TOTAL BURDEN ESTIMATES—Continued

[TANF, CW, Third Domain]

Instrument	Previously approved respondents for TANF & CW	Total number of respondents (TANF, CW, EHS/HS)	Number of responses per respondent	Average burden hours per response	Total burden hours with 3rd domain
Client interviews/focus groups	48	348	1	1	348
Client survey	600	840	1	.25	210
Staff Survey	120	144	1	.25	36
Evaluation					
Administrator interviews/focus groups	48	96	1	1	96
Staff interviews/focus groups	96	756	1	1	756
Client interviews/focus groups	96	696	1	1	696
Client survey	6,000	10,800	1	.25	2,700
Staff Survey	120	600	1	.25	150

Estimated Total Burden Hours: 5,418.

Authority: 42 U.S.C. 1310.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–15082 Filed 7–15–19; 8:45 am]

BILLING CODE 4184–07–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; State Temporary Assistance for Needy Families Case Studies (New Collection)

AGENCY: Office of Planning, Research, and Evaluation; Administration for Children and Families; HHS.

ACTION: Request for public comment.

SUMMARY: The Office of Planning, Research, and Evaluation (OPRE) is proposing a data collection activity as part of the State Temporary Assistance for Needy Families (TANF) Case Studies project. This study seeks to document innovative employment and training programs for low-income individuals including TANF recipients and examine the ways the programs provide or link families to wraparound services. Over a three-year period, the study will conduct up to 12 comprehensive qualitative case studies and up to 20 profiles of innovative programs to showcase promising approaches.

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 State TANF Case Studies project will involve several phases including: (1) Identifying innovative programs through a scan of the field and engagement with stakeholders; (2) visiting up to 12 selected programs to collect detailed information and produce comprehensive case studies of these programs to enhance policymakers' and other stakeholders' understanding of promising programs helping low-income individuals to succeed in the labor force; and (3) gathering information through telephone interviews to produce up to 20 shorter case studies. The proposed information collection activities are: (1) Semi-structured interviews with program and partner administrators and frontline staff; (2) in-depth interviews with participants to better inform and enhance understanding of client experiences and perspectives; (3) a guided case review with frontline staff to capture information about client characteristics as well as intensity, frequency, duration, and sequencing of services; and (4) an observation of program services, such as case management sessions, intakes and referrals, services delivered in a classroom setting, and work sites. The study will take place over a three year period.

Respondents: Respondents include program administrators, frontline program staff, and program participants. Program administrators include staff who administer and supervise the case study program under review, TANF and employment and training programs; child care and other wraparound supports; and other workforce programs and partners such as community colleges, adult basic education providers, and employers; and state decision makers, as appropriate. Frontline program staff include intake workers, case managers, job developers, and other direct service providers who work at TANF agencies and American Job Centers, employment and training providers such as community colleges, and providers of wraparound supports, such as child care subsidy frontline staff. TANF and other low-income program participants will also be respondents. All participants will be able to opt out of participating in the data collection activities.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Semi-structured program staff interview guide	200	67	1	1	67
In-depth participant interview guide	24	8	1	1.5	12
Case review guide	24	8	2	.75	12

Estimated Total Annual Burden Hours: 91.

Authority: Sec. 413, Pub. L. 115–31.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–15092 Filed 7–15–19; 8:45 am]

BILLING CODE 4184–09–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1006]

Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the Electronic Common Technical Document Specifications (Revision 7); 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 ''Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (Revision 7).'' FDA has identified certain submission types that FDA believes warrant an exemption (Type III drug master files (DMFs)) or a long-term waiver (certain positron emission tomography (PET) drug products and certain Type II DMFs supporting PET drugs or noncommercial submissions or applications) from the requirement to submit to the Agency in eCTD format. In addition, this guidance outlines certain circumstances where FDA may determine that a short-term waiver from electronic common technical document (eCTD) submission requirements could be granted. This guidance is a revision of the final guidance issued on January 29, 2019, and when finalized, will supersede that guidance.

DATES: Submit either electronic or written comments on the draft guidance by September 16, 2019 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–2014–N–1006 for ''Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (Revision 7).'' 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.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