to the survey). Two weeks after the final reminder email, the survey link will be disabled by the research team at the University of Kentucky, and they will not collect additional data.

6. Confidentiality of Respondents:

At the time of survey completion, participants are informed that: (1) their response to the survey is anonymous, (2) neither the researchers nor the pharmacy association will know who did or did not respond to the survey and (3) the research team will not attempt to trace responses back to individuals (Appendix 2).

7. Amount and Justification for Any Proposed Incentive:

No incentives will be provided for survey completion.

8. Questions of a Sensitive Nature:

The survey does not include questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. The survey for pharmacists includes questions about basic demographics (gender, education, years in practice, and practice setting) and questions about stocking and dispensing ADFs. Additionally, at the time of survey completion, all participants are informed that: participation is voluntary, they may skip survey questions they prefer not to answer, and they can discontinue participation at any time.

9. Description of Statistical Methods:

Research teams at the University of Kentucky and the University of North Carolina will summarize data from response binary surveys as frequencies and percentages. They will use the total number of respondents for each survey item as the denominator. Survey response analyses will be stratified by practice type and setting, whenever possible. Logistic regression models will examine the differences between opioid prescribing and dispensing decisions (decisions related to the dispensing of ADF versus non ADF opioids) among practice settings while controlling for the following: (1) respondent demographic characteristics, (2) years in practice, and (3) familiarity with ADFs. Data will be analyzed using the SAS® 9.4 analytic software package (SAS Institute Inc., Cary, North Carolina).

BURDEN HOUR COMPUTATION:

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Licensed Pharmacists (1 State)	1,200	6 minutes	120

REQUESTED APPROVAL DATE: August 2021

NAME OF PRA ANALYST & PROGRAM CONTACT:

Ila S. Mizrachi
Paperwork Reduction Act Staff
Ila.Mizrachi@fda.hhs.gov
301-796-7726

George Neyarapally
Office of Surveillance and Epidemiology
George.Neyarapally@fda.hhs.gov

FDA CENTER: CDER