

OMB control number 0910-0078. In accordance with the PRA, prior to publication of any final guidance document, FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this draft guidance that are new or that would represent material modifications to these previously approved collections of information found in FDA regulations.

**III. Comments**

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

**IV. Electronic Access**

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ProposedRegulationsandDraftGuidances/default.htm> or <http://www.regulations.gov>.

Dated: June 6, 2012.  
**Leslie Kux,**  
*Assistant Commissioner for Policy.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Substance Abuse and Mental Health Services Administration**

**Agency Information Collection Activities: Submission for OMB Review; Comment Request**

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

**Project: 2013 National Survey on Drug Use and Health—(OMB No. 0930-0110)—Revision**

The National Survey on Drug Use and Health (NSDUH) is a survey of the civilian, non-institutionalized population of the United States 12 years old and older. The data are used to determine the prevalence of use of tobacco products, alcohol, illicit substances, and illicit use of prescription drugs. The results are used by SAMHSA, ONDCP, Federal

government agencies, and other organizations and researchers to establish policy, direct program activities, and better allocate resources.

Data from clinical interviews completed in 2008 were combined with the main interview short scale data to develop a predictive model that was applied to the full main sample to estimate SMI. Follow-up clinical interviews continued to be conducted with NSDUH respondents from 2009 to 2012. Data from these interviews were analyzed annually to update the calibration of the screening measure. To maximize trend validity, this model has been applied to 2009-2011 data. With the completion of 1500 clinical interviews in 2012, SAMHSA will have accumulated a large enough sample (4,500) to update and improve the models. Therefore, the MHSS clinical interviewing will be discontinued in 2013.

For the 2013 NSDUH, a few questionnaire changes are proposed. The instrument has been updated to include new questions on military service, medical marijuana, physician substance use screening, and respondent characteristics.

As with all NSDUH/NHSDA surveys conducted since 1999, the sample size of the survey for 2013 will be sufficient to permit prevalence estimates for each of the fifty states and the District of Columbia. The total annual burden estimate is shown below:

**ESTIMATED BURDEN FOR 2013 NSDUH**

Instrument	Number of respondents	Responses per respondent	Hours per response	Total burden hours	Hourly wage rate	Annualized costs
Household Screening .....	145,474	1	0.083	12,074	\$14.45	\$174,469
Interview .....	67,500	1	1.000	67,500	14.45	975,375
Screening Verification .....	5,400	1	0.067	362	14.45	5,231
Interview Verification .....	10,125	1	0.067	678	14.45	9,797
<b>Total .....</b>	<b>145,474</b>	<b>.....</b>	<b>.....</b>	<b>80,614</b>	<b>.....</b>	<b>1,164,872</b>

Written comments and recommendations concerning the proposed information collection should be sent by July 12, 2012 to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via email to: [OIRA\\_Submission@omb.eop.gov](mailto:OIRA_Submission@omb.eop.gov). Although commenters are encouraged to

send their comments via email, commenters may also fax their comments to: 202-395-7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, DC 20503.

**Summer King,**  
*Statistician.*  
 [FR Doc. 2012-14197 Filed 6-11-12; 8:45 am]  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Substance Abuse and Mental Health Services Administration**

**Agency Information Collection Activities: Proposed Collection; Comment Request**

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health

Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Comments are invited on: (a) Whether the proposed collections of information are 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) ways to enhance 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.

**Proposed Project: Projects for Assistance in Transition From Homelessness (PATH) Program Annual Report (OMB No. 0930-0205)—Revision**

The Center for Mental Health Services awards grants each fiscal year to each of the States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands from allotments authorized under the PATH program established by Public Law 101-645, 42 U.S.C. 290cc-21 et seq., the Stewart B. McKinney Homeless Assistance Amendments Act of 1990 (section 521 et seq. of the Public Health Service (PHS) Act). Section 522 of the PHS Act requires that the grantee States and Territories must expend their payments

under the Act solely for making grants to political subdivisions of the State, and to non-profit private entities (including community-based veterans' organizations and other community organizations) for the purpose of providing services specified in the Act. Available funding is allotted in accordance with the formula provision of section 524 of the PHS Act.

This submission is for a revision of the current approval of the annual grantee reporting requirements. Section 528 of the PHS Act specifies that not later than January 31 of each fiscal year, a funded entity will prepare and submit a report in such form and containing such information as is determined necessary for securing a record and description of the purposes for which amounts received under section 521 were expended during the preceding fiscal year and of the recipients of such amounts and determining whether such amounts were expended in accordance with statutory provisions.

The proposed changes to the PATH Annual Report Survey are as follows:

**1. Format**

To create a PATH report that is easier to read, the formatting has been modified to be more table driven. In addition, the language has been made more concise. Although the online form and report is close in flow to the previous report, it is necessary to thoroughly read all reporting instructions to insure proper data entry.

**2. Estimated Counts**

The new PATH report does not include entry of estimated counts. Only actual counts should be entered.

**3. Homelessness Management Information System (HMIS) Data Integration**

The Data section of the report is expected to be propagated from the local HMIS when providers use HMIS. This includes client counts, services, referrals, and demographics. This data will be automatically aggregated from client-level data.

**4. Demographic Responses**

In order to facilitate integration of PATH data into HMIS, all data responses have been modified to fully align with valid HMIS responses. For example, the "Hispanic" response has been separated from "Race" and placed in "Ethnicity."

**5. Additional Data Items**

The PATH report now tracks demographic data for persons contacted, as well as those enrolled. For services and referrals, in addition to gathering the number of enrolled persons receiving the service or referral, there is a total count of the number of times that particular service was provided or referral made.

**6. Voluntary Outcome Measures**

The data previously entered as voluntary outcome measures has now been moved to the referral section of the report and are no longer considered "voluntary."

The estimated annual burden for these reporting requirements is summarized in the table below.

Respondents	Number of respondents	Responses/respondent	Burden per response (hrs.)	Total burden
States .....	56	1	19	1,064
Local provider agencies .....	503	1	34	17,102
Total .....	559	.....	.....	18,166

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 8-1099, One Choke Cherry Road, Rockville, MD 20857 or email a copy to [summer.king@samhsa.hhs.gov](mailto:summer.king@samhsa.hhs.gov). Written comments must be received before 60 days after the date of the publication in the **Federal Register**.

**Summer King,**  
*Statistician.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Substance Abuse and Mental Health Services Administration**

**Agency Information Collection Activities: Submission for OMB Review; Comment Request**

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Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

**Project: Minority AIDS Initiative (MAI) Rapid HIV Testing Clinical Information Form (OMB No. 0930-0295)—Revision**

This request is for a three-year generic clearance to continue rapid HIV testing data collection among 63 TCE-HIV Grantees and their clients and the additional 11 MAI-HIV Grantees and their clients. The primary purpose of the