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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-21-21DJ Docket No. CDC-2021-0020]

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 the 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 "American Academy of Pediatrics (AAP) Resident Training Program on Children with Fetal Alcohol Spectrum Disorders (FASD)". This project will collect data to evaluate the efficacy of a newly developed pediatric resident training curriculum regarding identification, referral and care of children with fetal alcohol spectrum disorders (FASD) and their families.

DATES: CDC must receive written comments on or before **[INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments, identified by Docket No.

CDC-2021-0020 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, N.E., 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 Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7118; E-mail: 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

American Academy of Pediatrics (AAP) Resident Training on Children with Fetal Alcohol Spectrum Disorders (FASD) - New - National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Prenatal exposure to alcohol and other teratogens can have serious neurodevelopmental impact including Fetal Alcohol Spectrum Disorders (FASD). FASD is an umbrella term that encompasses several, more specific, diagnoses. These conditions are associated with lifelong physical and neurodevelopmental abnormalities, including growth problems and prenatal brain damage. This brain damage may lead to developmental, behavioral and neurocognitive impairments. Infants with a FASD are rarely recognized at birth by hospital staff. Further, at later ages, these children may be overlooked or misdiagnosed. While there is no cure for FASDs, early identification and intervention can mitigate adverse effects.

In *Bright Futures*, the American Academy of Pediatrics (AAP) suggest routinely obtaining prenatal alcohol exposure history for all pediatric patients. The AAP also recommends developmental monitoring and screening for all patients for behavioral and neurodevelopmental issues. Pediatricians are critical in the process of early identification, referral and ongoing care of children with FASDs. Through regular well-child

appointments, addressing parental concerns, and managing a family's pediatric medical home, pediatricians are in a key position to obtain (and document) prenatal exposure history to alcohol and other drugs. Relatedly, their role in monitoring development enables them to identify issues early that in turn facilitates timely treatment, especially early intervention. It is important for pediatricians to learn these skills early in their clinical training to make them routine throughout their clinical practice careers.

To facilitate and strengthen pediatricians' role, with CDC funding, the American Academy of Pediatrics (AAP) has developed a curriculum and program to provide first year pediatric resident trainees with strategies, tools and resources necessary for; 1) obtaining prenatal history of exposure to alcohol and other drugs for all their patients, 2) recognizing clinical manifestation of FASD in pediatric primary care settings to expedite diagnostic evaluation referrals, and 3) caring for affected children and their families in the pediatric medical home. This program builds upon a pilot effort that was approved under GenIC Clearance for CDC/ATSDR Formative Research and Tool Development title: American Academy of Pediatrics Resident Training in Developmental Continuity Clinics with OMB Control Number 0920-1154.

The curriculum is presented in two phases. Phase One is a one-day, in-person, train-the-trainers session for attending physicians who oversee medical resident training in pediatrics.

Training will be provided by experts in identification, diagnosis and care of children with FASD. For Phase Two, the trainer attending physicians will implement a curriculum of continuing medical education activities with their first year pediatric residents. The curriculum contains both required and option activities that residents complete with support and facilitation from attending physicians. Evaluations are conducted only for required activities. It is estimated that 10 clinics will participate in the project which could include up to 10 attending physicians and an average of 25 pediatric residents per clinic (~260 respondents/year). Participant clinics are selected by a brief application to the AAP. All participation is voluntary. CDC requests approval for an estimated 32 annual burden hours. There is no cost to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses	Burden per Response (hours)	Burden in Hours
Pediatricians	Attending physicians Screening & Diagnosis Pretest	10	1	10/60	2
Pediatricians	Attending physicians Screening & Diagnosis Posttest	10	1	10/60	2
Pediatricians	Attending physicians	10	1	10/60	2

Type of Respondents	Form Name	Number of Respondents	Number of Responses	Burden per Response (hours)	Burden in Hours
	Treatment Across Lifespan Pretest				
Pediatricians	Attending physicians Treatment Across Lifespan Posttest	10	1	10/60	2
Pediatricians	Attending physicians Overcoming Social Attitudes Pretest	10	1	10/60	2
Pediatricians	Attending physicians Overcoming Social Attitudes Posttest	10	1	10/60	2
Pediatricians	Attending physicians Educational Care Pretest	10	1	10/60	2
Pediatricians	Attending physicians Educational Care Posttest	10	1	10/60	2
Pediatricians	Attending physicians Training Program Evaluation	10	1	15/60	3
Pediatricians	Resident Overall Effects &	25	1	15/60	3

Type of Respondents	Form Name	Number of Respondents	Number of Responses	Burden per Response (hours)	Burden in Hours
	Prevalence Video Pretest				
Pediatricians	Resident Overall Effects & Prevalence Video Posttest	25	1	15/60	3
Pediatricians	Resident Overall Program Evaluation	25	1	15/60	3
Pediatricians	Attending physicians Overall Program Evaluation	10	1	20/60	4
TOTAL		175			32

Jeffrey M. Zirger,

Lead,

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Office of Scientific Integrity,

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