

Act of 1990 as amended by the CCDBG Act of 2014 (Pub. L. 113–186).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021–09664 Filed 5–6–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB No. 0970–0214]

Proposed Information Collection Activity; Child and Family Services Reviews

AGENCY: Children's Bureau, Administration for Children, Youth and Families, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF) is requesting reinstatement of the activities associated with the *Child and Family Services Reviews* (CFSR) collection (OMB #0970–0214). Revisions have been made to the forms to clarify instructions and incorporate new guidance. The activities associated with the Title IV–E Foster Care Eligibility

Reviews and Anti-Discrimination Enforcement Corrective Action Plans have been removed from this collection.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: Copies of the proposed collection of information can be obtained and comments may be forwarded by emailing infocollection@acf.hhs.gov. Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation (OPRE), 330 C Street SW, Washington, DC 20201, Attn: ACF Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The following activities are associated with the CFSR collection: CFSR Statewide Assessment, CFSR On-site Review, and the CFSR Program Improvement Plan. The collection of information for review of state child and family services programs (45 CFR 1355.33(b), 1355.33(c) and 1355.35(a)) is to determine whether such programs are in substantial conformity with state plan requirements under titles IV–B and IV–

E of the Social Security Act (the Act) and is authorized by section 1123(a) [42 U.S.C. 1320a–2a] of the Act. The CFSR looks at the outcomes related to safety, permanency, and well-being of children served by the child welfare system and at seven systemic factors that support the outcomes. The information collection is needed to monitor state plan requirements under titles IV–B and IV–E of the Act and is required by federal statute. The resultant information will allow ACF to determine if states are in compliance with state plan requirements and are achieving desired outcomes for children and families. If necessary, ACF will require states revise applicable statutes, rules, policies and procedures, and provide proper training to staff, through the development and implementation of program improvement plans. The CFSR reviews not only address conformity with state plan requirements but also assist states in enhancing the capacities to serve children and families. In computing the number of burden hours for this information collection, ACF based the annual burden estimates on ACF's and states' experiences in conducting reviews and developing program improvement plans.

Respondents: State Title IV–E Agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
45 CFR 1355.33(b) Statewide Assessment	39	1	120	4,680	1,560
45 CFR 1355.33(c) On-site Review Instrument (OSRI) Stakeholder Interview Guide (SIG)	39	1	1,186	46,254	15,418
45 CFR 1355.35(a) Program Improvement Plan (PIP)	39	1	300	11,700	3,900

Estimated Total Annual Burden Hours: 20,878.

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: 42 U.S.C 1320a–2a.

Mary B. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Intent To Award a Single-Source Supplement; National Consumer Voice for Quality Long-Term Care

ACTION: Announcing the intent to award a single-source supplement for the

National Consumer Voice for Quality Long-Term Care for the National Ombudsman Resource Center cooperative agreement.

SUMMARY: The Administration for Community Living (ACL) announces the intent to award a single-source supplement to the current cooperative agreement held by the National Consumer Voice for Quality Long-Term Care for the National Ombudsman Resource Center. The COVID–19 pandemic has significantly impacted residents of long-term care facilities, staff, families, and Long-Term Care Ombudsman programs. During the pandemic the NORC has successfully provided the training, tools and resources for Ombudsman programs to

respond rapidly to this devastating pandemic. This supplemental award will allow NORC to enhance the capacity of LTC Ombudsman programs to address abuse, neglect and exploitation as programs begin to re-enter long-term care facilities. This supplemental is consistent with the Coronavirus Response and Relief Supplemental Appropriations Act of 2021: Grants to Enhance Capacity of Long-Term Care Ombudsman Programs to Respond to Complaints of Abuse and Neglect of Residents in Long-Term Care Facilities during the COVID-19 Public Health Emergency.

Program Name: National Ombudsman Resource Center.

Recipient: The National Consumer Voice for Quality Long-Term Care.

Period of Performance: The supplement award will be issued for the time period of April 1, 2021-September 30, 2022.

Total Award Amount: \$25,000, FY 2021.

Award Type: Cooperative Agreement Supplement.

Statutory Authority: This program is authorized under Section 202 of the Older Americans Act.

Basis for Award: The objective of the National Ombudsman Resource Center is to support credible and effective Long-Term Care Ombudsman programs through the provision of technical assistance and training to state Ombudsman programs and to state agencies on aging. Each year the NORC helps thousands of state and local Ombudsmen through its website, training and webinars and specialized technical assistance. It is the only resource center specialized to provide technical assistance to state Ombudsman programs. In addition, early in the pandemic NORC pivoted to provide relevant tools and training to help Ombudsman programs respond to the pandemic including the toolkit COVID-19 Recover and Re-entry and Trauma-Informed webinars and dialogue to assist Ombudsman programs.

For More Information Contact: For further information or comments regarding this program supplement, contact Louise Ryan, U.S. Department of Health and Human Services, Administration for Community Living, Administration on Aging (206) 615-2299; email Louise.Ryan@acl.hhs.gov.

Date: April 30, 2021.

Alison Barkoff,

Acting Administrator and Assistant Secretary for Aging.

[FR Doc. 2021-09661 Filed 5-6-21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0913]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; 513(g) Request for Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by June 7, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910-0705. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

513(g) Request for Information

OMB Control Number 0910-0705—Extension

This information collection supports Agency regulations and accompanying guidance. Section 513(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360c(g)) provides a means for obtaining the Agency’s views about the classification and regulatory requirements that may be applicable to a particular device. Section 513(g) provides that, within 60 days of the

receipt of a written request of any person for information respecting the class in which a device has been classified or the requirements applicable to a device under the FD&C Act, the Secretary of Health and Human Services shall provide such person a written statement of the classification (if any) of such device and the requirements of the FD&C Act applicable to the device. Regulations governing medical device classification procedures are codified under 21 CFR part 860.

The guidance document entitled “FDA and Industry Procedures for Section 513(g) Requests for Information Under the Federal Food, Drug, and Cosmetic Act; Guidance for Industry and Food and Drug Administration Staff”¹ establishes procedures for submitting, reviewing, and responding to requests for information respecting the class in which a device has been classified or the requirements applicable to a device under the FD&C Act that are submitted in accordance with section 513(g) of the FD&C Act. FDA does not review data related to substantial equivalence or safety and effectiveness in a 513(g) request for information. FDA’s responses to 513(g) requests for information are not device classification decisions and do not constitute FDA clearance or approval for marketing. Classification decisions and clearance or approval for marketing require submissions under different sections of the FD&C Act.

Relatedly, the FD&C Act, as amended by the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110-85), requires FDA to collect user fees for 513(g) requests for information. The guidance document entitled “User Fees for 513(g) Requests for Information; Guidance for Industry and Food and Drug Administration Staff”² assists FDA staff and regulated industry by describing the user fees associated with 513(g) requests. The Medical Device User Fee Cover Sheet (Form FDA 3601), which accompanies the supplemental material described in this information collection is approved under OMB control number 0910-0511.

In the **Federal Register** of January 13, 2021 (86 FR 2674), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received five comments; however, the comments

¹ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-procedures-section-513g-requests-information-under-federal-food-drug-and-cosmetic>.

² <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/user-fees-513g-requests-information>.