

Closed captioning will be provided during the meeting. If another reasonable accommodation for a disability is needed, please contact the Food and Drug Administration (FDA) Office of Equal Employment Opportunity and Diversity Management on (301) 827-4840, no later than Thursday, February 29, 2024. The agenda, roster, and minutes will be available from Jenny Griffith, Committee Management Officer, Agency for Healthcare Research and Quality, 5600 Fishers Lane, Rockville, Maryland 20857. Jenny Griffith's phone number is (240) 446-6799.

SUPPLEMENTARY INFORMATION:

I. Purpose

In accordance with the Federal Advisory Committee Act, this notice announces a meeting of the National Advisory Council for Healthcare Research and Quality (the Council). 5 U.S.C. 1009. The Council is authorized by section 941 of the Public Health Service Act, 42 U.S.C. 299c. In accordance with its statutory mandate, the Council is to advise the Secretary of the Department of Health and Human Services and the Director of AHRQ on matters related to AHRQ's conduct of its mission including providing guidance on (A) priorities for health care research, (B) the field of health care research including training needs and information dissemination on health care quality and (C) the role of the Agency in light of private sector activity and opportunities for public private partnerships. The Council is composed of members of the public, appointed by the Secretary, and Federal ex-officio members specified in the authorizing legislation.

II. Agenda

On Thursday, March 14, 2024, NAC members will meet to conduct preparatory work prior to convening the Council meeting at 11:15 a.m., with the call to order by the Council Chair, an introduction of NAC members, and approval of previous Council summary notes. The NAC members will then receive an update from the AHRQ Director. The agenda will also include

updates on the Subcommittee of the National Advisory Council (SNAC) for AHRQ's Patient-Centered Outcomes Research Trust Fund (PCORTF) Investments, the 20th Anniversary of Digital Healthcare, an update on the National Action Alliance to Advance Patient and Workforce Safety, and a discussion on diagnostic safety. The meeting is open to the public and will adjourn at 4 p.m. For information regarding how to access the meeting as well as other meeting details, including information on how to make a public comment, please go to <https://www.ahrq.gov/news/events/nac/>. The final agenda will be available on the AHRQ website no later than Thursday, March 7, 2024.

Dated: February 12, 2024.

Marquita Cullom,
Associate Director.

[FR Doc. 2024-03155 Filed 2-14-24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for Office of Management and Budget Review; Community-Based Child Abuse Prevention Program (Office of Management and Budget #: 0970-0155)

AGENCY: Children's Bureau, Administration on Children, Youth and Families, Administration for Children and Families, Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Children's Bureau, Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is requesting a three-year extension of the Program Instruction (PI) for the Community-Based Child Abuse Prevention (CBCAP) program (Office of Management and Budget (OMB) #: 0970-0155, expiration June 30, 2024), which outlines information collection requirements pursuant to receiving a

grant award. There are no changes requested to the information collection process.

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: The PI, prepared in response to the enactment of the CBCAP program, as set forth in Title II of the Child Abuse Prevention and Treatment Reauthorization Act of 2010 (Pub. L. 111-320) or CAPTA, provides direction to the states and territories to accomplish the purposes of (1) supporting community-based efforts to develop, operate, expand, and where appropriate to network, initiatives aimed at the prevention of child abuse and neglect, and to support networks of coordinated resources and activities to better strengthen and support families to reduce the likelihood of child abuse and neglect and (2) fostering an understanding, appreciation, and knowledge of diverse populations in order to be effective in preventing and treating child abuse and neglect. This PI contains information collection requirements that are found in CAPTA and pursuant to receiving a grant award. The information submitted will be used by the agency to ensure compliance with the statute, complete the calculation of the grant award entitlement, and provide training and technical assistance to the grantee.

Respondents: State governments, quasi-public entities, and non-profit private agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Application	52	1	40	2,080
Annual Report	52	1	24	1,248
Totals				3,328

Authority: The CAPTA Reauthorization Act of 2010; Title II of the CAPTA, Pub. L. 115–271 (42 U.S.C. 5116 *et seq.*).

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–03107 Filed 2–14–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0447]

Charging for Investigational Drugs Under an Investigational New Drug Application: Questions and Answers; 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 “Charging for Investigational Drugs Under an IND: Questions and Answers.” This guidance addresses frequently asked questions related to the implementation of FDA’s regulation on charging for investigational drugs under an investigational new drug application (IND) for the purpose of either clinical trials or expanded access for treatment use. This guidance finalizes the revised draft guidance of the same title issued on August 23, 2022, and replaces the final guidance issued on June 3, 2016.

DATES: The announcement of the guidance is published in the **Federal Register** on February 15, 2024.

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–2013–D–0447 for “Charging for Investigational Drugs Under an IND: 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, 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 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, 240–402–7500.

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

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Dat Doan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3334, Silver Spring, MD 20993–0002, 240–402–8926, Dat.Doan@fda.hhs.gov; or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Charging for Investigational Drugs Under an IND: Questions and Answers.” FDA’s regulation on charging for investigational drugs under an IND (21 CFR 312.8) for the purpose of either clinical trials or expanded access for treatment use allows sponsors to charge for investigational drugs under certain circumstances.

FDA issued a final guidance on June 3, 2016 entitled “Charging for