

an expedited review, CMS or its agents will communicate a decision for the prior authorization request to the submitter within 48-hours of the complete submission.

The following explains the various prior authorization scenarios:

- *Scenario 1:* A submitter sends a prior authorization request to the DME MAC with appropriate documentation, and all relevant Medicare coverage and documentation requirements are met for the PMD. The DME MAC then sends an affirmative prior authorization decision to the physician or treating practitioner, supplier, and Medicare beneficiary. The supplier submits the claim to the DME MAC, and the claim is linked to the prior authorization via the claims processing system. Provided all requirements in the applicable NCD/LCD are met, the claim is paid.

- *Scenario 2:* A submitter sends a prior authorization request, but all relevant Medicare coverage and documentation requirements are not met for the PMD. The DME MAC sends a non-affirmative prior authorization decision to the physician or treating practitioner, supplier, and Medicare beneficiary advising them that Medicare will not pay for the item. If the supplier delivers the PMD and submits a claim with a non-affirmative prior authorization decision, the DME MAC would deny the claim. The supplier or the Medicare beneficiary would then have the Medicare denial for secondary insurance purposes and would have full appeal rights. Existing liability provisions with respect to delivery of a valid ABN apply.

- *Scenario 3:* A submitter sends a prior authorization request where documentation is incomplete. The DME MAC sends back the prior authorization request to the submitter with an explanation about what information is missing and notifies the physician or treating practitioner, supplier, and Medicare beneficiary. The submitter may resubmit the prior authorization request.

- *Scenario 4:* An applicable PMD claim is submitted without a prior authorization decision or the DME supplier fails to submit a prior authorization request, but nonetheless delivers the item to the Medicare beneficiary and submits the claim to the DME MAC for payment. The claim will be stopped and documentation will be requested to conduct medical review. The PMD claim is reviewed under normal medical review processing timeframes, and if approved, a 25-percent payment reduction would apply.

++ If the claim is determined to be not medically necessary, or insufficiently documented, the claim will be denied. The supplier or Medicare beneficiary can appeal the claim denial. If the claim, after review, is deemed not payable, then all current Medicare beneficiary/supplier liability policies and procedures and appeal rights remain in effect.

++ If the claim is determined to be payable, it will be paid. However, a 25-percent reduction in the Medicare payment will be applied for failure to receive a prior authorization decision before the submission of a claim. This payment reduction will not be applied to competitive bidding program contract suppliers submitting claims for Medicare beneficiaries who maintain a permanent residence in a competitive bidding area according to the Common Working File (CWF). These contract suppliers will continue to receive the applicable single payment amount as determined in their contract. The 25-percent payment reduction is non-transferrable to the Medicare beneficiary for claims that are deemed payable and is not subject to appeal. In the case of capped rental items, the payment reduction will be applied to all claims in the series. After a claim is submitted and processed, appeal rights are available if necessary.

If the prior authorization request is not affirmed, and the claim is submitted by the supplier, the claim will be denied. Medicare beneficiaries may use existing appeal rights to contest claim denials. Suppliers must issue an ABN to the beneficiary, per CMS policy, prior to delivery of the item in order for the beneficiary to be held financially liable when a Medicare payment denial is expected for a PMD.

Additional information is available on the CMS Web site (<http://go.cms.gov/PADemo>).

III. Collection of Information Requirements

This notice announces the extension of the Medicare PMDs Demonstration and does not impose any new information collection burden under the Paperwork Reduction Act of 1995. However, there is an information collection burden associated with the demonstration that is currently approved under OMB control number 0938-1169 which expires January 31, 2018.

IV. Regulatory Impact Statement

This document announces an extension of the Medicare PMDs Demonstration. Therefore, there are no

regulatory impact implications associated with this notice.

Dated: July 1, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; 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.

Data collection efforts previously approved for JSA, include: Data collection activities to document program implementation, a staff survey and a baseline information form for program participants. These collection activities will continue with 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.

Annual Burden Estimates

EXTENSION OF PREVIOUSLY APPROVED INFORMATION COLLECTIONS

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	6,400	3,200	1	.2	640
Implementation Study Site Visits	600	300	1	1	300
JSA Staff Survey	440	220	1	.33	73

PROPOSED NEW INFORMATION COLLECTIONS

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	.333	1,066
Contact Update Form	6,400	3,200	11	.033	1,162

Estimated Total Annual Burden Hours: 3,241.

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, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. Email address: 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.

Karl Koerper,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

Preparation for International Cooperation on Cosmetics Regulation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA or we) is announcing a public meeting entitled "International Cooperation on Cosmetics Regulation (ICCR)—Preparation for ICCR-9 Meeting." The purpose of the meeting is to invite public input on various topics pertaining to the regulation of cosmetics. We may use this input to help us prepare for the ICCR-9 meeting that will be held November 4-6, 2015, in Brussels, Belgium.

Date and Time: The public meeting will be held on September 10, 2015, from 2 p.m. to 4 p.m.

Location: This meeting will be held at the Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., Wiley Auditorium (first floor), College Park, MD 20740.

Contact Person: Maria Rossana (Rosemary) Cook, Office of Cosmetics and Colors, Food and Drug Administration, 4300 River Rd., College Park, MD 20740, email: maria.cook@fda.hhs.gov, or FAX: 301-436-2975.

Registration and Requests for Oral Presentations: Send registration information (including your name, title, firm name, address, telephone number, fax number, and email address), written material, and requests to make an oral

presentation, to the contact person by August 27, 2015.

If you need special accommodations due to a disability, please contact Maria Rossana (Rosemary) Cook by September 3, 2015.

SUPPLEMENTARY INFORMATION: You may present proposals for future ICCR agenda items, data, information, or views, orally or in writing, on issues pending at the public meeting. Time allotted for oral presentations may be limited to 10 minutes or less for each presenter. If you wish to make an oral presentation, you should notify the contact person by August 27, 2015, and submit a brief statement of the general nature of the evidence or arguments that you wish to present, your name, address, telephone number, fax number, and email address, and indicate the approximate amount of time you need to make your presentation.

Transcripts: As soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may also be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20850. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information, (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

The Purpose of the Multilateral Framework on the ICCR: The purpose of the multilateral framework on the ICCR is to pave the way for the removal of regulatory obstacles to international trade while maintaining global consumer protection.