

exemptions (b)(4) and (b)(8) of the Freedom of Information Act.

Abstract: Section 208.63 of Regulation H requires state member banks to establish and maintain the same procedures. Sections 211.5(m)(1) and 211.24(j)(1) of Regulation K require Edge and agreement corporations and U.S. branches, agencies, and other offices of foreign banks supervised by the Federal Reserve to establish and maintain procedures reasonably designed to ensure and monitor compliance with the BSA and related regulations. There are no required reporting forms associated with this information collection.

Board of Governors of the Federal Reserve System, September 10, 2015.

Robert deV. Frierson,

Secretary of the Board.

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GOVERNMENT PUBLISHING OFFICE

Depository Library Council to the Director; Meeting

The Depository Library Council (DLC) to the Director, Government Publishing Office (GPO) will meet on Monday, October 19, 2015 through Wednesday, October 21, 2015 in Arlington, Virginia. The sessions will take place from 8 a.m. to 5:30 p.m., Monday and Tuesday and 8 a.m. to 12:30 p.m., on Wednesday. The meeting will be held at the Doubletree Hotel, 300 Army Navy Drive, Arlington, Virginia. The purpose of this meeting is to discuss the Federal Depository Library Program. All sessions are open to the public. The United States Government Publishing Office is in compliance with the requirements of Title III of the Americans with Disabilities Act and meets all Fire Safety Act regulations.

Davita Vance-Cooks,

Director, Government Publishing Office.

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BILLING CODE 1520-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-15-15BEZ; Docket No. CDC-2015-0081]

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 efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a newly proposed information collection request entitled *Improving Fetal Alcohol Spectrum Disorders Prevention Practice through Practice and Implementation Centers and National Partnerships*.

DATES: Written comments must be received on or before November 16, 2015.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2015-0081 by any of the following methods:

- Federal eRulemaking Portal: *Regulations.gov*. Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, 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. All relevant comments received will be posted without change to *Regulations.gov*, including any personal information provided. For access to the docket to read background documents or comments received, go to *Regulations.gov*.

Please note: All public comment should be submitted 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 the 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 OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Improving Fetal Alcohol Spectrum Disorders Prevention and Practice through Practice and Implementation Centers and National Partnerships—New—National Center on Birth Defects and Developmental Disabilities

(NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The National Center on Birth Defects and Developmental Disabilities seeks to collect training evaluation data from healthcare practitioners and staff in health systems where FASD-related practice and systems changes are implemented, and grantees of Practice and Implementation Centers and national partner organizations related to prevention, identification, and treatment of fetal alcohol spectrum disorders (FASDs).

Prenatal exposure to alcohol is a leading preventable cause of birth defects and developmental disabilities. The term “fetal alcohol spectrum disorders” describes the full continuum of effects that can occur in an individual exposed to alcohol in utero. These effects include physical, mental, behavioral, and learning disabilities. All of these have lifelong implications.

The purpose of this program is to expand previous efforts from FASD training programs and shift the perspective from individual training for practicing health care professionals to one that capitalizes on prevention opportunities and the ability to impact health care practice at the systems level.

Since 2002, CDC funded FASD Regional Training Centers (RTCs) to provide education and training to healthcare professionals and students about FASD prevention, identification, and treatment. In July 2013, CDC convened an expert review panel to evaluate the effectiveness of the RTC program overall and make recommendations about the program.

The panel highlighted several accomplishments of the RTCs and proposed several changes for future programming: (1) The panel identified a need for more comprehensive coverage nationally with discipline-specific trainings, increased use of technology, greater collaboration with medical societies, and stronger linkages with national partner organizations to increase the reach of training opportunities, and (2) The panel suggested that the training centers focus on demonstrable practice change and sustainability and place a stronger emphasis on primary prevention of FASDs. In addition, it was recommended that future initiatives have stronger evaluation components.

Based on the recommendations of the expert review panel, CDC is placing increased focus on prevention, demonstrating practice change, achieving national coverage, and strengthening partnerships between FASD Practice and Implementation Centers, or PICs (the newly redesigned RTCs), and medical societies and national partner organizations. The National Organization on Fetal Alcohol Syndrome (NOFAS) also participates in this project as a resource to the PICs and national partners. The PICs and national partners are asked to closely collaborate in discipline-specific workgroups (DSWs) and identify strategies that will increase the reach of the program on a national level. While a major focus of the grantees' work will be national, regional approaches will be used to develop new content and “test out” feasibility and acceptability of materials, especially among health care

providers and medical societies. In addition, CDC is placing a stronger emphasis on evaluation, with both individual DSW/NOFAS evaluations and a cross-site evaluation.

CDC requests OMB approval to collect program evaluation information from (1) healthcare practitioners from disciplines targeted by each DSW, including training participants, (2) health system staff, and (3) cooperative agreement grantees over a three-year period.

- Healthcare practitioners will complete surveys to provide information on whether project trainings impacted their knowledge and practice behavior regarding FASD identification, prevention, and treatment. The information will be used to improve future trainings and assess whether knowledge and practice changes occurred. Some participants will also complete qualitative key informant interviews to gain additional information on practice change.

- Health system employees will be interviewed as part of high impact evaluation studies. The high impact evaluation studies will be focused assessments of two to three specific grantee efforts that seem likely to result in achievement of program objectives.

- Grantees will complete program evaluation forms to track perceptions of DSW collaboration and perceptions of key successes and challenges encountered by the DSW.

It is estimated that 20,554 respondents will participate in the evaluation each year, for a total estimated burden of 4528.0 hours annually. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	DSW/ Organization	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
FASD Core Training Participants.	All	FASD Core Training Survey—Pre-Test.	4,013	1	15/60	1,003
FASD Core Training Participants.	All	FASD Core Training Survey—Post-Test.	4,013	1	15/60	1,003
FASD Core Training Participants.	All	FASD Core Training Survey—6 Month Follow-Up.	4,013	1	20/60	1,338
Project Grantee Staff	Westat (Cross-Site Evaluator).	DSW Report	90	2	10/60	30
Project Grantee Staff	Westat (Cross-Site Evaluator).	Key Informant Interview—DSW Project Director.	6	3	60/60	18
National Partner Staff	Westat (Cross-Site Evaluator).	Key Informant Interview—National Partner.	6	3	60/60	18
Health System Staff	Westat (Cross-Site Evaluator).	Key Informant Interview—Health System Staff.	60	3	30/60	90
Nurses	Nursing	Key Informant Interviews with Champions.	14	1	45/60	10
Nurses	Nursing	Online Survey with “Friends”/Members of the Network.	34	2	15/60	17

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	DSW/ Organization	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Healthcare Organization Representatives.	Nursing	Online Survey with Healthcare Organization Representatives.	67	1	30/60	33
Nurses and Nursing Stu- dents.	Nursing	Brief Online Questionnaire for Nursing Organization Memberships.	2,934	1	10/60	489
Physicians and students in allied health professions.	Obstetrics & Gynecology ..	Avatar Training Satisfac- tion Survey.	1,200	1	6/60	120
Students in allied health professions.	Obstetrics & Gynecology ..	Proficiency Ratings Scale—Standardized Patient Version.	600	1	6/60	60
Physicians	Obstetrics & Gynecology ..	Proficiency Ratings Scale—Provider—Base- line.	600	1	6/60	60
Physicians	Obstetrics & Gynecology ..	Proficiency Rating Scale— Provider—1 Month Fol- low-Up.	600	1	2/60	20
Physicians	Obstetrics & Gynecology ..	FASD Training Event Evaluation.	124	1	2/60	4
Residency Directors, Train- ing Coordinators, Clinic Directors.	Obstetrics & Gynecology ..	Pre- Assessment of Train- ing Implementation.	14	1	30/60	7
Residency Directors, Train- ing Coordinators, Clinical Directors, Physicians.	Obstetrics & Gynecology ..	Post-Assessment of Train- ing Implementation.	14	1	30/60	7
Physicians	Pediatrics	FASD Core Training Sur- vey—Pediatrics 3 Month Follow-Up.	120	1	15/60	30
Physicians	Pediatrics	Pediatrics DSW Baseline Survey.	535	1	4/60	36
Physicians	Pediatrics	Pediatrics DSW Year 4 Survey.	535	1	4/60	36
Physicians	Pediatrics	FASD Toolkit User Survey	50	1	15/60	13
Physicians	Social Work & Family Phy- sicians.	Family Medicine Com- prehensive Practice Evaluation.	62	1	8/60	8
Medical and allied health professionals.	National Organization on Fetal Alcohol Syndrome.	NOFAS Webinar Survey— Post-Test.	400	1	5/60	33
Medical and allied health professionals.	National Organization on Fetal Alcohol Syndrome.	NOFAS Webinar Survey— 3 Month Follow-Up.	400	1	5/60	33
General public	National Organization on Fetal Alcohol Syndrome.	NOFAS Outcomes Vi- gnette.	50	1	10/60	8
TOTAL	4,524

Leroy A. Richardson,

*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.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0609]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification

AGENCY: Food and Drug Administration,
HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by October 15, 2015.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the