

EXHIBIT 2—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
Preliminary Conference Call	12	12	^a \$67.15	\$806
Pre-Visit Questionnaire	6	6	^b 46.17	277
Practice Tour	6	6	^b 46.17	277
Interviews with Practice Manager and Physician Leader	12	12	^a 67.15	806
Interviews with Clinicians and Office Staff	111	111	^c 55.00	6,105
Survey of Clinicians and Office Staff	135	34	^d 45.98	1,563
Patient Interviews	36	18	^e 21.74	391
Review of the Workflow Process Map(s)	12	12	^a 67.15	806
Total	330	196	N/A	11,031

* Based upon the mean of the average hourly wages, National Compensation Survey: Occupational wages in the United States May 2011, "U.S. Department of Labor, Bureau of Labor Statistics."

^a The average wage for Practice Managers (\$46.17 per hour) and Physician Leaders (\$88.12 per hour) [\$88.12 reflects the average for Family and General Practitioners (\$85.26 per hour) and Internists, General (\$90.97 per hour)].

^b The average U.S. wage for Practice Managers is \$46.17 per hour.

^c The weighted average wage for physicians (\$88.12 per hour) [\$88.12 reflects the average for Family and General Practitioners (\$85.26 per hour) and Internists, General (\$90.97 per hour)], nurse practitioners and physician assistants (\$41.63 per hour) [\$41.63 reflects the average for Physician Assistants (\$43.01 per hour) and Health Diagnosing and Treating Practitioners, All (\$40.24 per hour)], nurses (\$33.23 per hour), and Office Staff (\$17.94) [reflects the average for Receptionists and Information Clerks (\$12.85 per hour), Office and Administration Support Workers, All Other (\$16.07 per hour), and Computer Support Specialists (\$24.91 per hour)].

^d The weighted average wage for physicians (\$88.12), nurse practitioners and physician assistants (\$41.63), nurses (\$33.23) and office staff (\$17.94).

^e The average U.S. hourly wage (\$21.74).

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: February 6, 2012.

Carolyn M. Clancy,

Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Tribal TANF Financial Report (ACF-196T).

OMB No.: 0970-0345.

Description: Tribes use Form ACF-196T to report expenditures for the Tribal TANF grant. Authority to collect and report this information is found in the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA), Public Law 104-193. Tribal entities with approved Tribal plans for implementation of the TANF program are required by Section 412(h) of the Social Security Act to report financial data. Form ACF-196T provides for the collection of data regarding Federal expenditures. Failure to collect this data would seriously compromise the Administration for Children and Families' (ACF) ability to monitor expenditures. This information is also used to estimate outlays and may be used to prepare ACF budget submissions to Congress. Financial management of the program would be seriously compromised if the expenditure data were not collected. 45 CFR part 286 subpart E requires the strictest controls on funding

requirements, which necessitates review of documentation in support of Tribal expenditures for reimbursement. Comments received from previous efforts to implement a similar Tribal TANF report Form ACF-196T were used to guide ACF in the development of the product presented with this submittal.

The American Recovery and Reinvestment Act (ARRA) of 2009, Public Law 111-5 has authorized emergency TANF funds to be awarded to States, Tribes, and Territories who meet certain eligibility requirements written in the legislation. TANF Policy Announcement TANF-ACF-PA-2009-01 provides additional guidance on eligibility requirements. Recipients of ARRA funds are to report spending and performance data to Federal agencies quarterly for posting on the public Web site, "Recovery.gov". Federal agencies are required to collect ARRA expenditures data and the data must be clearly distinguishable from the regular TANF (non-ARRA) funds. Therefore, in order to meet this data collection requirement, the ACF-196T has been modified with the addition two line items and a column to report ARRA expenditures. The collection and posting of this data is to allow the public to see where their tax dollars are spent.

Respondents: All Tribal TANF Agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF-196T	72	4	1.5	432

Estimated Total Annual Burden Hours: 432.

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, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: infocollection@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, Fax: 202-395-7285, Email: OIRA_SUBMISSION@OMB.EOP.GOV, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2013-03253 Filed 2-12-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2011-D-0893]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry and Food and Drug Administration Staff; Center for Devices and Radiological Health Appeals Processes

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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: Fax written comments on the collection of information by March 15, 2013.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-NEW and Guidance for Industry and Food and Drug Administration Staff; Center for Devices and Radiological Health Appeals Processes. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Daniel Gittleston, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, Daniel.Gittleston@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.

Guidance for Industry and Food and Drug Administration Staff; Center for Devices and Radiological Health Appeals Processes—(OMB Control Number 0910-NEW)

The guidance for industry and FDA staff entitled “Center for Devices and Radiological Health (CDRH) Appeals Processes” revises, updates, and combines two previous guidance documents: “Medical Device Appeals and Complaints: Guidance for Dispute Resolution,” dated February 1998, and “Resolving Scientific Disputes Concerning the Regulation of Medical Devices, A Guide to Use of the Medical Devices Dispute Resolution Panel; Final Guidance for Industry and FDA,” dated July 2001.

The document is intended to provide clarity to internal and external audiences regarding CDRH’s appeal processes. Individuals outside of FDA who disagree with a decision or action taken by CDRH and wish to have it reviewed or reconsidered have several processes for resolution from which to choose, including requests for supervisory review of an action, petitions, and hearings. In most cases, it is up to the party seeking resolution of an adverse action or resolution of a difference of opinion to determine the appropriate process for a given circumstance or issue. The guidance describes these mechanisms and includes the following topics: (1) Appealable actions (i.e., warning letters, post-approval study requirements, premarket decisions, deficiency letters, or requests for additional information); (2) paths and options available at different stages of appeals; (3) use of expedited or “paper” appeals versus appeal meetings or teleconferences; (4) recommended format for appeals; (5) appeal authorities; (6) appeal conflicts; and (7) issues that are appropriate for dispute resolution.

This guidance is intended to describe the processes available to outside stakeholders to request additional review of decisions and actions by CDRH employees. There are several processes for resolution, including a request for supervisory review of an action, petitions, and hearings. The proposed information collection seeks approval for the reporting burden associated with requests for additional review of decisions and actions by CDRH employees under this guidance. The guidance also refers to currently approved information collections found in FDA regulations.

The collections of information in 21 CFR 10.30, 10.33, and 10.35 have been approved under OMB control number 0910-0183; the collections of information in 21 CFR part 12 have been approved under OMB control number 0910-0184; the collections of information for 21 CFR part 807 subpart E have been approved under OMB control number 0910-0120; the collections of information under 21 CFR part 812 have been approved under OMB control number 0910-0078; the collections of information under 21 CFR