Bancshares of Texas, Inc., and indirectly, First National Bank of Paducah, both of Paducah, Texas.

Board of Governors of the Federal Reserve System, August 16, 2019.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2019–18059 Filed 8–21–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project ''Outcome Measure Harmonization and Data Infrastructure for Patient Centered Outcomes Research in Depression.''

DATES: Comments on this notice must be received by 60 days after date of publication.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at *doris.lefkowitz@AHRQ.hhs.gov.*

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by emails at *doris.lefkowitz@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Outcome Measure Harmonization and Data Infrastructure for Patient Centered Outcomes Research in Depression

The Agency for Healthcare Research and Quality's (AHRQ) mission is to produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable, and to work within the U.S. Department of Health and Human Services and with other partners to make sure that the evidence is understood and used.

In support of this mission, AHRQ funded a prior project to harmonize the outcome measures collected across patient registries and routine clinical practice, with the goals of supporting the development of a robust data infrastructure that can consistently and efficiently collect high-quality data on outcome measures that are relevant to patients and clinicians and supporting patient-centered outcomes research and quality improvement. Harmonized outcome measures would also form the foundation for learning healthcare systems. Of note, AHRQ has supported the development of the Outcome Measures Framework (OMF). The OMF is a conceptual model for classifying outcomes that are relevant to patients and providers across most conditions. AHRQ, in collaboration with the U.S. Food and Drug Administration and the National Library of Medicine, recently supported an effort to use the OMF as a content model for developing harmonized outcome measures in specific disease areas, including depression.

Major depressive disorder (MDD) is a common mental disorder that affects an estimated 16.2 million adults and 3.1 million adolescents in the United States. Characterized by changes in mood, cognitive function, and/or physical function that persist for two or more weeks, MDD can reduce quality of life substantially, impair function at home, work, school, and in social settings, and result in increased mortality due to suicide. MDD also is a major cause of disability, with an economic burden of approximately $210.5 billion per year in the United States.

Despite the burden of MDD and the availability of treatment, the condition is often undiagnosed and untreated. In 2016, the U.S. Preventive Services Task Force recommended screening for depression in the general adult population, including pregnant and postpartum women, and in adolescents. While routine screening is intended to improve diagnosis and treatment of MDD, many questions remain, such as about the comparative effectiveness of different treatment approaches, the incidence of adverse events, when to add medications for patients who do not respond to an initial course of treatment, how and why depression recurs, and how to classify and treat treatment-resistant depression. Patient registries capture a wealth of data on depression treatment patterns and outcomes in the United States and could serve as the foundation for a national research infrastructure to address these and other research questions. Yet, a lack of harmonization in the outcome measures collected by each registry makes it challenging, if not impossible, to link and compare data across registries and related efforts. As documented in the prior project, existing registries use different outcome measures (*e.g.,* remission as defined by the PHQ–9 vs. HAM–D) and capture data at different timepoints.

Depression registries offer an excellent opportunity to demonstrate the feasibility and value of implementing the harmonized outcome measures. Existing registries already capture some of the harmonized depression measures for quality reporting, although at different timepoints; capture of these measures and the additional measures at consistent intervals will enable the registries to generate more robust data suitable for research purposes.

AHRQ is now proposing to implement the harmonized depression outcome measures developed under the prior project in two patient registries (the PRIME Registry and PsychPRO) and a health system setting. The purpose of this project is to demonstrate that capturing the harmonized outcome measures in the clinical workflow and submitting these data to different registries can improve clinical care, reduce the burden of registry participation, and increase the utility of registry data for research purposes. The objectives of the project are to:

—Demonstrate that collection of the harmonized outcome measures is feasible, sustainable, and useful for clinicians participating in primary care and mental health patient registries.

—Demonstrate that collection of the harmonized outcome measures is feasible, sustainable, and useful for clinicians in a health system setting.

Evaluate whether collection of the harmonized measures increases the utility of registry data for research purposes.

The project is being conducted by AHRQ through its contractor, OM1, Inc., pursuant to AHRQ's statutory authority to conduct and support research on healthcare and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of healthcare services and with respect to the outcomes of such services. 42 U.S.C. 299a(a)(1) and (3).

Method of Collection

To achieve the goals of this project the following data collections will be implemented:

(1) Patient Health Questionnaire-9 (PHQ–9)—the PHQ–9 is a brief, 9-item

scale that is completed by patients and reviewed by clinicians at three points during this project. The scale is used to measure depression severity, to monitor changes in depression severity over time, and to calculate the harmonized outcome measures for depression remission, response, recurrence, and suicide ideation and behavior.

(2) Frequency, Intensity, and Burden of Side Effects Ratings (FIBSER)—the FIBSER is a brief, 3-item scale that is completed by patients and reviewed by clinicians at three points during this project. The scale is used to measure the burden of side effects related to depression treatment and to calculate the harmonized outcome measure for adverse events.

(3) Clinician Survey—the clinician survey is a brief, 20-question survey that clinicians in the health system setting will be asked to complete once at the conclusion of the project. The survey captures information on the value of the harmonized outcome measures for informing patient care.

Users of the information captured in this project will fall into two categories: Clinicians providing care for patients with depression; and researchers using the de-identified data to answer a patient-centered outcomes research question. AHRQ will receive summary findings from the data analysis only; no patient-level data will be shared with AHRQ.

Estimated Annual Respondent Burden

A key objective of this project is to demonstrate that the harmonized outcome measures can be captured as part of the routine clinical workflow, with little to no added burden for clinicians and patients. The harmonized measures will be calculated primarily with existing data extracted from electronic medical records (EMRs). Extraction of these data will not represent an additional burden for clinicians. Patients participating in this project will be asked to complete up to two patient-reported outcome measures—the Patient Health Questionnaire-9 (PHQ–9) and the Frequency, Intensity, and Burden of Side Effects Ratings (FIBSER). Burden is estimated below for completion of these instruments by the patient respondent. Clinicians participating in the health system component of the project will be asked to complete the Clinician Survey. Burden is estimated below for completion of this survey by the clinician respondent.

Exhibit 1 shows the estimated annualized burden hours for the patient respondent's time to complete the PHQ–9 and FIBSER at three time points as part of this project and for the clinician respondent to complete the Clinician Survey at one time point during this project. The PHQ–9 is a brief, 9-item scale used to measure depression severity. The FIBSER is a brief, 3-item scale used to measure the burden of side effects related to depression treatment. The Clinician Survey is a brief, 20-question survey designed to assess the value of the harmonized outcome measures for informing patient care. The PHQ–9 is used in routine clinical practice to screen for depression and monitor changes in depression severity over time, as recommended by the U.S. Preventive Services Task Force. For some participants in this project, completion of the PHQ–9 is part of their existing clinical care routine and does not represent an extra burden. For example, the PHQ–9 is already captured routinely for participants in the PsychPRO registry. The estimates below do not include participants in the PsychPRO registry for that reason.

Because the primary objective of this project is to determine the feasibility and value of extracting the relevant data and calculating the measures, a formal sample size has not been calculated. We estimate that the 20 participating sites in the two patient registries will each enroll 10 patients, for a total of 200 patients. We estimate that the 5 participating sites at the health system will each enroll 10 patients, for a total of 50 patients. We did not include the PsychPRO enrollment in the PHQ–9 estimates, as the PHQ–9 is already collected in this registry and does not represent extra burden. We also do not anticipate implementing the FIBSER at the health system sites. Therefore, the total number of respondents for the PHQ–9 is estimated at 150, and the total number of respondents for the FIBSER is estimated at 200. We anticipate that three clinicians associated with each of the five health system sites will complete the Clinician Survey. Therefore, the total number of respondents for the Clinician Survey is estimated at 15.

Based on existing literature, it is estimated that completion of the PHQ–9 takes, on average, 3 minutes, and the FIBSER takes, on average, 2 minutes to complete. Participants in the patient registries will be asked to complete the PHQ–9 and FIBSER three times over the course of a year, for a total time of 15 minutes per year. Participants from the health system will be asked to complete the PHQ–9 three times over the course of a year. Clinicians from the health system sites will be asked to complete the Clinician Survey once, at the conclusion of the project; the survey is designed to be completed in 5 minutes or less. If 150 respondents complete the PHQ–9 three times over the course of one year, the estimated annualized burden would be 22.5 hours. If 200 respondents complete the FIBSER three times over the course of one year, the estimated annualized burden would be 20 hours. If 15 clinicians complete the Clinician Survey once over the course of one year, the estimated annualized burden would be 1.25 hours. The total estimated annualized burden would be 43.75 hours.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Minutes per response	Total burden hours
PHQ–9	150	3	3	22.5
FIBSER	200	3	2	20
Clinician Survey	15	1	5	1.25
Total	365			43.75

Exhibit 2 shows the estimated cost burden associated with the respondent's time to complete the PHQ–9, FIBSER, and Clinician Survey as part of this project. The total cost burden to respondents is estimated at an average of $1,110.93 annually. The duration of this project is one year.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate	Total cost burden
PHQ–9	150	22.5	*$24.98	$562.05
FIBSER	200	20	*24.98	499.6
Clinician Survey	15	1.25	#39.42	49.28
Total	365	42.5	24.98	1,110.93

*Based on the mean wages for all occupations, 00–0000. May 2018 National Occupational Employment and Wage Estimates. U.S. Department of Labor, Bureau of Labor Statistics. Available at: *https://www.bls.gov/oes/current/oes_nat.htm#00-0000.*

#Based on the mean wages for Healthcare Practitioners and Technical Occupations, 29–0000. May 2018 National Occupational Employment and Wage Estimates. U.S. Department of Labor, Bureau of Labor Statistics. Available at: *https://www.bls.gov/oes/current/oes_nat.htm#29-0000.*

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: August 19, 2019.

Virginia L. Mackay-Smith,

Associate Director.

[FR Doc. 2019–18113 Filed 8–21–19; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Informational Meeting: The Importation of Infectious Biological Agents, Infectious Substances and Vectors; Public Webcast

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of public webcast.

SUMMARY: The Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS), is hosting a public webcast to address import permit regulations for infectious biological agents, infectious substances, and vectors. Besides CDC, presenters for this webcast may include representatives from the U.S. Department of Transportation, U.S. Department of Agriculture, Department of Homeland Security, and U.S. National Authority for Containment (NAC) of Polioviruses.

DATES: The webcast will be held on December 4, 2019, from 11 a.m. to 4 p.m. (EST). Registration instructions are found on the HHS/CDC Import Permit Program website, *https://www.cdc.gov/cpr/ipp/index.htm.*

ADDRESSES: The webcast will be broadcast from the Centers for Disease Control and Prevention, 1600 Clifton Road NE, Atlanta, Georgia 30329.

FOR FURTHER INFORMATION CONTACT: Samuel S. Edwin, Director, Division of Select Agents and Toxins, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H–21–7, Atlanta, Georgia 30329. Telephone: (404) 718–2000.

SUPPLEMENTARY INFORMATION: This webcast is an opportunity for all interested parties (*e.g.,* academic institutions; biomedical centers; commercial manufacturing facilities; federal, state, and local laboratories, including clinical and diagnostic laboratories; research facilities; exhibition facilities; and educational facilities) to obtain specific guidance and information regarding import permit regulations for the importation of infectious biological agents, infectious substances and vectors. The webcast will also provide assistance to those interested in applying for an import permit from federal agencies within the United States. Instructions for registration are found on the HHS/CDC Import Permit Program website, *https://www.cdc.gov/cpr/ipp/index.htm.*

Participants must register by November 22, 2019. This is a webcast-only event and there will be no on-site participation at the HHS/CDC broadcast facility.

Dated: August 19, 2019.

Sandra Cashman,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2019–18100 Filed 8–21–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–P–0076]

Determination That ZONEGRAN (Zonisamide) Capsules, 50 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that ZONEGRAN (zonisamide) capsules, 50 milligrams (mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Daniel Gottlieb, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6210, Silver Spring, MD 20993–0002, 301–796–6650, *Daniel.Gottlieb@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an