

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' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.
3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786-1326.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (*see ADDRESSES*).

CMS-10400 Establishment of Qualified Health Plans and American Health Benefit Exchanges Under the 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 requires federal agencies to publish a 60-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.

Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Establishment of Qualified Health Plans and American Health Benefit Exchanges; *Use:* The Patient Protection and Affordable Care Act, Public Law 111-148, enacted on March 23, 2010, and the Health Care

and Education Reconciliation Act, Public Law 111-152, enacted on March 30, 2010 (collectively, "Affordable Care Act"), expand access to health insurance for individuals and employees of small businesses through the establishment of new Affordable Insurance Exchanges (Exchanges), including the Small Business Health Options Program (SHOP).

As directed by the rule *Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers* (77 FR 18310) (Exchange rule), each Exchange will assume responsibilities related to the certification and offering of Qualified Health Plans (QHPs). To offer insurance through an Exchange, a health insurance issuer must have its health plans certified as QHPs by the Exchange. A QHP must meet certain minimum certification standards, such as network adequacy, inclusion of Essential Community Providers (ECPs), and non-discrimination. The Exchange is responsible for ensuring that QHPs meet these minimum certification standards as described in the Exchange rule under 45 CFR 155 and 156, based on the Affordable Care Act, as well as other standards determined by the Exchange. The reporting requirements and data collection in the Exchange rule address Federal requirements that various entities must meet with respect to the establishment and operation of an Exchange; minimum requirements that health insurance issuers must meet with respect to participation in a State based or Federally-facilitated Exchange; and requirements that employers must meet with respect to participation in the SHOP and compliance with other provisions of the Affordable Care Act. *Form Number:* CMS-10400 (OMB Control Number: 0938-1156); *Frequency:* Monthly, Annually; *Affected Public:* Private Sector; *Number of Respondents:* 11,004; *Number of Responses:* 11,485; *Total Annual Hours:* 55,774.5. (For policy questions regarding this collection contact Leigha Basini at 301-492-4380).

Dated: November 17, 2015.

William N. Parham, III,

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

[FR Doc. 2015-29725 Filed 11-20-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Job Search Assistance (JSA) Strategies Evaluation.

OMB No.: 0970-0440.

Description: The Administration for Children and Families (ACF) is proposing a data collection activity as part of the Job Search Assistance (JSA) Strategies Evaluation. The JSA evaluation aims to determine which JSA strategies are most effective in moving TANF applicants and recipients into work. The impact study will randomly assign individuals to contrasting JSA approaches and then compare their employment and earnings to determine their relative effectiveness. The implementation study will describe services participants receive under each approach as well as provide operational lessons gathered directly from practitioners.

Two data collection efforts have been previously approved for JSA, including one for data collection activities to document program implementation, to administer a staff survey and to collect baseline information of program participants. These collection activities will continue under this new request.

This **Federal Register** Notice provides the opportunity to comment on a proposed new information collection activity for JSA: A follow-up survey for JSA participants approximately 6 months after program enrollment.

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.

Respondents: JSA study participants and program staff.

EXISTING 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
Baseline Information Form	8,000	4,000	1	0.2	800
Implementation Study Site Visits	150	75	1	1	75
JSA Staff Survey	440	220	1	0.33	73

Total Previously Approved Annual Burden: 948.

PROPOSED NEW 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
6 Month Follow-Up Survey	6,400	3,200	1	0.333	1,066
Participant Contact Update Form	1,200	600	1	0.083	50
Tracking Surveys	2,800	1,400	5	0.167	1,169

Estimated Total NEW Annual Burden Hours: 2285.

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: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: 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,
Attn: Desk Officer for the
Administration for Children and
Families.

Robert Sargis,

ACF Reports Clearance Officer.

[FR Doc. 2015-29749 Filed 11-20-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-4012]

Sunscreen Innovation Act; Withdrawal of a 586A Request or Pending Request; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Sunscreen Innovation Act: Withdrawal of a 586A Request or Pending Request." This draft guidance provides recommendations for the process for withdrawing a 586A request submitted under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Sunscreen Innovation Act (SIA), and withdrawing a pending request, as defined by the SIA. The recommendations in this guidance apply to 586A requests and pending requests that seek a determination from FDA of whether a nonprescription sunscreen active ingredient, or a combination of nonprescription sunscreen active ingredients, is generally recognized as safe and effective (GRASE) for use under specified conditions and should be included in the over-the-counter (OTC) sunscreen drug monograph. We are issuing this draft guidance under the SIA, which directs FDA to issue guidance on various topics, including guidance on the process by which a

request under section 586A or a pending request is withdrawn.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by January 22, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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