

**DATES:** Comments on the collection(s) of information must be received by the OMB desk officer by February 15, 2018.

**ADDRESSES:** When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-5806 *OR*, Email: [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov).

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).
3. Call the Reports Clearance Office at (410) 786-1326.

**FOR FURTHER INFORMATION CONTACT:** William Parham at (410) 786-4669.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Medicare Authorization to Disclose Personal Health Information; *Use:* Unless permitted or required by law, the

Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (§ 164.508) prohibits Medicare (a HIPAA covered entity) from disclosing an individual's protected health information without a valid authorization. In order to be valid, an authorization must include specified core elements and statements. Medicare will make available to Medicare beneficiaries a standard, valid authorization to enable beneficiaries to request the disclosure of their protected health information. This standard authorization will simplify the process of requesting information disclosure for beneficiaries and minimize the response time for Medicare. Form CMS-10106, the Medicare Authorization to Disclose Personal Health Information, will be used by Medicare beneficiaries to authorize Medicare to disclose their protected health information to a third party. *Form Number:* CMS-10106 (OMB control number: 0938-0930); *Frequency:* Occasionally; *Affected Public:* Individuals or Households; *Number of Respondents:* 2,200,000; *Total Annual Responses:* 2,200,000; *Total Annual Hours:* 550,000. (For policy questions regarding this collection contact Sam Jenkins at 410-786-3261.)

Dated: January 9, 2018.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2018-00486 Filed 1-12-18; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

[OMB NO.: 0970-0440]

#### Proposed Information Collection Activity; Comment Request; Job Search Assistance (JSA) Strategies Evaluation—Extension

*Description:* The Administration for Children and Families (ACF), is proposing the extension without changes to an existing data collection activity as part of the Job Search Assistance (JSA) Strategies Evaluation. The JSA evaluation will aim to determine which JSA strategies are most effective in moving TANF applicants and recipients into work and will produce impact and implementation findings. To date, the study has randomly assigned individuals to

contrasting JSA approaches. The study will next compare participant employment and earnings to determine the relative effectiveness of these strategies. The project will also report on the implementation of these strategies, including measures of services participants receive under each approach, as well as provide operational lessons gathered directly from practitioners.

Data collection efforts previously approved for JSA, include: Data collection activities to document program implementation, a staff survey, a baseline information form for program participants, and a follow-up survey for JSA participants approximately 6 months after program enrollment. Approval for these activities expires on February 28, 2018.

This **Federal Register** Notice provides the opportunity to comment on the extension of the 6-month follow-up survey to allow follow-up data to be collected for all study participants. Although the enrollment period was originally estimated to span 12 months, it took 18 months to complete enrollment, leaving insufficient time to complete the 6-month follow-up survey. A four-month extension is requested in order to allow individuals randomly assigned between June and August 2017 to complete the follow-up survey in the same timeframe as earlier enrollees. The purpose of the survey is to follow-up with study participants and document their job search assistance services and experiences including their receipt of job search assistance services, their knowledge and skills for conducting a job search, the nature of their job search process, including tools and services used to locate employment, and their search outputs and outcomes, such as the number of applications submitted, interviews attended, offers received and jobs obtained. In addition, the survey will provide an opportunity for respondents to provide contact data for possible longer-term follow-up. There are no changes to the currently approved instruments.

*Respondents:* JSA study participants.

#### Annual Burden Estimates

This extension is specific to the 6-month survey and covers the remaining 766 participants that may be completing the six-month follow up survey during the four-month extension period. All other information collection under 0970-0440 will be complete by the original OMB expiration date of February 28, 2018.

Instrument	Total/annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
<b>Extension of Previously Approved Information Collection</b>				
6-Month Follow-Up Survey .....	766	1	.333	255

*Estimated Total Annual Burden Hours: 255.*

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.

**Mary Jones,**

*ACF/OPRE Certifying Officer.*

[FR Doc. 2018-00612 Filed 1-12-18; 8:45 am]

**BILLING CODE 4184-09-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2017-N-5569]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices; Device Tracking

**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 February 15, 2018.

**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 0910-0442. Also include the FDA docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@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.

#### Medical Devices; Device Tracking—21 CFR Part 821

*OMB Control Number 0910-0442—Extension*

Section 211 of the Food and Drug Administration Modernization Act of

1997 (FDAMA) (Pub. L. 105-115) became effective on February 19, 1998. FDAMA amended the previous medical device tracking provisions under section 519(e)(1) and (2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360i(e)(1) and (2)) that were added by the Safe Medical Devices Act of 1990 (SMDA) (Pub. L. 101-629). Unlike the tracking provisions under SMDA, which required tracking of any medical device meeting certain criteria, FDAMA allows FDA discretion in applying tracking provisions to medical devices meeting certain criteria and provides that tracking requirements for medical devices can be imposed only after FDA issues an order. In the **Federal Register** of February 8, 2002 (67 FR 5943), FDA issued a final rule that conformed existing tracking regulations to changes in tracking provisions effected by FDAMA under part 821 (21 CFR part 821).

Section 519(e)(1) of the FD&C Act, as amended by FDAMA, provides that FDA may require by order that a manufacturer adopt a method for tracking a class II or III medical device, if the device meets one of the three following criteria: (1) The failure of the device would be reasonably likely to have serious adverse health consequences, (2) the device is intended to be implanted in the human body for more than 1 year (referred to as a “tracked implant”), or (3) the device is life-sustaining or life-supporting (referred to as a “tracked l/s-l/s device”) and is used outside a device user facility.

Tracked device information is collected to facilitate identifying the current location of medical devices and patients possessing those devices, to the extent that patients permit the collection of identifying information. Manufacturers and FDA (where necessary) use the data to: (1) Expedite the recall of distributed medical devices that are dangerous or defective and (2) facilitate the timely notification of patients or licensed practitioners of the risks associated with the medical device.

In addition, the regulations include provisions for: (1) Exemptions and variances; (2) system and content requirements for tracking; (3)