DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Prenatal Alcohol and Other Drug Exposures in Child Welfare (PAODE–CW) Study.

OMB No.: New Collection.

Description: The Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS) is proposing a data collection activity as part of the Prenatal Alcohol and Other Drug Exposures in Child Welfare (PAODE–CW) Study. The study examines the current state of child welfare practice regarding the identification and provision of services for children with prenatal substance exposures, including alcohol and other drugs.

The descriptive study will document the policies and practices of child welfare agencies and related organizations to identify, assess, and refer to services children who may have been exposed to prenatal substances and/or diagnosed with a resulting condition such as fetal alcohol spectrum disorders (FASD). The study will document procedures as well as challenges faced and lessons learned to inform the field of practice as well as policy makers, program administrators, and funders at various levels.

The proposed information collection activities consist of semi-structured interviews and surveys conducted at 28 child welfare agency sites. Focus groups conducted at 8 of the 28 sites will gather information on needs, challenges, and strategies to support children with prenatal substance exposures and their families within the child welfare system.

Respondents: State and child welfare agency directors, child welfare staff and supervisors; agency partners and service providers; and family members and caregivers of children who may have been prenatally exposed to substances.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Interview Protocol for Local Agency Staff—Frontline Only	28	1	1	28
Interview Protocol for Local Agency Staff—Ongoing Only	28	1	1	28
Interview Protocol for Local Agency Staff—Frontline and Ongoing	15	1	1.25	19
Interview Protocol for Local Agency Medical Staff	14	1	1	14
Interview Protocol for Local Agency Director	14	1	1	14
Focus Group of Caregivers	32	1	1.5	48
Survey Instrument for Local Agency Staff—Form A General	140	1	.5	70
Survey Instrument for Local Agency—Form B General	90	1	.5	45
Survey Instrument for Local Agency Form B Differential Response	50	1	.5	25
Survey Instrument for Service Providers	12	1	.5	6
Interview Protocol for Data Staff	6	1	1.5	9

Estimated Total Annual Burden Hours: 305.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201. Attention Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Study of Coaching Practices in Early Care and Education Settings (SCOPE).

OMB No.: New Collection.

Description: The Administration for Children and Families (ACF) at the U.S. Department of Health and Human Services (HHS) seeks approval to collect descriptive information for the Study of Coaching Practices in Early Care and Education Settings (SCOPE) project. The goal of this information collection is to identify how professional development coaching practices for early care and education (ECE) providers are implemented and vary in ECE classrooms serving children supported by Child Care and Development Fund (CCDF) subsidies or Head Start grants. This study will focus primarily on coaching used for delivering professional development services to ECE teachers and caregivers to improve knowledge and practice in center-based classrooms and family child care (FCC) homes serving preschool-age children. This study aims to advance understanding of how core features of coaching are implemented in ECE classrooms, how the features may vary by key contextual factors and implementation drivers, and which are ripe for more rigorous evaluation. The study tasks will include gathering information to inform selection of states in which to conduct the study, designing and conducting a descriptive study to examine the occurrence and variability of coaching features in ECE classrooms, and conducting case studies to examine program or systems-level drivers of coaching and the features being implemented.

Respondents: State administrators knowledgeable about coaching and

coaching funders or providers, ECE center directors, coaches, teachers, and FCC providers.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
State coaching informant interview protocol	45	23	1	1	23
ECE setting eligibility screener	173	87	1	0.25	22
Center director survey	60	30	1	0.5	15
Coach survey	90	45	1	0.5	23
Teacher/FCC provider survey	172	86	1	0.58	50
Center director semi-structured interview protocol	12	6	1	1.5	9
Coach semi-structured interview protocol	12	6	1	1	6
Teacher/FCC provider semi-structured interview protocol	12	6	1	1	6
Coach supervisor semi-structured interview protocol	12	6	1	0.5	3

Estimated Total Annual Burden Hours: 157.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments 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) the quality, utility, and clarity of the information to be collected; and (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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Mary Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2017–27578 Filed 12–21–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0307]

Amendment to ''Revised Preventive Measures To Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Products; Guidance for Industry;'' Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft document entitled ''Amendment to 'Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Products; Guidance for Industry;' Draft Guidance for Industry.'' The draft guidance document provides blood collection establishments with revised recommendations intended to reduce the possible risk of transmission of variant Creutzfeldt-Jakob Disease (vCJD) by blood and blood products by revising and removing certain recommended deferrals for geographic risk of bovine spongiform encephalopathy (BSE) exposure and recommending deferral for individuals with a history of blood transfusion in Ireland from 1980 to the present. The recommendations apply to the collection of Whole Blood and blood components intended for transfusion or for use in further manufacturing into injectable and non-injectable products, including recovered plasma, Source Leukocytes and Source Plasma.

The draft guidance, when finalized, will amend the document entitled ''Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Products; Guidance for Industry'' updated January 2016 (''2016 vCJD Guidance'') by incorporating into an updated final guidance any new recommendations adopted. All other recommendations in the 2016 vCJD Guidance will remain unchanged.

DATES: Submit either electronic or written comments on the draft guidance by March 22, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the