information from the public. Under the Paperwork Reduction Act of 1995 (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 a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate 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 on the collection(s) of information must be received by the OMB desk officer by August 2, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

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.*

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

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. 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 (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-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 that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Evaluation of the Centers for Medicare & Medicaid Services (CMS) Network of Quality Improvement and Innovation Contractors (NQIIC); *Use:* The purpose of this Information Collection Request (ICR) is to collect data using telephone surveys to inform the program evaluation of the CMS NQIIC initiative. The purpose of NQIIC is to support quality improvement efforts across settings and programs for maximum impact to health care and value to taxpayers in a manner that aligns with CMS' and Department of Health and Human Services (HHS) priorities. The NQIIC quality improvement efforts involve the QIN–QIO Program, which is one of the largest federal programs dedicated to improving health quality for Medicare beneficiaries.

CMS evaluates the quality and effectiveness of the QIN–QIO Program as authorized in Part B of Title XI of the Social Security Act. This ICR is to conduct data collection using surveys with administrators or managers of nursing homes and hospitals. Subsequent to publishing the 60-day **Federal Register** notice on March 9, 2021 (86 FR 13566), CMS conducted pre-testing with nursing home and hospital administrators using cognitive interviews, which provided substantive input from the targeted respondents to make sure that questions are clearly stated and understood as intended. We have made the required changes to questions to optimize response validity before fielding the survey. There was a slight decrease in burden hours. *Form Number:* CMS–10769 (OMB control number: 0938–NEW); *Frequency:* Yearly; *Affected Public:* State and Private Sector (Business or other for-profits); *Number of Respondents:* 1,000; *Total Annual Responses:* 1,000; *Total Annual Hours:* 290. (For policy questions regarding this collection, contact Jeff Mokry at 214–767–4021.)

Dated: June 29, 2021.

William N. Parham, III,

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

[FR Doc. 2021–14227 Filed 7–1–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Assessing the Implementation and Cost of High-Quality Early Care and Education: Field Test, OMB 0970–0499

AGENCY: Office of Planning, Research, and Evaluation, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF) at the U.S. Department of Health and Human Services (HHS) seeks approval to collect new information to use in testing measures of the implementation and costs of high-quality early care and education as part of the project, Assessing the Implementation and Cost of High-Quality Early Care and Education (ECE–ICHQ). The study received approval for a field test to validate and improve the psychometric properties of these measures in November 2019. This request is to add a measure to the approved field test to help further assess the associations between measures of implementation, cost, and quality.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about 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.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or using the search function.

SUPPLEMENTARY INFORMATION:

Description: ACF seeks approval to collect new information to use in testing measures of the implementation and costs of high-quality early care and education as part of the ECE–ICHQ

project. The project's goal is to create a technically sound and feasible instrument that will provide consistent, systematic measures of the implementation and costs of education and care in center-based settings that serve children from birth to age 5. The resulting measures will inform research, policy, and practice by improving understanding of variations in what centers do to support quality, their associated costs, and how resources for ECE may be better aligned with expectations for quality. The study received approval for a field test to validate and improve the psychometric properties of these measures in November 2019. For all previously approved materials for this study, see *https://www.reginfo.gov/public/do/PRAOMBHistory?ombControlNumber=0970-0499.* This request is to add a measure to the approved field test to help further assess the associations between measures of implementation, cost, and quality. The field test and this additional measure will include only remote data collection.

Respondents: Teachers and aids.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Avg. burden per response (in hours)	Total/annual burden (in hours)
Center re-engagement call and roster update for teaching staff survey	80	1	.50	40
Teaching staff survey	1,120	1	.50	560

Estimated Total Annual Burden Hours: 600.

Authority: § 658O(a)(5) as amended by the CCDBG Act of 2014 § 9.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021–14148 Filed 7–1–21; 8:45 am]

BILLING CODE 4184–24–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–0420]

Providing Regulatory Submissions in Alternate Electronic Format; 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 final guidance for industry entitled ''Providing Regulatory Submissions in Alternate Electronic Format.'' Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), Congress granted FDA the authority to implement the statutory electronic submission requirements in guidance. In response, FDA implemented binding guidance requiring that new drug applications (NDAs), abbreviated new drug applications (ANDAs), certain drug master files (DMFs), certain biologics license applications (BLAs), and certain investigational new drug applications (INDs) be submitted to the Agency in electronic common technical document format. Recognizing that some submissions are exempt from this requirement and that waivers of the requirement may be granted on a case-by-case basis, the Agency is issuing this guidance to provide recommendations on an alternate electronic format for submissions covered under such exemptions and waivers. This guidance replaces the draft guidance of the same title issued on March 11, 2020.

DATES: The announcement of the guidance is published in the **Federal Register** on July 2, 2021.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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 manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–D–0420 for ''Providing Regulatory Submissions in Alternate Electronic Format.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available