

**Substance Abuse Prevention and Treatment Block Grant
Synar Report Format, FFY 2011-2013**

SUPPORTING STATEMENT

A. JUSTIFICATION

1. Circumstances of Information Collection

The Substance Abuse and Mental Health Services Administration (SAMHSA) is requesting OMB approval for a revision to the current Synar report format that implements requirements in the Final Rule (45 CFR Part 96) for the Substance Abuse Prevention and Treatment (SAPT) Block Grant, regarding the sale or distribution of tobacco products to individuals under age eighteen, as authorized by Section 1926 of the Public Health Service (PHS) Act [42 USC 300x-26]. This collection is approved under OMB No. 0930-0222, which expires on 10/31/2010. The SAPT Block Grant application (OMB No. 0930-0080) is due no later than October 1 of the fiscal year for which the Block Grant funding is being requested. The annual Synar report is due by regulation not later than December 31 of the same fiscal year. Because of the difference of due dates, OMB determined in July 2001 that the two reports should be approved under different control numbers.

States applying for SAPT Block Grant funding are required to submit an Annual Synar Report to the Secretary describing their progress in complying with section 1926 of the PHS Act (See 42 U.S.C. 300x-26 and 45 C.F.R. 96.130). Section 1926 of the Public Health Service Act stipulates that funding agreements for alcohol and drug abuse programs for fiscal year 1994 and subsequent fiscal years require States to have in effect a law providing that it is unlawful for any manufacturer, retailer, or distributor of tobacco products to sell or distribute any such product to any individual under the age of 18.

Section 1926 further requires that States conduct annually, random, unannounced inspections to ensure compliance with the law; that the State submit annually a report describing the results of the inspections, and the activities carried out by the State to enforce the required law, the success the State has achieved in reducing the availability of tobacco products to individuals under the age of 18, and the strategies to be utilized by the State for enforcing such law during the fiscal year for which the grant is sought. Before making an award to a State under the Block Grant, the Secretary must make a determination that the State has maintained compliance with the regulations. If a determination is made that the State is not in compliance, penalties shall be applied. The penalty for failure to comply with the Synar requirements is a reduction of 40 percent of the SAPT Block Grant award.

Respondents include the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, Palau, Micronesia, and the Marshall Islands.

The Annual Synar Report application includes the format and instructions to implement the tobacco reporting requirements. SAMHSA is requesting a 3-year approval revising the Annual Synar Report format for Federal Fiscal Years (FFY) 2011-2013.

The changes to the Annual Synar Report are described in item A.2 below. The report format is not changing significantly. Any changes in either formatting or content are being made to simplify the reporting process for the States and to clarify the information as the States report it; both outcomes will facilitate consistent, credible, and efficient monitoring of Synar compliance across the States. These changes will reduce reporting burden by the States. All of the information required in the new report format is already being collected and reported by the States. A copy of the proposed Annual Synar Report format and the instructions to States for completing the Annual Synar Report for FY 2011-2013 are in Attachments A and B.

2. Purpose and Use of Information

Section 1926(b) (2) (B) of the PHS Act requires the States to annually submit to the Secretary a report describing the strategies and activities carried out by the State to enforce youth access to tobacco laws during the fiscal year for which the State is seeking SAPT Block Grant funds, and the extent of success the State has achieved in reducing the availability of tobacco products to minors. In accordance with the tobacco regulations, the States are required to provide detailed information on progress made in enforcing youth tobacco access laws (Annual Synar Report, Section I FFY Compliance Progress) and future plans to ensure compliance with the Synar requirements to reduce youth tobacco access rates (Annual Synar Report, Section II, FFY Intended Use Plan). These data are required by 42 U.S.C. 300x-26 and will be used by the Secretary to evaluate State compliance with the statute. Part of the mission of the Center for Substance Abuse Prevention (CSAP) is to assist States by supporting Synar activities and providing technical assistance helpful in determining the type of enforcement measures and control strategies that are most effective. This information is helpful to CSAP in improving technical assistance resources and expertise on enforcement efforts and tobacco control program support activities, including State Synar Program support services through an enhanced technical assistance program involving conferences and workshops, development of training materials and guidance documents, and on-site technical assistance consultation. Under the provisions of the law, a State may receive its SAPT Block Grant allotment only after the State has been found in compliance with the Synar regulation requirements.

The revisions to the Annual Synar Report format do not change the scope of the Synar reporting requirement. Any changes in either formatting or content have been made to simplify the reporting process for the States and to clarify the information as the States report it; both outcomes will facilitate consistent, credible, and efficient monitoring of Synar compliance across the States and will reduce the reporting burden by the States. All of the information required in the new report format is already being collected and reported by the State.

Formatting changes

The report format has been minimally reformatted to increase the clarity of the State report and

to decrease the need for supplemental questions and reporting. To decrease the need for supplemental questions and reporting, additional instruction has been included in at least 4 portions of the report. As a result, the revised report format is designed to reduce the State's overall reporting burden.

Content changes

The content of the Synar Report has changed little. The content changes that have been made address the need to 1) clarify the intent of information requested via additional instructions or the addition of clarifying questions, 2) reduce the reporting burden to States created by State Project Officer questions to supplement the originally submitted Report. These additions and changes are essential to SAMHSA's ability to adequately assess State and Jurisdictional compliance with the Synar regulation.

In Section I (Compliance Progress), the following changes are being made with respect to the Annual Synar Report:

Question 4a: Responsible Agency – This question, which asks the State to describe the coordination and collaboration that occur between the agency responsible for tobacco prevention and the agency responsible for oversight of the Synar requirements has been edited to include a descriptive clause following the term “agency responsible for tobacco prevention.” The added clause describes this agency as “the agency that receives the Centers for Disease Control and Prevention’s National Tobacco Control Program funding.” This change has been made to reduce State confusion as to which State agency is being referred to in this question.

Question 5b: Evidence of Enforcement – The instructions for this table have been revised to indicate that if State law does not allow for an item, the State should mark “NA” (not applicable) and if the response for an item is unknown, the State should mark “UNK.” These response options are necessary to incorporate the reality of differing State youth tobacco access laws and reporting systems. For example, some States do not have tobacco retailer licensing, and other States (especially those where enforcement is conducted in a decentralized manner) do not have a centralized database that collects information on the adjudication (resulting fines) of citations. Additionally, the accompanying “Instructions for Completing the Annual Synar Report” has been updated for this question to clearly state that in order to comply with the Synar Legislation and its implementing regulation, the State must report citations issued for violations of youth tobacco access laws.

Question 5c: Level of Enforcement – This question, which asks the State to select whether enforcement is conducted only at those outlets randomly selected for the Synar survey, only at a subset of outlets not randomly selected for the Synar survey, or a combination of the two, has been newly added to the ASR format. It has been added to provide additional information about State enforcement programs, which is frequently requested by partner agencies and can also be used to target technical assistance.

Question 5d: Frequency of Enforcement – This question, which asks the State to select whether every tobacco outlet in the State did or did not receive at least one enforcement compliance

check in the last year, has been newly added to the ASR format. It has been added to provide additional information about State enforcement programs, which is frequently requested by partner agencies and can also be used to target technical assistance.

Question 5e: Additional Activities to Support Enforcement and Compliance: The second response option to this question has been modified to clarify its intent. Specifically, the response option “Incentives for merchants who are in compliance (e.g. reward and reminder)” has been changed to “Non-enforcement compliance checks in which compliant retailers are given positive reinforcement and non-compliant retailers are warned about youth access laws.” This change is necessary to prevent States from erroneously thinking we are referring to a specific commercially sold program marketed under the name “Reward and Reminder”.

Question 5f: Enforcement's Risk of Bias to Synar Survey – This question, which asks States who issues citations or warnings to retailers or clerks who sell tobacco to minors for inspections that are part of the Synar survey to describe how they minimize the risk of bias to the survey results, has been edited to include a descriptive clause following the phrase “minimizing the risk of bias to the survey results.” The added clause (“from retailers alerting each other to the presence of the survey teams”) describes the bias that is being referred to and has been added to reduce questions from States about the intent of this question.

Question 5g. Relationship of State Synar Program to FDA-Funded Enforcement Program – This question, which asks the State to describe the relationship between the State’s Synar program and the Food and Drug Administration (FDA)-funded enforcement program, has been added to the ASR format. The Family Smoking Prevention and Tobacco Control Act, recently signed into law by President Obama, requires the FDA to reissue the 1996 regulation aimed at reducing young people’s access to tobacco products and curbing the appeal of tobacco to the young. This regulation must be reissued by April 2010. As part of the implementation of this regulation, FDA will be contracting with States to enforce new Federal youth access provisions. This question asks the State to describe the relationship and coordination between its Synar program and the enforcement program funded by FDA.

Question 7b. Synar Survey Results for States that Do Not Use the Synar Survey Estimation System (SSES) – Two items have been added to this question (accuracy rate and completion rate). These items were added to ensure that the same statistical parameters are asked of both States that do and do not use the SSES to analyze their Synar survey results.

In Appendix B (Synar Survey Sampling Methodology), the following changes are being made with respect to the Annual Synar Report:

Question 10. Provide the following information about sample size calculation for the current FFY Synar survey. This question has been added to Appendix B and asks the State to provide information about the specific input values used to calculate the effective, target and original sample sizes for the current FFY Synar survey. This question will reduce the need for SAMHSA/CSAP to request additional clarifying information from the State when SAMHSA/CSAP is unable to match the sample sizes reported by the State.

In Appendix D (List Sampling Frame Coverage Study), the following changes are being made with respect to the Annual Synar Report:

Question 2. Percent Coverage Found. This question has been split into 4 sub-parts, asking the State to report the unweighted percent coverage found, the weighted percent coverage found, the number of outlets found through canvassing, and the number of outlets matched on the list frame. The question has been split into these sub-parts to avoid SAMHSA/CSAP having to request additional clarifying information from the State during the review process.

Question 3. Description of the Coverage Study Methods and Results. This question has been expanded from one question to ten questions, which ask the State to provide specific information about the coverage study methods and results. Specifically, instead of one general question asking the State to “provide a description of the coverage study methods and results,” the ten new questions query the State about specific aspects of the coverage study design, methodology and results. These specific questions will reduce the need for SAMHSA/CSAP to request additional clarifying information from the State during the review process.

There are no changes to Section II (Intended Use), or to Forms 1-5 or Appendix C.

3. Use of Information Technology

The information collected and maintained by States and U.S. Jurisdictions represents an amount of data necessary to evaluate State compliance with the Synar legislation and its implementing regulation. Since the FFY 2009 application year, States and Jurisdictions have been required to submit their Annual Synar Reports online using SAMHSA’s electronic Web SAPT Block Grant Application System (WebBGAS). States and Jurisdictions are also required to provide one hard copy of the ASR complete with the Governor's signature or his designee to SAMHSA's Office of Program Services, Division of Grants Management.

4. Efforts to Identify Duplication

There has been and continues to be extensive consultation with representatives of State Substance abuse agencies, and no duplication of information collection has been identified. The reporting requirements are narrative and statistical in nature and describe each State's progress in achieving the goals of previous fiscal year’s State plan and the proposed activities and services for the fiscal year for which the State is applying.

5. Involvement of Small Entities

The annual Synar report is prepared and submitted by State agencies and does not directly affect small entities.

6. Consequences If Information Collected Less Frequently

The Synar statute requires States to submit to the Secretary an annual report describing the strategies and activities carried out by the State to enforce youth access to tobacco laws during the fiscal year for which the State is seeking SAPT Block Grant funds. Less frequent reporting would be in violation of the statute and would also result in difficulty linking activities with fiscal year funding, Federal reporting requirements for annual and triennial reports to Congress, as well as intervening requirements for legislative testimony before Congress covering specific Synar-related issues, and so require the availability of up-to-date information.

7. Consistency with the Guideline in 5 CFR 1320.5(d) (2)

This information collection activity fully complies with 5 CFR 1320.5(d) (2).

8. Consultation Outside the Agency

No Agencies outside SAMHSA were consulted in the creation of these clarifying changes to the ASR Questionnaire for States; however, a notice soliciting public comment on this collection of information was published in the Federal Register, Vol. 74, No. 204, pages 54831-54832 on October 23, 2009, and three comments were received (Attachment C). One commenter indicated that the proposed changes to the ASR format would not create any compliance issues for the State. The second respondent's comments did not address the proposed changes to the ASR format, but instead requested that the ASR be disconnected from the annual SAPT Block Grant application. Such a change would require Legislative action and is outside the scope of the October 23, 2009 solicitation for comment. The final respondent suggested that additional questions be included in the ASR format to clarify State coverage study methodology and Synar sample size calculations. These questions have been added to Appendix B (Synar Survey Sampling Methodology) and Appendix D (List Sampling Frame Coverage Study).

9. Payment to Respondents

Respondents do not receive payment.

10. Assurance of Confidentiality

The State plan is made public within the State in such a manner as to facilitate comment from any person (including any Federal or other public agency) prior to its submission and that copies of the annual report be made available upon request to any interested person (including any public agency).

11. Questions of a Sensitive Nature

The Synar reporting requirements do not solicit information of a sensitive nature.

12. Estimates of Annualized Hour Burden

The burden estimated for reporting on Synar activities is based, in part, on discussions with select State Directors responsible for these activities and represents the total hours to assemble,

format, and produce the Synar report in accordance with the requirements of the statute (sec. 1932 of the PHS Act) and regulation (45 CFR Part 96). CSAP estimates the burden to States is approximately 1,062 hours. This estimate was derived based on discussions with CSAP staff experienced in estimating time burdens for similar data reporting activities and with State program coordinators responsible for preparing the annual Synar report. The estimate includes data collection and reporting, and preparation and completion of the narrative information, including data analysis and calculation of sample survey results. It is important to note that the time frame for completing the annual Synar report varies from State to State depending on the size of the State and its tobacco outlet population.

45 CFR citation	Numbers of respondents	Responses per Respondent ¹	Hours per response	Total burden	Cost per Hour	Total Cost
Annual report (Section I – States and Territories) 96.130(e) (1-3)	59	1	15	885	\$25	\$22,125
State Plan (Section II– States and Territories) 96.130(e) (4, 5); 196.130(g)	59	1	3	177	\$25	\$4,425
Total	59			1,062		\$26,550

¹ Red Lake Indian Tribe is not subject to tobacco requirements.

² The estimated hourly cost is based on a composite estimate of professional and support per hour cost. There is wide variation from State to State.

13. Estimates of Annualized Cost Burden to Respondents

There are no capital or start up costs associated with annual Synar report. Similarly, States incur only minimal uncompensated costs in order to complete the annual Synar inspections reported to the Secretary.

14. Estimates of Annualized Cost to the Government

The total average annual cost to the Federal Government of the annual review of State Synar reports is estimated to be \$200,000 for Sections I and II, plus the additional estimated cost of \$100,000 for technical assistance to the States. This includes staff costs associated with

reviewing State reports, e.g., distribution, review (for completeness and compliance), written correspondence, and other administrative activities.

15. Changes in Burden

There is no burden hour change.

16. Time Schedule, Publication, and Analysis Plans

Section 1926(b)(2)(B) of the PHS Act requires the States to submit to the Secretary annually a Synar report describing the strategies and activities carried out by the State to enforce its tobacco access laws during the fiscal year for which the State is seeking a SAPT Block Grant. Following is a typical schedule of activities following receipt of the annual Synar report:

<u>Activity</u>	<u>Timeframe</u>
Complete early alert (review for regulatory compliance)	Within 8 working days of receipt
Complete initial review and draft revision request	Within 30 working days of receipt
Process report approval for SAPT award	1 week after Project Officer approval

Data from the States' Synar report will be accessed by the Federal Government to meet the requirement to submit an annual report to the Secretary on the Synar Activities of the States and their progress in meeting overall compliance with the Synar requirements. Information will also be used for a wide variety of other oversight, administrative, and statistical purposes of the Federal Government, State governments, and Congress. Data will be tabulated and analyzed using standard descriptive and statistical analytic techniques and will be published through the reports noted above, as well as through the publication of special analytic studies.

17. Display of Expiration Date

The Synar report format will display the expiration date.

18. Exceptions to the Certification Statement

This collection of information involves no exceptions to the Certification for Paperwork Reduction Act submissions.

List of Attachments

<u>Attachment</u>	<u>Description</u>
A	Proposed FFY 2011-2013 Annual Synar Report Format (Clean Copy)
B	Instructions to States for Completing the Annual Synar Report (Clean Copy)
C	Public Comments