ESTIMATED ANNUALIZED BURDEN HOURS

Instrument/Activity	Number of respondents	Number of responses per respondent	Average burden per response	Total burden hours per collection
Client Surveys: Children 0–7.				
Screening and Diagnosis Tool	1400	1	0.17	238
Positive Monitor Tracking	450	1	0.03	14
Services Child is Receiving at the time of the FASD Diagnosis	750	1	0.17	128
Services Planned and Provided based on Diagnostic Evaluation	750	1	0.33	248
Services Delivery Tracking Form	750	12	0.08	720
End of Intervention/Program Improvement Measure—Case Manager	750	1	0.02	15
End of Intervention/Program Improvement Measure—Parent/Guardian	750	1	0.02	15
End of Intervention/Program Customer Satisfaction with Service	750	1	0.03	23
Outcome Measures (Children 0–7 years)	750	3	0.08	180
Lost to follow-up	135	1	0.03	4
Client Surveys: Children 8–18:				
Screening and Diagnosis Tool	100	1	0.17	17
Services Child is Receiving at the time of the FASD Diagnosis	50	1	0.17	9
Services Planned and Provided based on Diagnostic Evaluation	50	1	0.33	17
Services Delivery Tracking Form	50	12	0.08	48
End of Intervention/Program Improvement Measure—Case Manager	50	1	0.02	1
End of Intervention/Program Improvement Measure—Parent/Guardian	50	1	0.02	1
End of Intervention/Program Customer Satisfaction with Service	50	1	0.03	2
Outcome Measures (Children 8–18 years)	50	3	0.08	12
Lost to follow-up	15	1	0.03	1
TOTAL	7,700	45	—	1,693

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 7–1044, One Choke Cherry Road, Rockville, MD 20857 *AND* e-mail her a copy at *summer.king@samhsa.hhs.gov*. Written comments should be received within 60 days of this notice.

Dated: November 4, 2009.

Elaine Parry,

Director, Office of Program Services.

[FR Doc. E9–27524 Filed 11–16–09; 8:45 am]

BILLING CODE 4162–20–P

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 (SAMHSA) 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: Substance Abuse Prevention and Treatment (SAPT) Block Grant Uniform Application Guidance and Instructions FY 2011–2013 and Regulations (OMB No. 0930–0080)—Revision

Sections 1921 through 1935 of the Public Health Service Act (U.S.C. 300x–21 to 300x–35) provide for annual allotments to assist States to plan, carry out and evaluate activities to prevent and treat substance abuse and for related activities. Under the provisions of the law, States may receive allotments only after an application is submitted and approved by the Secretary, DHHS. For the Federal fiscal years (FY) 2011–FY 2013 Substance Abuse Prevention and Treatment (SAPT) Block Grant application cycles, SAMHSA will provide States with revised application guidance and instructions to implement changes made in accordance with recommendations from the National Association of State Alcohol and Drug Abuse Directors (NASADAD) and their member States in the revisions and clarification of data reporting requirements and instructions.

During negotiations with the States resulting in agreement on the National Outcome Measures (NOMs) for substance abuse treatment and prevention, SAMHSA pledged to the States to:

1. Reduce respondent burden;
2. Work with the States to improve performance management of the SAPT Block Grant;
3. Improve the availability, timeliness, and quality of data available to Federal, State, and provider administrators of block grant funded programs.

This revision of the Uniform Application and Regulation for the SAPT Block Grant takes additional steps toward implementing these commitments. SAMHSA, in consultation with NASADAD, has provided States the ability to reduce their application burden by consolidating the FY 2011–FY 2013 State Plan into a 3-year plan. With the exception of the projected annual budget form, States only would be expected to submit any proposed revisions to its approved three-year plan but would otherwise not have to resubmit a State Plan during FY 2012 and FY 2013. Individual States may reduce their respondent burden further by selecting the option of using SAMHSA pre-populated tables for Section IVa and IVb. The data for these tables would be drawn from SAMHSA data sets known as Drug and Alcohol Services Information System (DASIS) Treatment Episode Data Set (TEDS) and

National Survey on Drug Use and Health (NSDUH) by SAMHSA and provided to the States. In addition, the Web-based Block Grant Application System now facilitates completion of the provider entity table through added pre-populated data items. The data for this table would be drawn from SAMHSA data set known as DASIS National Survey of Substance Abuse Treatment Services (N–SSATS). SAMHSA will continue to work with NASADAD and the States to assess the feasibility and usefulness of pre-populating additional sections of the application with data extracted from SAMHSA data sets to further reduce respondent burden.

SAMHSA continues to provide the States with the option of reporting on prevention expenditures utilizing the six primary prevention strategies or utilizing the Institute of Medicine classification of Universal, Selective or Indicated. SAMHSA has designed the State Prevention Framework State Incentive Grant (SPF SIG) competitive program and funded contracts in States without an SPF SIG to support data driven prevention planning by the Single State Agencies for Substance Abuse. States are expected to use the State level data collected with support from these programs in the planning in section II of the Uniform Application.

The Uniform Application has been modified to move needs assessment, planning narrative and future year budget forms into Section II, the FY 2011–FY 2013 Plan section.

In December 2004, SAMHSA and the States agreed on the goal of having all States reporting the NOMs measures as defined at the meeting by the end of a 3-year implementation period starting in FY 2005 and concluding at the end of FY 2007. By January 2006, supportive technical assistance on information technology design and payment for data submitted became available by the State Outcomes Measurement and Management System (SOMMS) program. States who have participated in the SOMMS/NOMs subcontracts may choose to have their data pre-populated which would significantly reduce their reporting burden for this application. During the subsequent three years, SAMHSA in partnership with the States and all other SAPT Block Grant stakeholders have continued to work towards improving standards for analyzing and responding to the results of NOMs data appropriate to each level of block grant funded administration including Federal, State, and Provider roles and responsibilities.

SAMHSA realigned resources to address the need for technical assistance in information technology (IT) and software purchasing to implement and maintain NOMs data standards. This technical assistance first became available in September 2006 and IT support continues.

Revisions to the previously-approved Uniform Application resulting from such stakeholder input reflect the following changes: (1) Section I, *Form 2,* ''Table of Contents,'' was revised to appropriately enumerate the specific items within each section; (2) In Section II, the former single year ''Intended Use Plan'' is aggregated into a *''Three Year State Plan''* to reduce the States' annual plan reporting burden. The first *''Three Year Plan''* will cover FYs 2011–2013. In the next two subsequent years, only revisions or updates to the 3-year plan will be required in the States' FY 2012 and FY 2013 Uniform Applications. Planned expenditures of each Federal Fiscal Year award will still be collected annually; (3) In Section II, the Form formerly specified as Form 12 has been removed; (4) In Section III, Narratives covering the Federal requirements, financial expenditure reports and services utilization reports are consolidated into the ''*Annual Report Section'';* (5) In Section IV subparts IVa and IVb, Treatment and Prevention Performance Reporting Forms are maintained and are to be completed annually.

The total annual reporting burden estimate is shown below:

FY 2011

	Number of respondents	Responses per respondent	Number of hours per response	Total hours
Sections I–III—States and Territories	60	1	*480	28,800
Section IV–A	60	1	40	2,400
Section IV–B	60	1	42.75	2,565
Recordkeeping	60	1	16	960
Total	60			34,725

* (additional 10 hours per completion of Section II per State due to addition of FYs 2012 and 2013 in *''Three Year Plan''*).

FY 2012 AND FY 2013

[Due to the reduction in section II]

	Number of respondents	Responses per respondent	Number hours per response	Total hours
Sections I–III—States and Territories	60	1	440	26,400
Section IVa	60	1	40	2,400
Section IVb	60	1	42.75	2,565
Recordkeeping	60	1	16	960
Total	60			32,325

* (reduction of approximately 40 hours per respondent due to reductions in response burden for Section II, *''Three Year Plan''*).

Average Annual Total Burden is projected to be 33,125 or a decrease of about 800 hours.

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 7–1044, One Choke Cherry Road, Rockville, MD 20857 *and* e-mail a copy to *summer.king@samhsa.hhs.gov.*

Written comments should be received within 60 days of this notice.

Dated: November 10, 2009.

Elaine Parry,

Director, Office of Program Services.

[FR Doc. E9–27523 Filed 11–16–09; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

National Mammography Quality Assurance 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: National Mammography Quality Assurance 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 January 25, 2010, from 9 a.m. to 5 p.m.

Location: Holiday Inn, Walker-Whetstone Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Normica Facey, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–5914, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512397. Please call the Information Line for up-to-date information on this meeting. 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 and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On January 25, 2010, the committee will discuss guidance documents issued since the last meeting. The committee will also receive updates on: Interventional mammography accreditation programs, recently approved alternative standards, facility inspection findings, the status of current inspection followup actions, and the radiological health program.

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 appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before January 4, 2010. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10:30 a.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before December 28, 2009. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by December 29, 2009.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, 301–796–5996, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 10, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–27492 Filed 11–16–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Oncologic 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: Oncologic 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 December 17, 2009, from 8 a.m. to 1 p.m.

Location: Hilton Washington DC North/Gaithersburg, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD. The hotel phone number is 301–977–8900.

Contact Person: Nicole Vesely, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301–827–6793, fax: 301–827–6776, e-mail: *nicole.vesely@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512542. Please call the Information Line for up-to-date information on this meeting. 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 and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On December 17, 2009, the committee will discuss new drug application (NDA) 022–555, proposed