

performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

(Authority: 42 U.S.C. 5101 *et seq.*)

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; Data Collection for the Next Generation of Enhanced Employment Strategies Project (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) within the Administration for Children and Families (ACF) is proposing data collection activities conducted for the Next Generation of Enhanced Employment Strategies (NextGen) Project. The objective of this project is to identify and rigorously evaluate innovative interventions designed to promote employment and economic security among low-income individuals with complex challenges to employment. The project will include

an experimental impact study, descriptive study, and cost study.

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 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: To further build the evidence around effective strategies for helping low-income individuals find and sustain employment, OPRE is conducting the NextGen Project. This project will identify and test up to 10 innovative, promising employment interventions designed to help individuals facing complex challenges secure a pathway toward economic independence. These challenges may be physical and mental health conditions, a criminal history, or limited work skills and experience.

The project is actively coordinating with the Building Evidence on Employment Strategies for Low-Income Families Project (0970-0537), another OPRE project focused on strengthening ACF's understanding of effective interventions aimed at supporting low-income individuals to find jobs, advance in the labor market, and improve their economic security. Additionally, the project is working closely with the Social Security Administration (SSA) to incorporate a focus on employment-related early interventions for individuals with current or foreseeable disabilities who have limited work history and are

potential applicants for Supplemental Security Income (SSI).

The NextGen Project will use a two-phased approach for approval of this proposed information collection activity. In Phase 1 (current request) the research team seeks approval to formally recruit programs, to administer the informed consent form and baseline participant survey, and to collect identifying and contact information for study participants. The project intends for these data collections to be uniform across programs selected for evaluation and it does not anticipate that they will require revisions.

Under Phase 2 of the request, the project will update the information collection request for the remaining instruments to tailor to each program selected for the evaluation, as needed.

The proposed information collection activities cover an experimental impact study, descriptive study, and cost study. Data collection activities for the impact study include: (1) Baseline survey and identifying and contact information data collection, (2) a first follow-up survey, and (3) a second follow-up survey. Data collection activities for the descriptive study include: (1) Program service receipt tracking; (2) staff characteristics survey; (3) program leadership survey; (4) semi-structured program discussion guide (conducted with program leaders, supervisors, partners, staff, and providers); (5) semi-structured employer discussion guide (for those interventions that include an employer component); and (6) in-depth participant interviews. Data collection activities for the cost study include an Excel-based cost workbook.

Respondents: Program staff, program partners, employer staff, and individuals enrolled in the NextGen Project. Program staff and partners may include case managers, health professionals, workshop instructors, job developers, supervisors, managers, and administrators. Employers may include administrators, human resources staff, and worksite supervisors.

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
PHASE 1					
Baseline survey & identifying and contact information—participants	10,000	3,333	1	0.42	1,400
Baseline survey & identifying and contact information—staff	200	67	50	0.42	1,407
Estimated Total Annual Burden Hours, Phase 1:					2,807

ANNUAL BURDEN ESTIMATES—Continued

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
PHASE 2 ESTIMATES					
First follow-up survey—participants	8,000	2,667	1	0.83	2,214
Second follow-up survey—participants	8,000	2,667	1	0.83	2,214
Service receipt tracking—program staff	200	67	250	0.08	1,340
Staff characteristics survey—program staff	200	67	1	0.42	28
Program leadership survey—program leaders	50	17	1	0.25	4
Semi-structured program discussion guide—program lead-ers	40	13	1	1.5	20
Semi-structured program discussion guide—program su-pervisors and partners	80	27	1	1.0	27
Semi-structured program discussion guide—program staff, providers	80	27	1	0.75	20
Semi-structured employer discussion guide—employers	50	17	1	1.0	17
In-depth participant interview guide—participants	200	67	1	2.0	134
Cost workbook—program staff	40	13	1	32.0	416
Estimated Total Annual Burden Hours, Phase 2:					6,434

Authority: Section 413 of the Social Security Act, as amended by the FY 2017 Consolidated Appropriations Act, 2017 (Public Law 115–31).

Mary B. Jones,
ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2019-N-3077; FDA-2013-N-0403; FDA-2013-N-0579; FDA-2016-N-2474; FDA-2013-N-0717; FDA-2018-N-3728; FDA-2013-N-0797; FDA-2013-N-0578; FDA-2013-N-0879; FDA-2012-N-0197; FDA-2016-N-3586; FDA-2016-N-4319; and FDA-2013-N-0764]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at <http://www.reginfo.gov/public/do/PRAMain>. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB Control No.	Date approval expires
Obtaining Information to Understand Challenges and Opportunities Encountered by Compounding Outsourcing Facilities	0910-0883	1/31/2021
Protection of Human Subjects; Informed Consent; and Institutional Boards	0910-0130	1/31/2023
Biological Products: Reporting and Biological Product Deviations and Human Cells, Tissues, and Cellular and Tissue-Based Deviations in Manufacturing	0910-0458	1/31/2023
Reporting Associated with Designated New Animal Drugs for Minor Use and Minor Species	0910-0605	1/31/2023
Evaluation of the Food and Drug Administration’s General Market Youth Tobacco Prevention Campaign	0910-0753	1/31/2023
Collection of Conflict of Interest Information for Participation in Food and Drug Administration Non-Employee Fellowship and Traineeship Programs	0910-0882	1/31/2023
Human Tissue Intended for Transplantation	0910-0302	2/28/2023
General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension, Postmarketing Studies Status Reports, and Form FDA 356h	0910-0338	2/28/2023
Procedures for the Safe Processing and Importing of Fish and Fishery Products	0910-0354	2/28/2023
Medical Devices; Shortages Data Collection System	0910-0491	2/28/2023
Focus Groups About Drug Products as Used by the Food and Drug Administration	0910-0677	2/28/2023