DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10291]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Department of Health and Human Services.

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 January 2, 2018.

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' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

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 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–10291 State Collection and Reporting of Dental Provider and Benefit Package Information on the Insure Kids Now! Web site and Hotline

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:* State Collection and Reporting of Dental Provider and Benefit Package Information on the Insure Kids Now! Web site and Hotline; *Use:* On the Insure Kids Now (IKN) Web site, the Secretary is required to post a current and accurate list of dentists and providers that provide dental services to children enrolled in the state plan (or waiver) under Medicaid or the state child health plan (or waiver) under CHIP. States collect the information pertaining to their Medicaid and CHIP dental benefits. *Form Number:* CMS–10291 (OMB control number: 0938–1065); *Frequency:* Yearly and quarterly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 51; *Total Annual Responses:* 255; *Total Annual Hours:* 11,781. (For policy questions regarding this collection contact Andrew Snyder at 410–786–1274.)

Dated: October 31, 2017.

William N. Parham, III,

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

[FR Doc. 2017–24013 Filed 11–2–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Culture of Continuous Learning Project: A Breakthrough Series Collaborative for Improving Child Care and Head Start Quality.

OMB No.: New Collection.

Description: The Office of Planning, Research and Evaluation (OPRE) in the Administration for Children and Families (ACF) is proposing an information collection activity for the Culture of Continuous Learning Project. The goal of the project is to assess the feasibility of implementing continuous quality improvement methods in early care and education programs to support the use and sustainability of evidence-based practices. A Breakthrough Series Collaborative (BSC), a specific model designed to support learning and improvement among practitioners at all levels of an organization, will be implemented in Head Start and child care settings. The BSC methodology has not been tested rigorously in early care and education programs, but has been studied in health care and other fields. The findings will be of broad interest to child care early education programs as well as training and technical assistance providers and researchers, all of whom are interested in improving the quality of services young children receive.

Head Start and child care programs that voluntarily participate in the BSC will be asked to complete a number of implementation tools as part of the BSC activities. Data collection for the feasibility study will involve focus

groups, online surveys, direct observation, and document review.

Respondents: Up to 18 early childhood centers will be invited to express interest in participating in the BSC. Up to 8 centers will be selected to participate in the BSC and feasibility study. Core BSC Teams consisting of up to 6 individuals (*e.g.,* directors, lead teachers, assistant teachers, teacher aides, parents, curriculum specialists, etc.) each from four Early Head Start or Head Start programs and four child care programs in a selected geographic location (for a total of 48 individuals); and up to 24 additional teachers or program staff at the same centers who are not part of the Core BSC Team.

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
BSC Selection Questionnaire	18	9	1	1	9
Pre-Work Assignment: Team Building Activities	48	24	1	1	24
Pre-Work Assignment: Data Collection Planning Worksheet	16	8	1	2	16
Plan, Do, Study, Act Planning Form & Tracker	48	24	48	.25	288
Discussion Forum Prompts	48	24	48	.25	288
Learning Session Day 1 Evaluation	48	24	4	.17	16
Learning Session Overall Evaluation	48	24	4	.25	24
Action Planning Form	48	24	4	.25	24
Teaching Pyramid Observation Tool (TPOT)/Teaching Pyramid Infant-Toddler Observation Scale (TPITOS)	28	14	2	.33	9
Early Childhood Work Environment Survey (ECWES)	72	36	2	.25	18
Pre/Post Survey	72	36	2	.68	49
Self-report of BSC Activities	72	36	1	.17	6
Core BSC Team Focus Group Topic Guide	48	24	1	1.25	30

Estimated Total Annual Burden Hours: 801.

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, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *OPREinfocollection@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.

Mary Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2017–23970 Filed 11–2–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1147]

Controlled Correspondence Related to Generic Drug Development; 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 guidance for industry entitled ''Controlled Correspondence Related to Generic Drug Development.'' This guidance provides information regarding the process by which generic drug manufacturers and related industry can submit controlled correspondence to FDA requesting information related to generic drug development and the Agency's process for providing communications related to such correspondence. This guidance also describes the process by which generic drug manufacturers and related industry can submit requests to clarify ambiguities in FDA' controlled correspondence response and the Agency's process for responding to those requests. This draft guidance revises the guidance for industry ''Controlled Correspondence Related to Generic Drug Development'' issued in September 2015.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by January 2, 2018.

ADDRESSES: You may submit comments 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