

initial states in the demonstration, after the first 3 months of the expanded demonstration, we will assess a payment reduction in the new states for claims that, after review, are deemed payable, but did not first receive a prior authorization decision. As evidence of compliance, the supplier must submit the prior authorization number on the claim in order to not be subject to the 25-percent payment reduction. The 25-percent payment reduction is non-transferrable to the Medicare beneficiary and not subject to appeal. In the case of capped rental items, the payment reduction will be applied to all claims in the series.

The 25-percent reduction in the Medicare payment is for each payable base claim not preceded by a prior authorization request except in competitive bidding areas. If a competitive bid contract supplier submits a payable claim for a Medicare beneficiary with a permanent residence in a competitive bidding area that is included in the supplier's contract, without first receiving a prior authorization decision, that competitive bid contract supplier would receive the applicable single payment amount under the competitive bid program, and would not be subject to the 25 percent reduction. These suppliers must still adhere to all other requirements of the demonstration.

- **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:** 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 PMD claim is reviewed under normal medical review processing timeframes and if approved the 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, the

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 (CBA) 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. This payment reduction amount will begin 3 months after the start of the expanded demonstration 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

In the February 7, 2012 **Federal Register** (77 FR 6124) and the May 29, 2012 **Federal Register** (77 FR 31616), we published a 60-day and a 30-day notice, respectively, announcing and soliciting comments concerning the information collection requirements associated with the Medicare Prior Authorization for PMDs Demonstration implemented on September 1, 2012. The information collection request for the demonstration was approved under OMB control number 0938-1169. Subsequent to the initial approval, we published an additional **Federal Register** notice (79 FR 18913) announcing that we were seeking emergency review and approval from OMB regarding the expansion of the demonstration; specifically, we revised the information collection request to account for the addition of 12 new states to the program. The emergency revised information collection request was approved on June 13, 2014, and is still approved under OMB control number 0938-1169 with

an expiration date of December 31, 2014.

Dated: June 27, 2014.

Marilyn Tavenner,

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

Proposed Projects: Evaluation of the Transitional Living Program (TLP)

Title: Evaluation of the Transitional Living Program (TLP)

OMB No.: 0970-0383

Description: The Runaway and Homeless Youth Act (RHYA), as amended by Public Law 106-71 (42 U.S.C. 5701 et seq.), provides for the Transitional Living Program (TLP), a residential program lasting up to 18 months designed to prepare older homeless youth ages 16-21 for a healthy and self-sufficient adulthood. Section 119 of RHYA requires a study on the long-term housing outcomes of youth after exiting the program.

The proposed collection is being carried out in two steps:

1. Interviews with TLP grantee administrators and front line staff about program structure, implementation, and approaches to service delivery.

2. A set of surveys to be administered to run away and homeless youth to measure their short-term and longer-term outcomes such as demographic characteristics, receipt of TLP or "TLP-like" services, housing, employment, education, social connections (e.g., social relationships, civic engagement), psychosocial well-being (e.g., depressive symptoms, traumatic stress, risky behavior, history of abuse), and other measures related to self-sufficiency and well-being (exposure to violence, financial competence).

This information will be used to better understand the most effective practices that improve the long-term outcomes for runaway and homeless youth and reduce future episodes of homelessness.

Respondents: (1) Youth ages 16-21 participating in Transitional Living Programs and (2) the Executive Director and front line staff representing TLP grantees.

ANNUAL BURDEN ESTIMATES

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|--|-----------------------|------------------------------------|-----------------------------------|--------------------|
| Site Visit Interviews: | | | | |
| Program Overview Survey: Executive Director Interview Guide (1 Executive Director respondent per grantee) | 14 | 1 | 1.00 | 14.00 |
| Program Overview Survey: Program Staff Interview Guide (4 Program Staff respondents per grantee) | 56 | 1 | 2.00 | 112.00 |
| Youth Development Survey Interview Guide (1 Executive Director and 1 Program Staff respondent per grantee) | 28 | 1 | 0.50 | 14.00 |
| Young Adult Surveys: | | | | |
| Young Adult Baseline Survey | 1250 | 1 | 0.75 | 937.50 |
| Young Adult 3-Month Follow Up Survey | 1250 | 1 | 0.54 | 675.00 |
| Young Adult 6-Month Tracking Survey | 1250 | 1 | 0.17 | 212.50 |
| Young Adult 9-Month Tracking Survey | 1250 | 1 | 0.17 | 212.50 |
| Young Adult 12-Month Follow Up Survey | 1250 | 1 | 0.25 | 312.50 |
| Young Adult 15-Month Tracking Survey | 1250 | 1 | 0.17 | 212.50 |
| Young Adult 18-Month Follow Up Survey | 1250 | 1 | 0.75 | 937.50 |

Estimated Total Annual Burden Hours: 3640.

In compliance with the requirements of Section 506(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: ACF Reports Clearance Officer. Email address: infocollection@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-2014-N-0001]

Nonprescription Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Nonprescription Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 4, 2014, from 8 a.m. to 5 p.m. and September 5, 2014, from 8 a.m. to 12 noon.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Cindy Hong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-

796-9001, FAX: 301-847-8533, email: NDAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss the scope of safety testing that should be required for sunscreen active ingredients to be marketed in U.S. over-the-counter (OTC) sunscreen products. This discussion will take into consideration that sunscreens are typically used chronically in individuals over the age of 6 months to help prevent skin cancer and skin aging. The need for various types of safety data, including clinical data and nonclinical data, will be discussed.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the