

Medicare Administrative Contractors (MACs) and CMS of co-located providers. The requirement regarding collection of information at § 412.22 concerning a LTCH's (or a LTCH satellite's) notification to its MAC and CMS of its co-located status is needed in order for Medicare to appropriately pay co-located hospitals-within-hospitals (HwHs) and satellites. Under §§ 412.22(e)(3) and (h)(6), an LTCH or a satellite of an LTCH that occupies space in a building used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital must notify its MAC and CMS in writing of its co-location within 60 days of its first cost reporting period that began on or after October 1, 2002. *Form Number:* CMS-10088 (OMB control number: 0938-0897); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profit, not-for-profit institutions); *Number of Respondents:* 25; *Total Annual Responses:* 25; *Total Annual Hours:* 6. (For policy questions regarding this collection contact Emily Lipkin at 410-786-3633.)

Dated: September 10, 2019.

William N. Parham, III,

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

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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 (0970-0499)

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

ACTION: Request for public comment.

SUMMARY: This information request is part of the project, Assessing the Implementation and Cost of High

Quality Early Care and Education (ECE-ICHQ). 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.

DATES: *Comments due within 30 days of publication.* 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.

ADDRESSES: 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.

Copies of the proposed collection may be obtained by emailing *OPREinfocollection@acf.hhs.gov*. Alternatively, copies can also 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, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: 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. This information collection is part of the project, Assessing the

Implementation and Cost of High Quality Early Care and Education (ECE-ICHQ). 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 goals of the study are (1) to test and refine a data collection approach to gather information about implementation activities and costs of key functions within ECE centers and (2) to develop new measures of implementation and costs for use together in understanding ways to support quality. The study has completed two phases of data collection to develop the data collection tools and measures. The study team collected data through on-site visits to 15 centers as part of an initial phase of data collection to pre-test information collections (data collected under clearance #0970-0355). A second phase (OMB #0970-0499) relied on remote data collection through an electronic cost workbook, telephone interviews, and web-based surveys to gather information from 30 centers in three states to develop preliminary measures of implementation and cost and further reduced and refined the data collection tools.

This proposed new information collection is focused on a field test of the measures to assess the psychometric properties of the implementation measures and to examine the associations between measures of implementation, cost, and quality. The field test will include a mix of remote and on-site data collection.

Respondents: ECE site administrators or center directors, program directors, education specialists, financial managers or accountants, teachers, and aides.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Center recruitment call (to gain participation; assumes outreach to 10 centers for every 1 center needed):				
Center director	800	1	.33	264
Umbrella organization administrator	75	1	.33	25
Center engagement call (to gather basic characteristics and plan steps for participation; assumes 20% may withdraw after this step)	100	1	.50	50

ANNUAL BURDEN ESTIMATES—Continued

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Implementation interview protocol:				
Center director	80	1	3	240
Additional center staff	20	1	3	60
Electronic cost workbook	80	1	8	640
Staff rosters for time use survey	80	1	.25	20
Time-use survey	1,120	1	.25	280
Classroom rosters for observations	80	1	.50	40
Total Burden				1,619

Authority: Social Security Act § 418 as extended by the Continuing Appropriations Act of 2017 and the TANF Extension Act of 2019.

Mary B. Jones,
ACF/OPRE Certifying Officer.

[FR Doc. 2019–20115 Filed 9–16–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–3324]

Reconditioning of Fish and Fishery Products by Segregation: Guidance for Industry; Draft Guidance: Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled “Reconditioning of Fish and Fishery Products by Segregation.” The draft guidance, when finalized, will provide industry with an explanation of two potential approaches to recondition fish and fishery products by effectively segregating adulterated portions of an article from portions not containing the adulterant to ensure that only safe and wholesome product reaches consumers. **DATES:** Submit either electronic or written comments on the draft guidance by November 18, 2019 to ensure that we consider your comment on the draft guidance before we begin 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 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–2019–D–3324 for “Reconditioning of Fish and Fishery Products by Segregation.” 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.

• **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.” We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).