

ANNUAL BURDEN ESTIMATES—Continued

	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hour per response	Annual burden hours
Administrative Data List	30	10	2	5.00	100

Estimated Total Annual Burden Hours: 849.

Additional Information: Copies of the proposed collection may 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 should be identified by the title of the information collection. Email address: OPREinfocollection@acf.hhs.gov.

OMB Comment: 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. 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.

Mary B. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review: Updates to Approved Information Collection

AGENCY: Office of Planning, Research, and Evaluation; ACF; HHS.

ACTION: Public comment request.

Title: Evaluation of Employment Coaching for TANF and Other Low-Income Populations (0970-0506).

SUMMARY: The Administration for Children and Families (ACF) is proposing an increase in the number of sites for data collection activities to be conducted as part of the Evaluation of Employment Coaching for TANF and Other Low-Income Populations. The Office of Management and Budget (OMB) Office of Information and Regulatory Affairs approved this information collection in March 2018 (0970-0506). As approved, we planned to include three employment programs. We have since identified three additional employment programs to include in the study. This Notice provides the opportunity for public comment on the addition of three sites.

This study will provide an opportunity to learn more about the potential of coaching to help clients achieve self-sufficiency and other desired employment-related outcomes.

The programs included in the study are Temporary Assistance for Needy Families (TANF) agencies and other public or private employment programs that serve low-income individuals.

Selected sites include a robust coaching component and have the capacity to conduct a rigorous impact evaluation, among other criteria. This study will provide information on whether coaching helps people obtain and retain jobs, advance in their careers, move toward self-sufficiency, and improve their overall well-being. To meet these objectives, this study includes an impact and implementation study.

The impact study involves participants being randomly assigned to either a “program group,” who will be paired with a coach, or to a “control group,” who will not be paired with a coach. The effectiveness of the coaching will be determined by differences between members of the program and control groups in outcomes such as obtaining and retaining employment, earnings, measures of self-sufficiency, and measures of self-regulation.

The implementation study will document coaching practices, describe lessons learned from implementing coaching, and enhance interpretation of the impact study findings.

The proposed information collection activities have not changed since OMB/OIRA approval. The only change to this information collection is to add three additional sites.

Respondents: Program staff and individuals enrolled in the Evaluation of Employment Coaching for TANF and Other Low-Income Populations. Program staff may include coaches, case managers, workshop instructors, job developers, supervisors, and managers. All participants will be able to opt out of participating in the data collection activities.

ANNUAL BURDEN ESTIMATES

Instrument	Original request: Total number of respondents	Updated request: Total number of respondents	Updated request: Annual number of respondents	Number of responses per respondent	Average burden hours per response	Updated request: Annual burden hours
Baseline data collection—study participants	6,000	6,000	2,000	1	.33	660
Baseline data collection—staff	60	60	20	100	.33	660
First follow-up survey	2,400	4,800	1,600	1	1	1,600
Semi-structured staff interviews	66	132	44	1	1.5	66
Staff survey	48	96	32	1	.75	24
In-depth participant interviews	24	48	16	1	2.5	40
Staff reports of program service receipt ..	30	60	20	5,200	.03	3,120
Video recordings of coaching sessions ...	27	54	18	10	.1	18

Estimated Total Annual Burden Hours: 6,188.

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 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 should be identified by the title of the information collection. Email address: OPREinfocollection@acf.hhs.gov.

(Authority: Section 413 of the Social Security Act, as amended by the FY 2017 Consolidated Appropriations Act, 2017 (Pub. L. 115-31))

Mary B. Jones,
ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-2434]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Formal Meetings With Sponsors and Applicants for Prescription Drug User Fee Act Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each

proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection contained in the guidance for industry on formal meetings with sponsors and applicants for Prescription Drug User Fee Act (PDUFA) products.

DATES: Submit either electronic or written comments on the collection of information by September 10, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 10, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of September 10, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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-2018-N-2434 for "Guidance for Industry on Formal Meetings with Sponsors and Applicants for PDUFA Products." Received comments, those filed in a timely manner (see **ADDRESSES**), 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.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 <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.