B. Statistical Methods (used for collection of information employing statistical methods)

1. Respondent Universe and Sampling Methods

The sampling frame includes all TLPs funded in FY2013, and 14 TLPs will be selected to participate in the study. The selection process is purposive. A pool of 28 candidate TLPs were initially identified from among FYSB's TLP grantees for recruitment into the study based on two primary criteria:

1. Contrast, which measures the level of expected service contrast between the TLP and its corresponding Continuum of Care (CoC),
2. Expected entries, which estimates the TLP service volume over an 18-month period

In addition, Maternity Group Homes are excluded from consideration because these programs serve a special subpopulation and offer a unique set of services to address their needs. New TLPs with little prior program experience will also be excluded.

The contractor was provided a complete list of TLP grantees currently funded, as well as information about their service volume. The contrast metric represents the proportion of a CoC's projected, 18-month service volume in any type of transitional housing program that is provided by a TLP. The metric is used to identify TLPs that will provide the greatest level of contrast to other services available in the community. The expected entries metric is an estimate of the TLP service volume and is a gauge of the grantee's size. To identify an initial set of 14 grantees, TLPs were sorted by contrast, and the top quartile (31 TLPs) was given priority status as "high contrast TLPs". The high contrast TLPs were then rank-ordered according to their projected service volume to identify TLPs with a high service volume. Also, FY2013 TLP grantees within a 1-hour drive (or in the same CoC) of one of the high-contrast and high-service-volume TLPs will also be considered to minimize the potential for cross-over (i.e., control group members who receive the TLP services).

The contractor is currently in the process of screening the 28 candidate TLPs to identify those to include in the evaluation. This involves evaluating grantees based on three primary criteria:

1. Size of the agency,
2. Oversubscription (i.e., excess demand for services or the size of the waiting list or turn away rate), and
3. Control environment (i.e., likelihood of crossover).

Achieving the requisite sample size for both treatment and control groups requires that the study target relatively large TLPs with adequate excess demand for services. Size is important because large TLPs evince high youth entry/exit rates and thus contribute significantly to the ability to recruit enough youth in the study to produce reliable outcome estimates. We estimate needing a sample of at least 1,250 to adequately power the impact analysis, which means that on average TLPs participating in the study would need to enroll 89 youth in the study. Most TLPs serve a relatively small number of youth. In FY2010, the average number of youth served in a TLP was 35, ranging from 10 to 187 youth during the year.

Related to the size of the agency is the program's level of subscription—i.e., whether the agency has a waiting list from which youth can be enrolled into the

study when a bed becomes available. The level of subscription is critical, because those that have the capacity to serve more youth than enroll in the program (i.e., under-subscribed programs) risk serving fewer youth than would have been the case without the random assignment study, because a portion of their applicants will be assigned to the control group. By contrast, those programs that are over-subscribed (that have more applicants than they can serve at any given time) are better candidates for this study, because the high demand-to-service-slot ratio facilitates random assignment. For example, assume that an agency with no waiting list has an available bed. An eligible youth approaches the agency, agrees to participate in the study, and is subsequently assigned randomly to the control group. The available bed will remain vacant until another eligible youth approaches the agency for services and is potentially assigned randomly to the treatment group. An empty bed is not ideal from a service provider perspective and could lead to frustration on the part of TLP staff. When an agency has a waiting list, the assignment of an applicant to the control group provides another eligible youth in the queue with the opportunity for enrollment into the study, possibly as a treatment group member. The likelihood that a service slot will remain empty diminishes as the size of the waiting list increases. For these reasons, over-subscription is an important inclusion criterion.

Finally, the control environment is important because impacts reflect the differences between the treatment and control conditions. Thus, the availability of other TLPs in the broader community must be considered. The aim of the selection process is to achieve a “high contrast” between the treatment and control conditions, meaning that the TLP services offered to the treatment group are distinct from those otherwise available to them in the community. A high treatment-control contrast implies a low likelihood of “cross-over,” which occurs when control group members enroll in a TLP or receive a combination of services similar to what they would have received had they been assigned to the treatment group. For these reason, the selection process will prioritize TLPs in environments that lack other TLPs or TLP-like programs. When multiple TLPs exist within a city or metropolitan area, we would opt to include all of them in the study so as to reduce the likelihood that control group members would enroll in an alternate TLP. Ideally, control environments would also be similar across sites, as this will assist in interpreting the results, but this is a lesser consideration than the strength of the treatment-control contrast

Across the 14 ultimately grantees included in the study, the intent is to randomly assign a total sample of 1,250 youth. Thus, the average agency will enroll 89 youth in the study over an estimated 18-month period, assigning 59 of them to the TLP treatment and the remaining 30 assigned to the control group. This sample will allow us to detect impacts of TLP on binary outcomes (e.g., stable housing) of between 5 and 10 percentage points. In Exhibit B.1.1, we present calculated Minimum Detectable Effects (MDEs) for this design. The exhibit shows MDEs of 0.20 standard deviations for continuous outcomes (e.g., delinquency score at18 months) and 5 - 10 percentage points for binary outcomes. These estimates assume that two-thirds of 1,250 enrolled youth are randomly assigned to the treatment group and one-third is assigned to a control group. The estimated MDEs also assume a response rate of 70 percent for the follow-up survey and a regression R-square of 0.04. This low R-square was selected to provide a conservative MDE estimate. Impact estimates with a higher R-square value

would yield smaller MDEs. It is based on effects observed on homelessness in a study of housing vouchers on welfare families. For analyses involving the entire study sample,

Exhibit B.1.1

Number of Youth Enrolled in Study:	N = 1250
Continuous Outcomes [a]	0.20 (standard deviations)
Binary Outcomes [2]	
Control Mean of 10% (or 90%)	6 percentage points
Control Mean of 30% (or 70%)	9 percentage points
Control Mean of 50%	10 percentage points

2. Procedures for the Collection of Information

The evaluation will collect information on youth baseline characteristics and behaviors from approximately 1250 youth across 14 grantees. The research approach uses a series of web-based surveys to collect data from youth. A secure, encrypted, passcode protected website will serve as the portal for data collection and will allow research staff to monitor survey completion rates. The website will permit youth survey respondents to log-in using a unique username and password and complete their respective surveys online.

The baseline survey will be taken at TLP facilities. Prior to the baseline survey, trained TLP staff will obtain youth consent and administer the baseline survey, which involves seating each sample member at a computer (in the designated private space) and assisting them in registering and logging into the web portal in order to complete the survey. English and Spanish versions of the survey will be available, so the respondent can choose their preferred language. The respondent is then left to complete the survey in private. Once the sample member has completed the survey, the last screen will inform youth that they have completed the survey and ask them to confirm the method though which they would like to receive their incentive (an electronic gift card or gift card code, sent by email or text or mail if neither of those options is possible). The youth will leave the computer, real-time verification of completion will be recorded in the survey database, and the youth will receive their incentive.

For the follow-up surveys administration will be individual. The contracted research team will invite all youth enrolled in the study will be invited to complete the 3, 12, and 18 month follow up surveys as well as the 6, 9, and 15 month tracking surveys using agree-upon communication strategy (email, texting, etc.) as well as assistance from program staff, when possible, to remind them about the follow-up survey and provide instructions on how to access the Web survey and a PIN/password to enable access. Repeated reminders will be sent by electronic media until the survey has been accessed and completed.

The evaluation will also collect information from grantees during site visits. The procedures for this data collection involve in-person interviews with management-level and frontline staff at each grantee. Interviews will be conducted by trained members of the research team, using the Program Overview Survey – Executive Director Interview Guide, the Program Overview Survey – Program Staff Interview Guide, and the Youth Development Survey Interview Guide. A total of five staff members per grantee will be interviewed: One management level and four frontline staff.

3. Methods to Maximize Response Rates and Deal with Non Responses

Collecting data from homeless youth will be the greatest challenge of this study because many are expected to be transitory and lack fixed addresses. To obtain adequate response rates, we will implement a robust data monitoring and tracking process. (For information about projected response rate and statistical power, see "Sample Size and Statistical Power" below.) The study team will employ several outreach tactics to obtain the highest response rates possible from study participants for each of the surveys. The primary mode of outreach will be email or cell phone text message. (Note that upon enrollment into the study, youth will have an opportunity to refuse text messaging from the study team if this approach forces youth to incur additional costs. Some cell phone data plans have unlimited text messaging, while others have an additional charge.)

- **Survey Invitations and Reminders: Abt SRBI (via their call center) will send email or text message invitations for the 3-, 12-, and 18-month surveys. The invitations will include a link to the study's web portal where youth will login using their unique username and password (set up during enrollment). Up to two email/text reminders will be sent to non-responders before moving them to phone contact. Those who do not complete one of those surveys within 48 hours of the email/text invitation will receive up to five telephone calls. The telephone calls will prompt youth to go to the study web portal and complete the survey. Staff will use secondary and tertiary contact information obtained on the baseline and tracking surveys to contact individuals who may know of the youth's whereabouts or have updated contact information for them. If the second telephone reminder does not result in a completed interview, Abt SRBI will attempt to complete the survey by phone with each youth.**

- **Tracking Surveys: Abt SRBI (via their call center) will send email and cell-phone text messages to youth in-between the survey deployments (i.e., at months 6 and 9) to invite youth to confirm or update their contact information. The invitations will include a link to the study's web portal where youth will login using their unique username and password (set up during enrollment). Up to 2 reminder emails and 2 text reminders will be sent to non-responders over the course of 4 weeks after the initial invitation is sent. Note that invitations to complete the 6 and 9 month tracking surveys will not be followed by phone calls to encourage completion or obtain data.**

- **Private Messages via Social Media: Abt or Abt SRBI may send private messages that only the youth can see through social networking sites such as Twitter and Facebook (if the youth opt to provide these points of contact). Private messages are not posted publically on the external-facing portion of these websites. Such messages would be sent out at the 6- and 9 - month tracking milestones to update youth's contact information with a link to the study's web portal and a reminder of the incentive payment. Youth can update contact information by logging into the web-based survey portal using their username and password. Similar messages would also be sent to youth at the 3-, 12-, and 18-month survey milestones with a link to the study's web portal and a reminder of the incentive payment. Because Facebook routinely changes its privacy policies and the software that enforces them, we plan to have a research team member regularly monitor Facebook's and Twitter's privacy and security policies and upgrades to protect against the unintended exposure of participant information to others. This is a requirement of the study's Institutional Review Board.**

- **Monitoring: Monitor data collection and produce bi-weekly reports on the status (e.g., response rates) of each participating TLP agency.**

- **Incentives: Distribute youth incentives as surveys are completed.**

Recent research suggests that homeless and runaway youth are connected to the Internet[1] —that is, youth access the internet frequently and use social networking sites. Thus, social networking presents new opportunities to maintain contact with study participants and remind them to complete the study surveys. Social networking opportunities are a low-cost approach to tracking youth. Under this approach, we will create a Twitter and Facebook profile using nondescript/neutral profile names for the study and then "follow" (on Twitter) or "friend" (on Facebook) study participants. We will activate privacy and confidentiality settings within these social networking sites to ensure that study participants cannot see the profiles of other study participants, thereby protecting the confidentiality of each participant. We will also be required to develop additional protocols that govern how researchers use Twitter and Facebook, how to limit exposure to other information posted on each participant's social webpages (e.g., Facebook's "wall"), and how and when communications with youth are permissible. We have had preliminary discussions with members of Abt's IRB to gauge the viability of this approach, and the response has been encouraging. We will work closely with the IRB to develop these social media protocols and plan to submit them in a modification to the IRB package at a later date.

4. Test of Procedures or Methods to be Undertaken

Early versions of the youth surveys was subjected to a pretest involving fewer than 10 individuals. This pretested occurred during visits to three agencies, during which time youth in three TLPs, the same group to be measured, were asked to take and review the surveys. Since that time, the surveys have been significantly modified to include additional outcome measures and a revised design strategy that includes random assignment and measurement of service dosage. The modified surveys were pretested with three junior members of the contractor staff for the purposes of timing survey administration under differing response scenarios. The surveys rely heavily on questions that have been validated and used in many other national studies, especially the questions associated with the study's key outcome domains—e.g., homelessness, psychosocial wellbeing, and employment and education. As such, the study team and HHS are confident that the survey questions are worded properly and thus there are no plans to cognitively test the surveys with a sample of youth. However, HHS and the study team will monitor survey completion rates throughout the study to assess whether study participants are completing the survey. If survey completion rates are low, the study team will engage grantees to understand if study participants are having difficulties with the survey questions.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

[1] Recent research by David E. Pollio and colleagues suggests a high use of the internet and social networking sites. For example, 93 percent of youth in Denver and Los Angeles use the internet weekly, 46 percent use it daily, and the average number of days per week on social networking websites is 3.8. See Pollio, D.E., Batey, D.S., Bender, K., Ferguson, K., Thompson, S.J. (2013). Technology use among emerging adult homeless in two U.S. cities. Social Work, 58(2), 173-175.

Administration of the data collection will be overseen by Abt Associates (statistical and research contractor) and its subcontractor, Abt SRBI. The same contractor will analyze data with support from evaluation colleagues at Wayne State University. Members of this research team include:

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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.

[FR Doc. 2014–17805 Filed 7–28–14; 8:45 am]

BILLING CODE 4120–01–P

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.

[FR Doc. 2014–17725 Filed 7–28–14; 8:45 am]

BILLING CODE 4184–01–P

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