OMB Control Number: 0910-0847
Data to Support Social and Behavioral Research as Used by the FDA
Summary of Survey to be Conducted

The aim of this project "Methodologic Advances in Evaluating Abuse Deterrent Opioid Analgesics: Physician and Pharmacist Surveys" 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.

What was the problem to be investigated? 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.

The method used to obtain the sample. Survey questionnaires will be administered electronically, using REDCap, a secure web application for building and managing online surveys and databases. 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 at 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.

Burden imposed

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Licensed Pharmacist (KY)	1000	10 minutes	167
Licensed Physicians (KY)	1500	10 minutes	250
Licensed Pharmacist (additional 4 states)	4000	10 minutes	667