is used to electronically submit fellowship applications, fellowship host site proposals, and to maintain fellowship alumni directories online. FMS is a flexible and robust electronic information system that is standardized and tailored for each CDC fellowship, collecting only the minimum amount of information needed. Thus, streamlining data management for CDC and reducing the burden for respondents. FMS is key to CDC's ability to protect the public's health by supporting training opportunities that strengthen the public health workforce.

The proposed Revision will contribute significant enhancements and provide CDC with an efficient, effective, and secure electronic mechanism for collecting, processing, and monitoring fellowship information. The update to the technology platform will make it easier for additional fellowships to choose to use FMS. The increased efficiencies will allow programs to conduct their administrative data collection and monitor fellows' learning outcomes with a reduced burden and minimal development requirements.

The mission of DSEPD is to improve health outcomes through a competent, sustainable, and empowered public health workforce. Professionals in public health, epidemiology, medicine, economics, information science, veterinary medicine, nursing, public policy, and other related professionals seek opportunities, through CDC fellowships, to broaden their knowledge, and skills to improve the science and practice of public health. CDC fellows are assigned to state, tribal, local, and territorial public health agencies; federal government agencies, including CDC and Department of Health and Human Services' (HHS) operational divisions, such as Centers for Medicare & Medicaid Services; and to nongovernmental organizations, including academic institutions, tribal organizations, and private public health organizations.

A three-year revision will allow all fellowship applicants, public health agencies that host fellowship participants, and fellowship alumni the continued use of FMS for submission of electronic data. The annual burden table reflects OMB-approved changes since 2017. There is no cost to respondents other than their time. Total Burden Hours requested are 6361. 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)
Fellowship applicants	FMS Application Module	2,216	1	105/60	3,878
Subset of FMS Fellowship Applicants **.	FMS Application Module	** 200	1	30/60	100
Reference Letter Writers	FMS Application Module	4,412	1	15/60	1,103
Public Health Agency or Organization Staff.	FMS Activity Tracking Module	350	2	15/60	175
Fellowship Alumni	FMS Alumni Directory	1,732	1	15/60	433
Public Health Agency or Organization Staff.	FMS Host Site Module	448	1	90/60	672
Total					6,361

** Subset of the total 2216 applicants.

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–18210 Filed 8–22–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–19–0010]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Birth Defects Study To Evaluate Pregnancy exposureS (BD–STEPS) to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on March 4, 2019 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) 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;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) 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 submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov.* Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202)

395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Birth Defects Study To Evaluate Pregnancy exposureS (OMB Control No. 0920–0010, Exp. 02/29/2020)—Revision—National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Birth defects are associated with substantial morbidity and mortality in the United States. About one in every 33 babies is born with a birth defect, which are the leading cause of infant mortality and the fifth leading cause of loss of potential years of life before age 65. One in five infant deaths is due to birth defects.

CDC's National Center on Birth Defects and Development Disabilities (NCBDDD) works to identify causes of birth defects, improve the health of those living with birth defects, and find and promote opportunities for prevention. For example, vaccination programs have reduced the incidence of congenital rubella syndrome, Rh hemolytic disease of the newborn can be prevented by appropriate medical practice, and genetic counseling can provide parents with information about the increased risk of Down syndrome associated with advanced maternal age. Perhaps most importantly, folic acid intake before and during pregnancy can prevent many cases of fatal or permanently disabling neural tube defects, such as anencephaly and spina bifida.

For most birth defects, however, the causes are not known, making prevention efforts challenging to develop. To improve understanding of the causes of birth defects, CDC initiated active surveillance of birth defects in the wake of the thalidomide tragedy. The system has been in continuous operation since 1967 and is the longest running active surveillance system in the world. Over this period CDC adapted the system to both utilize and contribute to new findings about the epidemiology and causes of birth defects. Previous related efforts include the ''Metropolitan Atlanta Congenital Defects Program'' (MACDP) and the ''National Birth Defects Prevention Study'' (NBDPS).

In its current form, CDC conducts birth defects surveillance through the Birth Defects Study To Evaluate Pregnancy exposureS (BD–STEPS, OMB No. 0920–0010). BD–STEPS is a CDC-funded collaborative effort involving six CDC-funded, state-based Centers for Birth Defects Research and Prevention (CBDRP) that have legislative authority to collect population-based information on infants with major congenital malformations (Arkansas, California, Iowa, Massachusetts, New York, and North Carolina). CDC serves as an additional site on behalf of Georgia. Information collection for BD–STEPS is based on a case-control design that builds upon information obtained from state-based vital records and birth defects tracking systems. At all CBDRP sites, mothers who have given birth to infants with birth defects are invited to participate in a computer-assisted telephone interview (CATI) to discuss their medical history, pregnancies, environmental exposures, and medications. In addition, interviews are conducted with mothers of control-infants from each CBDRP, selected randomly from live-born infants without a major birth defect. Controls are identified either from vital records (birth certificates) or from hospitals of birth, and represent the birth population from which the case infants were identified. Two CBDRP sites (Arkansas and Massachusetts) also conduct interviews with mothers of infants who are stillborn without major birth defects, and controls. In states that allow retrieval of blood spots, BD–STEPS participants are asked for permission to share a portion of the newborn blood spot for the child who is part of the study, and for mothers of multiples, the co-siblings of this child. Finally, the interviews identify mothers who work in one of eight occupational categories of interest. These respondents are asked to complete a supplemental online questionnaire designed to assess the impact of the workplace on reproductive outcomes.

During the next OMB approval period, CDC plans to implement a number of changes, many reflecting increased emphasis on birth defects with established or suspected association with maternal infection. Five new birth defect case groups will be added. In addition, the maternal interviews will include new questions on infections, travel history, and marijuana use during pregnancy. The new case groups and questions will increase the estimated burden per interview from 45 minutes to 55 minutes. CBDRPs will also begin asking mothers for permission to access information on reportable infectious diseases from their state health departments. The estimated burden per response is 15 minutes. CDC will discontinue plans for a medical records review that was previously approved but never implemented.

Additional changes will also affect burden estimates. The estimated number of case interviews per site will increase from 200 to 270, and the number of control interviews per site will increase from 75 to 100. The number of interviews with mothers who gave birth to a stillborn infant will remain constant (220 interviews per site for the two CBDRP sites participating in this information collection activity, plus 100 control interviews per site). The number of respondents who complete the online occupational questionnaire will increase but there is no change to the estimated burden per response of 20 minutes. The number of mothers who are asked to provide permission for bloodspot retrieval will also increase, but the burden per response will not change.

CDC will use BD–STEPS data to identify modifiable maternal risk factors and to apply findings to prevention programs for birth defects and stillbirths. Data will also be used to examine hypotheses for gene-environment interactions involved in the etiology of birth defects.

OMB approval is requested for three years. Participation is voluntary and there are no costs to respondents other than their time. The total estimated annualized burden will increase from 3,034 hours to 4,433 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Mothers of birth defects cases and controls ..	Telephone Consent Script and BD-STEPS Computer Assisted Telephone Interview.	3,030	1	55/60
Mothers of birth defects cases and controls ..	Consent for bloodspot retrieval	1,850	1	15/60

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Mothers of birth defects cases and controls ..	Online Occupational Questionnaire	830	1	20/60
Mothers of birth defects cases and controls ..	Infectious Disease Request Form	2,590	1	15/60
Mothers of stillbirths and controls	Telephone consent and supplemental interview.	640	1	25/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–18207 Filed 8–22–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–367a–d]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by October 22, 2019.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–367a–d Medicaid Drug Program

Under the 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. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicaid Drug Program; *Use:* Labelers transmit drug product and pricing data to CMS within 30 days after the end of each calendar month and quarter. CMS calculates the unit rebate amount (URA) and the unit rebate offset amount (UROA) for each new drug application (NDC) and distributes to all State Medicaid agencies. States use the URA to invoice the labeler for rebates and the UROA to report onto the CMS–64. The monthly data is used to calculate Federal Upper Limit (FUL) prices for applicable drugs and for states that opt to use this data to establish their pharmacy reimbursement methodology. *Form Number:* CMS–367 (OMB control number: 0938–0578); *Frequency:* Monthly, quarterly, and on occasion; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 743; *Total Annual Responses:* 14,117; *Total Annual Hours:* 219,185. (For policy questions regarding this collection contact Andrea Wellington at 410–786–3490.)

Dated: August 20, 2019.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2019–18214 Filed 8–22–19; 8:45 am]

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