

## ANNUAL BURDEN ESTIMATES

Instrument	Respondent	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
1—Screening questions for parenting intervention.	Applicant .....	4,000	1,333	1	0.083	111
	Staff .....	36	12	111	0.083	111
2—Screening questions for employment intervention.	Applicant .....	900	300	1	0.250	75
	Staff .....	12	4	75	0.250	75
3—Consent Materials for Parents of Fathers under 18.	Parent of Applicant.	500	167	1	0.167	28
	Staff .....	36	12	14	0.167	28
4—B3-specific eligibility data .....	Applicant .....	6,400	2,133	1	0.017	36
	Staff .....	72	24	89	0.017	36
5—B3-specific enrollment data .....	Applicant .....	2,700	900	1	0.153	138
	Staff .....	72	24	38	0.151	138
6—B3 tracking of attendance in services for program group members.	Staff .....	72	24	363	0.008	70
7—Additional nFORM burden for non-Grantee site.	Applicant .....	450	150	1	0.250	38
	Staff .....	12	4	1,969	0.0343	270
8 & 9—Baseline surveys .....	Applicant .....	2,842	947	1	0.800	758
10 & 11—6 month follow-up surveys.	Applicant .....	2,430	810	1	0.667	540
12 & 13—Staff and management semi-structured interviews.	Staff .....	240	80	2	1.5	240
14 & 15—Staff surveys .....	Staff .....	240	80	1	0.667	53
16—Participant focus groups .....	Applicant .....	160	53	1	2.0	106
17—Mother Focus Groups .....	Co-parent of Applicant.	80	27	1	1.0	27
18 & 19—Mobile device surveys .....	Applicant .....	1,350	450	5	0.117	263
20—Post-session debrief for sites testing parenting intervention.	Staff .....	36	12	104	0.083	104

Estimated Total Annual Burden Hours: 3,245.

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](mailto: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](mailto:OIRA_SUBMISSION@OMB.EOP.GOV), Attn:

Desk Officer for the Administration for Children and Families.

**Robert Sargis,**

*ACF Reports Clearance Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Proposed Information Collection Activity; Comment Request

**Title:** Personal Responsibility Education Program (PREP) Performance Measures and Adult Preparation Subjects (PMAPS) Studies—Data Collection Related to the Performance Measures Study.

**OMB No.:** New Collection.

**Description:** The Office of Data Analysis, Research, and Evaluation (HHS/ACF/ACYF/ODARE) and the Family and Youth Services Bureau (HHS/ACF/ACYF/FYSB) in the Administration for Children and Families (ACF) propose a data collection activity as part of the

Personal Responsibility Education Program (PREP) Performance Measures and Adult Preparation Subjects (PMAPS) Studies. The goals of the PMAPS studies are to collect, analyze, and report on performance measure data for PREP programs and to develop and test Adult Preparation Subjects (APS) conceptual models.

The PMAPS studies consist of two components: The “Performance Measures Study,” and the “Adult Preparation Subjects Study.” This notice is specific to data collection activities for the Performance Measures Study only. The Performance Measures Study component includes collection and analysis of performance measure data from State PREP (SPREP), Tribal PREP (TPREP), Competitive PREP (CPREP), and Personal Responsibility Education Innovative Strategies (PREIS) grantees. Data will be used to determine if PREP and PREIS grantees are meeting performance benchmarks related to the program’s mission and priorities.

**Respondents:** Performance measurement data collection instruments will be administered to individuals representing SPREP, TPREP, CPREP, and PREIS grantees, their subawardees, and program participants.

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Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Participant Entry Survey .....	504,279	168,093	1	.25	42,023
Participant Exit Survey .....	551,847	183,949	1	.50	91,975
Performance reporting system data form—grantees .....	951	317	2	30	19,020
Performance reporting system data form—subawardees ...	5,883	1,961	2	14	54,908

*Estimated Total Annual Burden Hours:* 207,926

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded 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. Email address: [OPREinfocollection@acf.hhs.gov](mailto:OPREinfocollection@acf.hhs.gov). All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper 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.

**Robert Sargis**

*Reports Clearance Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0306]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Administrative Detention and Banned Medical Devices

**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 May 11, 2016.

**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](mailto:oira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0114. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@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.

#### Administrative Detention and Banned Medical Devices—21 CFR 800.55(g)(1) and (g)(2), 800.55(k), 895.21(d), and 895.22; OMB Control Number 0910-0114—Extension

FDA has the statutory authority under section 304(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 334(g)) to detain during established inspections devices that are believed to be adulterated or misbranded. Section 800.55 (21 CFR 800.55), on administrative detention, includes among other things, certain reporting requirements and recordkeeping requirements. Under § 800.55(g), an applicant of a detention order must show documentation of ownership if devices are detained at a place other than that of the appellant. Under § 800.55(k), the owner or other responsible person must supply records about how the devices may have become adulterated or misbranded, in addition to records of distribution of the detained devices. These recordkeeping requirements for administrative detentions permit FDA to trace devices for which the detention period expired before a seizure is accomplished or injunctive relief is obtained.

FDA also has the statutory authority under section 516 of the FD&C Act (21 U.S.C. 360f) to ban devices that present substantial deception or an unreasonable and substantial risk of illness or injury. Section 895.21 (21 CFR 895.21), on banned devices, contains certain reporting requirements. Section 895.21(d) describes the procedures for banning a device when the Commissioner of Food and Drugs (the Commissioner) decides to initiate such a proceeding. Under 21 CFR 895.22, a manufacturer, distributor, or importer of a device may be required to submit to FDA all relevant and available data and information to enable the Commissioner to determine whether the device presents substantial deception, unreasonable and substantial risk of illness or injury, or unreasonable, direct, and substantial danger to the health of individuals.

During the past several years, there has been an average of less than one new administrative detention action per