Estimated Total Annual Burden Hours: 11,500.

Authority: Public Law 115–123, Section 511(h)(2)(A) of Title V of the Social Security Act.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–00593 Filed 1–15–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Building Capacity To Evaluate Child Welfare Community Collaborations To Strengthen and Preserve Families (CWCC) Cross-Site Process Evaluation (New Collection)

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) intends to collect data for an evaluation of the initiative, Community Collaborations to Strengthen and Preserve Families (also referred to as Child Welfare Community Collaborations [CWCC]). The cross-site process evaluation will provide insight to ACF about the various factors that promote or impede the implementation of child welfare community collaborations.

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 evaluation will involve seven data collection requests:

- *Four Site Visit Discussion Guides:* To systematically document the approaches and strategies used by the first two cohorts of CWCC grantees (FY18 and FY19 awardees), the evaluation team will conduct initial and follow-up interviews with: (1) Project Directors from Lead Grantee organizations and Leaders from partner organizations, and (2) staff from the lead and partner organizations. These interviews will take place during site visits. Each grantee will participate in four site visits.
- *Survey Invitee Template:* The evaluation team will ask the Project Director of each CWCC grant to fill out a Survey Invitee Template to gather contact information for leaders and staff from lead and partner organizations who the evaluation team will invite to complete the Collaboration Survey (see below).
- *Collaboration Survey:* This electronic survey will document perceptions that leaders and staff from the CWCC lead and partner organizations have regarding their organizational/group processes, implementation activities, and progress towards goals. This survey will be administered to staff at all grantee and partner organizations on an annual basis during each cohort's grant period.
- *Site Visit Planning Template:* Each Project Director (or their designee) will complete a Site Visit Planning Template to schedule site visit activities prior to each annual site visit.

Respondents: Leadership and staff from CWCC lead (grantee) organizations and from partner organizations.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Cohort 1 Data Collection for FY18 Grantees					
Site Visit Discussion Guide for Project Directors and Leaders from Partner Organizations—Interview #1	12	1	2	24	8
Site Visit Discussion Guide for Staff from Lead and Partner Organizations—Interview #1	36	1	1	36	12
Site Visit Discussion Guide for Project Directors and Leaders from Partner Organizations—Follow-Up Interviews	12	2	1.5	36	12
Site Visit Discussion Guide for Staff from Lead and Partner Organizations—Follow-Up Interviews	36	2	1	72	24
Survey Invitee Template	4	3	1	12	4
Annual Collaboration Survey	260	3	0.5	390	130
Site Visit Planning Template	4	3	2	24	8
Cohort 2 Data Collection for FY19 Grantees					
Site Visit Discussion Guide for Project Directors and Leaders from Partner Organizations—Interview #1	27	1	2	54	18
Site Visit Discussion Guide for Staff from Lead and Partner Organizations—Interview #1	81	1	1	81	27
Site Visit Discussion Guide for Project Directors and Leaders from Partner Organizations—Follow-Up Interviews	27	2	1.5	81	27
Site Visit Discussion Guide for Staff from Lead and Partner Organizations—Follow-Up Interviews	81	2	1	162	54

ANNUAL BURDEN ESTIMATES—Continued

Instrument	Total number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Survey Invitee Template	9	3	1	27	9
Annual Collaboration Survey	585	3	0.5	878	293
Site Visit Planning Template	9	3	2	54	18

Estimated Total Annual Burden Hours: 644.

Authority: Section 105(b)(5) of the Child Abuse Prevention and Treatment Act (CAPTA) of 1978 (42 U.S.C. 5106(b)(5)), as amended by the CAPTA Reauthorization Act of 2010 (Pub. L. 111–320).

Mary B. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–4752]

Pediatric Study Plans for Oncology Drugs: Questions and Answers; 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 ''Pediatric Study Plans for Oncology Drugs: Questions and Answers.'' This draft guidance provides information to sponsors regarding the submission of an initial pediatric study plan (iPSP), as required by the Federal Food, Drug, and Cosmetic Act (FD&C Act), for oncology drugs only. Specifically, when finalized, this draft guidance will provide FDA's current thinking regarding iPSPs for oncology drugs in light of the amendments to the FD&C Act made by the FDA Reauthorization Act of 2017 (FDARA). FDA has received a number of questions on this topic and, as a result, is providing this draft guidance in a question and answer format, addressing the most frequently asked questions.

DATES: Submit either electronic or written comments on the draft guidance by March 16, 2020 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–2019–D–4752 for ''Pediatric Study Plans for Oncology Drugs: Questions and Answers.'' 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.'' 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 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.govinfo.gov/content/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 *https://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)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10001