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

TITLE OF INFORMATION COLLECTION: Methodologic Advances in Evaluating Abuse Deterrent Opioid Analgesics: Physician and Pharmacist Surveys

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Statement of Need:

This specific collection of data is necessary to complete deliverables for FDA BAA-17-00123 "Methodological Advances in Evaluating Abuse Deterrent Opioid Analgesics." [HHSF22320280283C]

The scope of work for the project is to perform research to enhance FDA's understanding of the uptake and use of abuse deterrent opioid product formulations (ADFs) after approval and their impact on patterns of misuse, abuse, addiction, overdose, and death in communities; improve knowledge about the data systems and methods available to study their impact; and develop new data resources and methods in this area. [FDA BAA-17-00123 Section 4.2.3]

2. Intended Use of Information:

The goal of these surveys is to provide insight on practice-level decisions that impact how opioids are prescribed and dispensed, focusing on motivators of physician and pharmacist behavior surrounding opioids, including ADFs. In the clinical setting, decisions by physicians and other prescribers directly impact who is issued a prescription for an ADF opioid versus traditional formulations. 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 cumulate in determining 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.

Results from this survey will be used by research teams at the University of Kentucky, the University of North Carolina, and the FDA. Results from prescriber and pharmacist surveys will be compiled in a white paper that will be distributed to stakeholders and available for download on the project website (https://iprc.unc.edu/methodological-advances-in-evaluating-abuse-deterrent-opioid-analgesics/). Additionally, results will be presented at relevant state association conferences and disseminated through presentations at national conferences. The data collection instruments, raw data sets, and codebook will be made available to other researchers for secondary data analysis.

Under BAA-17-00123, a joint working group that includes members from the University of Kentucky, the University of North Carolina, and the FDA has been established. The survey questions have been reviewed by this working group as well as at other relevant FDA units to identify duplication.

3. Description of Respondents:

a. Kentucky Licensed Pharmacists and Physicians

b. Licensed Pharmacists in Up to 4 Additional States

4. Date(s) to Be Conducted and Locations:

a. Kentucky Physician and Pharmacist Survey Administration - Complete by December 2019

b. Kentucky Physician and Pharmacist Survey Analysis - Complete by June 2020

c. Kentucky Physician and Pharmacist Survey Outputs – Complete by December 2020

d. Multistate Pharmacist Survey Administration – Complete by February 2021

e. Multistate Pharmacist Survey Analysis – Complete by June 2021

f. Multistate Pharmacist Survey Outputs – Complete by September 2021

5. How the Information Is Being Collected:

Survey questionnaires will be administered electronically using REDCap, a secure web application for building and managing online surveys and databases (https://www.project-redcap.org/).

Data Collection Procedures:

State Pharmacy and Physician licensure Boards will send an introductory email to licensees, notifying them of an upcoming survey and encouraging them to respond. A follow-up email, containing a cover letter with an explanation of the study and a link to the electronic survey will be sent to all licensees practicing within the state via the respective licensure board lists. No identifying information or linkages to either respondent email addresses or IP addresses will be recorded with survey responses. Reminder emails will be sent one week and two weeks following the initial survey to convert non-responders. Two weeks after the final reminder email is sent, the survey link will be disabled, and no additional data will be collected.

6. Confidentiality of Respondents:

Respondent identity and information will remain secure to the extent permitted by law. 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/physician licensing boards 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.

7. Amount and Justification for Any Proposed Incentive:

No incentives will be provided for survey completion.

8. Questions of a Sensitive Nature:

The surveys do 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 regarding stocking and dispensing of ADFs. The survey for physicians includes questions about basic demographics (gender, education, years in practice, and practice setting) and questions regarding prescription of ADFs. Additionally, at the time of survey completion, all participants are informed that participation is voluntary and that they may skip survey questions they prefer not to answer or discontinue participation at any time.

9. Description of Statistical Methods:

Response binary survey data will be summarized as frequencies and percentages with the total number of respondents for each survey item as the denominator. Survey response analysis will be stratified by practice type and setting, whenever possible. Logistic regression models will examine the differences between opioid prescribing/dispensing decisions among practice settings, while controlling for respondent demographic characteristics, years in practice, and familiarity with ADFs. Data will be analyzed using the SAS® 9.4 analytic software package (SAS Institute Inc., Cary, NC).

BURDEN HOUR COMPUTATION:

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Licensed Pharmacists (KY)	1,000	10 minutes	167
Licensed Physicians (KY)	1,500	10 minutes	250
Licensed Pharmacists (Additional 4 States)	4,000	10 minutes	667
TOTAL	**6,500**	**10 minutes**	**1,084**

REQUESTED APPROVAL DATE: November 2019.

NAME OF PRA ANALYST & PROGRAM CONTACT:

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

Gretchen Opper
Office of Surveillance and Epidemiology
Gretchen.Opper@fda.hhs.gov
240-402-8339

FDA CENTER: Center for Drug and Evaluation and Research