

Description: This descriptive study aims to provide insight into the models that have been used to centralize services; organizations’ history of and impetus for centralizing services; the benefits, challenges, and costs of centralizing services from the perspectives of staff and clients; and how organizations have coordinated their centralized services virtually. This

project will include site visits to three centralized community resource centers (CCRCs). The proposed information collection activities include interviews with staff, including leadership and administrative staff, frontline staff, finance staff, and IT/data staff, and focus groups with clients. The research team will also conduct observations of program activities.

Respondents: Respondents will include leadership and administrative staff at the CCRC, staff who manage finances at the CCRC, staff who manage data and/or technology at the CCRC, staff who provide services directly to clients at the CCRC, and clients who have accessed services at the CCRC.

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)
Interview guide for administrative/leadership staff	18	1	1.25	23
Interview guide for frontline staff	48	1	1.25	60
Interview guide for finance staff	9	1	1	9
Interview guide for IT/data staff	9	1	1	9
Focus group guide for clients	30	1	1.5	45

Estimated Total Annual Burden Hours: 146.

Comments: 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.

Authority: Authorized by the Social Security Act 1110 [42 U.S.C. 1310], appropriated by the Continuing Appropriations Act of 2019.

Mary B. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB #0970–0391]

Proposed Information Collection Activity; National Survey of Early Care and Education COVID–19 Follow-Up

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), U.S. Department of Health and Human Services (HHS), plans to request from the Office of Management and Budget (OMB) an extension to complete data collection for a two-wave COVID–19 Follow-up data collection currently underway as part of the National Survey of Early Care and Education (NSECE). The objective of the NSECE COVID–19 Follow-up is to document the nation’s current supply of early care and education services (that is, home-based providers, center-based providers, and the center-based provider workforce). There are no changes proposed.

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 by using the search function.

SUPPLEMENTARY INFORMATION:

Description: In the context of the COVID–19 pandemic, the NSECE COVID–19 Follow-up will deepen our understanding of the state of ECE supply and the ECE workforce following the initial period of crisis, including changes in supply or departures from and re-entries to the workforce. The NSECE COVID–19 Follow-up is collecting information from center-based ECE providers to children birth through age 5 years, not yet in kindergarten, home-based ECE providers that serve children under age 13, as well as the ECE workforce providing these services. The collection consists of three coordinated nationally representative surveys:

1. A two-wave survey of individuals who provided paid care for children under the age of 13 in a residential setting as of 2019 and participated in the 2019 NSECE (Home-based Provider Interview),

2. a two-wave survey of providers of care to children ages 0 through 5 years of age (not yet in kindergarten) in a non-residential setting (Center-based Provider Interview) as of 2019 and that participated in the 2019 NSECE, and

3. a two-wave survey conducted with individuals employed in center-based

child care programs working directly with children in classrooms (Center-based Classroom Staff [Workforce Interview] as of 2019 and who participated in the 2019 NSECE.

Respondents: Home-based providers as of 2019 serving children under 13 years (listed and unlisted paid)—

regardless of their status serving children in 2020–2022, center-based child care providers as of 2019 serving children ages 0 through 5 years of age (not yet in kindergarten)—regardless of their status serving children in 2020–2022, and classroom-assigned instructional staff members working

with children ages 0 through 5 years of age (not yet in kindergarten) in center-based child care providers as of 2019, regardless of their employment status in 2020–2022.

Annual Burden Estimates: This request is for an extension through spring 2022.

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Avg. burden per response (in hours)	Total burden (in hours)
Home-based Provider Interview, Wave 2—In ECE during focal week	2,025	1	0.35	709
Home-based Provider Interview, Wave 2—Not in ECE during focal week	506	1	0.25	126
Center-based Provider Interview, Wave 2 spring or fall; in ECE during focal week	3,291	1	0.38	1,251
Center-based Provider Interview, Wave 2 spring or fall; not in ECE during focal week	1,097	1	0.22	241
Center-based Provider Fall 2021 Funding Receipt Supplement	1,255	1	0.20	251
Center-based Provider Interview Wave 2 fall; Centers completing in Wave 2 spring also	1,136	1	0.29	329
(Center-based) Workforce Interview—Wave 2; In ECE during Focal Week ..	1,775	1	0.37	657
(Center-based) Workforce Interview—Wave 2; Not in ECE during Focal Week	874	1	0.24	210

Estimated Total Burden Hours: 3,774.

Authority: Child Care and Development Block Grant (CCDBG) Act of 1990 as amended by the CCDBG Act of 2014 (Pub. L. 113–186).

Mary B. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0399]

Good Manufacturing Practices for Animal Cells, Tissues, and Cell- and Tissue-Based Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance for industry #253 entitled “Good Manufacturing Practices for Animal Cells, Tissues, and Cell- and Tissue-Based Products.” FDA’s Center for Veterinary Medicine (CVM) is issuing this guidance to provide establishments that manufacture animal cells, tissues, and cell- and tissue-based products (ACTPs) meeting the definition of new animal drugs with recommendations for meeting

requirements for current good manufacturing practices (CGMPs). All new animal drugs, including ACTPs, are required to be manufactured in accordance with CGMPs to ensure that such drugs meet the requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act) as to safety, and have the identity, strength, quality, and purity characteristics, which they purport to or are represented to possess. This guidance also provides FDA’s recommendations for those aspects of manufacturing specific to ACTPs in accordance with existing CGMP regulations, as applicable, and with the FD&C Act. In this guidance, we specifically address the methods, facilities, and controls used for manufacturing ACTPs.

DATES: Submit either electronic or written comments on the draft guidance by November 22, 2021 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 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–2021–D–0399 for “Good Manufacturing Practices for Animal Cells, Tissues, and Cell- and Tissue-Based Products.”