EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents/ POCs	Total burden hours	Average hourly wage rate *	Total cost burden
Eligibility/Registration Forms	60	3	$44.89	$135
Data Use Agreement	60	3	44.89	135
Nursing Home Site Information Form	60	25	44.89	1,122
Data Files Submission	60	60	44.89	2,693
Total	240	91	NA	4,085

* The wage rate in Exhibit 2 is based on May 2017 National Industry-Specific Occupational Employment and Wage Estimates, Bureau of Labor Statistics, U.S. Dept. of Labor. Mean hourly wages for nursing home POCs are located at *https://www.bls.gov/oes/current/naics3_623000.htm.* The hourly wage of $44.89 is the weighted mean of $45.81 (General and Operations Managers 11–1021; N = 40) and $43.04 (Medical and Health Services Managers 11–9111; N = 20).

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.

Francis D. Chesley, Jr.,

Acting Deputy Director.

[FR Doc. 2018–11657 Filed 5–30–18; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–FY–18ACD; Docket No. CDC–2018–0043]

Proposed Data Collection Submitted for Public Comment and Recommendations

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

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take an opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled StopAnthrax™. This new generic clearance will support the collection of information from (1) persons exposed to an intentional release of anthrax that were given post-exposure prophylactic medical countermeasures—antibiotics or antibiotics and vaccine and (2) persons participating in points of dispensing (PODs) exercises conducted by state and local health departments. CDC will use this information to (1) inform response activities during an anthrax incident and (2) improve the StopAnthrax™ program.

DATES: CDC must receive written comments on or before July 30, 2018.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2018–0043 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

Please note: Submit all comments through the Federal eRulemaking portal (*regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology,

e.g., permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

StopAnthrax™—New—Office of Public Health Preparedness and Response (OPHPR), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC) Community and Health Systems Team (CHST), in collaboration with Oak Ridge Associated Universities (ORAU), and the Center for Surveillance, Epidemiology, and Laboratory Services (CSELS) developed the StopAnthrax™ mobile app push notification program (hereafter referred to as StopAnthrax™) to be activated following an aerosolized release of anthrax in the United States. The purpose of this program is to use mobile app procedures to collect data about medication adherence and adverse drug event symptoms and to enhance self-reporting of medical countermeasure (MCM) adverse events to existing surveillance systems. The focus of StopAnthrax™ is on MCMs—ciprofloxacin, doxycycline, amoxicillin, and Anthrax Vaccine Adsorbed (AVA)—distributed to communities after an anthrax incident.

CDC operationalized StopAnthrax™ into a mobile app for ease of use with any smart phone. CDC will initiate activation of StopAnthrax™ following an anthrax incident and adults receiving anthrax MCMs will be able to voluntarily enroll in the program. Respondents will provide information through the CDC-developed mobile application. StopAnthrax™ will collect information necessary to send, personalize, and tailor messages as much as possible for the individual respondent (*e.g.,* first name, zip code, which MCM the respondent is taking, if they are pregnant or have a child also taking MCMs), to understand their level of medication adherence, and capture any adverse symptoms attributed to taking the medication or anthrax disease. The information collection (IC) will take place within the United States in any area(s) affected by an anthrax incident. Respondents will include adults who were in or near the affected area during the time of the anthrax incident and have been given the select MCMs for post-exposure prophylaxis (PEP) of anthrax. Respondents may include English or Spanish-speaking single adults, adults with one or more children affected, and pregnant women. Respondents enrolled in StopAnthrax™ may choose to respond to the IC at any location in which they are utilizing their cellular phones (*e.g.,* home, school, work). The IC will occur following an anthrax incident and will continue for up to 120 days after the incident.

StopAnthrax™ and the IC will be overseen by CDC. State and local public health workers in the affected area will be responsible for promoting enrollment into the program utilizing a standardized enrollment process. All respondents will voluntarily opt into the program by downloading the app from the Apple or Google stores and following an easy enrollment process. Once enrolled, respondents will answer a short series of questions to ensure they are enrolled in the appropriate protocol (*i.e.,* population and MCM-specific). Respondents will receive push notifications for a period of up to 60 days and will periodically be asked questions about their medication adherence and any adverse symptoms resulting from taking the MCM or from anthrax. Respondents will utilize their cellular telephones to send responses back to the system, which will store the information in a secure CDC-managed database.

In a post-incident setting, such as an aerosolized release of anthrax, wide-spread administration of MCMs in diverse populations is anticipated. CDC and the Food and Drug Administration (FDA) are responsible for monitoring the safety of these MCMs. The Vaccine Adverse Event Reporting System (VAERS) and the FDA Adverse Event Reporting System (FAERS) are two national surveillance systems used to monitor adverse drug events. VAERS and FAERS serve as early warning systems to detect possible safety issues related to drugs, such as the MCMs distributed during an anthrax inhalation incident. However, these systems are passive and may not provide the timely information useful in a response. Data collected from StopAnthrax™ is intended to supplement VAERS and FAERS surveillance and provide near real-time safety monitoring and information. CDC and FDA can use the de-identified information provided by the vendor to more effectively respond to the incident. In addition, the program has an added benefit for those participating as it provides medication reminders, prompts for directing those who experience adverse event symptoms to seek medical treatment, and provides relevant health education messages about MCMs and anthrax.

CDC will disseminate de-identified information through a variety of methods dependent on the type of anthrax incident and subsequent response. During a response, information will be disseminated within the CDC response teams and other federal agencies engaged in the response, such as FDA. Information will be disseminated to federal agency responders through situation reports which may include report outs over the phone, data summaries, and action reports that would be sent electronically. After the IC period ends (*e.g.,* StopAnthrax™ is no longer active), CDC may elect to present the findings at a professional conference or submit a manuscript to a professional peer-reviewed journal. Data will only be reported in the aggregate and would focus on the process and actions taken before and during a response. The IC is completely voluntary.

Any individuals receiving MCMs that elect to enroll and provide data will be part of the sample. All recipients will be given the opportunity to enroll in StopAnthrax™. There is no planned sample size as this would depend on the scale of the incident and enrollment into StopAnthrax™. Information about StopAnthrax™ and enrollment into the program will be available to all recipients of MCMs. Information will be collected electronically via push notification prompted by a series of questions contained within StopAnthrax™.

StopAnthrax™ spans a total of 60 days. Those enrolled will not be asked to respond to questions every day. The amount of time that one may take in responding to the messages will vary depending on the individual's situation (*i.e.,* they may be asked a series of follow up questions based on their responses). On average, it is not expected to take longer than 1.5 hours for one respondent to respond to all questions contained in the 60 day program.

All respondents will be informed that their participation is voluntary, and they can opt out at any time after enrollment; their information will be treated in a secure manner, and protected to the extent allowed by law. Although some respondents may feel some level of embarrassment in indicating they experienced certain adverse event symptoms (*e.g.,* severe diarrhea), none of the information being collected is of a highly sensitive nature. Data will be housed on secure servers to which only project staff from CDC and contractors will have access, and all data will be de-identified in any reports or other materials produced by CDC. The IC is expected to have limited impact on respondents' privacy. Mobile apps are a relatively private method in which to collect information (as compared to focus groups and other

methods). Although it is possible that notifications or responses may be intercepted or seen by someone who is not part of the team collecting the data, it is not likely that this will have a major impact on the respondents' privacy.

CDC and contractors will also conduct periodic usability and user experience tests of StopAnthrax™ in conjunction with points of dispensing (PODs) exercises conducted by state and local health departments across the US. The purpose of these tests would be to evaluate the acceptability of the program with members of the potential target audience following an anthrax incident and to ensure proper functionality of the StopAnthrax™ protocols within the system. These tests will occur no more than twice a year and feedback on the program will be collected from volunteers participating in the jurisdictional exercises through one or more of the following mechanisms; in-person focus groups, online survey, online discussion groups.

CDC is requesting approval for this new generic clearance for data collection for a period of three years. The total burden hours for respondents is 38,000 hours. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Adult MCM recipient	60-day StopAnthrax™ program	20,000	1	90/60	30,000
POD volunteer participating in user experience/usability testing of shortened StopAnthrax™ protocol.	Shortened (10-day) StopAnthrax protocol.	4,000	1	30/60	2,000
POD volunteer participating in user experience/usability testing.	Online Survey	2,000	1	1	2,000
POD volunteer participating in user experience/usability testing.	Discussion/focus groups	2,000	1	2	4,000
Total					38,000

Jeffrey M. Zirger,

Acting Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2018–11648 Filed 5–30–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2018–0054]

Proposed Assisted Reproductive Technology (ART) Success Rates Reporting and Data Validation Procedures

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

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) requests comments on a plan to (1) revise the definition and characterization of Assisted Reproductive Technology (ART) success rates and (2) introduce clinic validation footnotes for the annual ART Fertility Clinic Success Rates Report. The footnotes will identify clinics that are selected by CDC to participate in the validation process of the National ART Surveillance System (NASS) data and that: (1) Do participate, (2) do participate and have major data discrepancies identified through this process, and/or U3) decline to participate in the data validation process. CDC requests comments on this plan in order to continue to ensure that the public has access to accurate and transparent data pursuant to the Fertility Clinic Success Rate and Certification Act of 1992.

DATES: Written comments must be received on or before July 2, 2018.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2018–0054 by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Sara Crawford, Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway NE, MS F–74, Atlanta, Georgia 30341. Phone: (770) 488–6370. Email: *artinfo@cdc.gov.*

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *http://regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Sara Crawford, Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway NE, MS F–74, Atlanta, Georgia 30341. Phone: (770) 488–6370. Email: *artinfo@cdc.gov.*

SUPPLEMENTARY INFORMATION:

I. Success Rates

A. Background

Section 2(a) of Public Law 102–493 (42 U.S.C. 263a–1(a)), the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA), requires that each assisted reproductive technology (ART) program report annually to the Secretary of the Department of Health and Human Services through the Centers for Disease Control and Prevention (CDC) pregnancy success rates achieved through assisted reproductive technology. The FCSRCA also requires the CDC to annually publish and distribute to the public reported pregnancy success rates. According to the FCSRCA, the definitions of pregnancy success rates should be developed in consultation with appropriate consumer and professional organizations, should take into account the effect on success rates of age, diagnosis, and other significant factors, and should include the live birth rate per attempted ovarian stimulation procedure and the live birth rate per successful oocyte retrieval.

Specifics about the reporting process and requirements are described in