

**Substance Abuse Prevention and Treatment Block Grant
Synar Report Format, FFY 2008-2010
(OMB No. 0930-0222)**

SUPPORTING STATEMENT

A. JUSTIFICATION

1. Circumstances of Information Collection

This is a request for approval of revisions to the current Synar report format that implements requirements in the Final Rule (45 CFR Part 96) for the 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]. A copy of the Final Rule can be found in Attachment A. The Office of Management and Budget (OMB) approved the information collection language of the regulation under control number 0930-0163. The SAPT Block Grant application (OMB No. 0930-0080) is due not 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 (Attachment A) 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.

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.

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, under

which States are required to have in effect a State law that makes it 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; and, to enforce such laws in a manner that can reasonably be expected to reduce the extent to which tobacco products are available to individuals under age 18 (See 42 U.S.C. 300x-26 and 45 C.F.R. 96.130).

The Synar report describes 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 of whether 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 structure currently provides for a 40 percent penalty. 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 Synar report format for Federal Fiscal Years (FFY) 2008-2010.

The changes to the Annual 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 transmittal letter, Synar report format and accompanying materials for FY **2008-2010** is in Attachment **B**; Attachment **C** contains a markup showing changes from the 2007 Synar report submission.

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 allotment only after the State has been found in compliance with the Synar regulation requirements.

The revisions to the report format do not change the scope of the Synar reporting requirement. However, the report format has changed significantly for a variety of reasons explained below. 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. For example, the table in Question 5.b. of Section I of the report has been simplified and Form 5 of Appendix A has been modified to reflect the General Accounting Office (GAO) recommendation that States not use 14 year-old youth inspectors in the conduct of State Synar survey inspections. To decrease the need for supplemental questions and reporting, additional instruction has been included in at least 5 portions of the report. A copy of the GAO report can be found in Attachment D. 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) address a primary GAO recommendation to SAMHSA, and 3) 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 regulations, as well as to address the GAO recommendation to eliminate the use of 14 year-old youth inspectors from the conduct of Synar surveys.

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

Question 2: Public Comment - The phrase, "prior to submission of the ASR" has been added to this question given the requirement that Synar activities must be completed by September 30th and the ASR is not due for submission until December 31st. In addition to this and among the options a State may select to respond to this Synar requirement for making the Synar report public is the option that reads: "Posted on a State agency Web site". The parenthetical statement, "(please provide exact web address)", has been added given that many States select this option and either do not list the State's website, or the website that is provided does not route one to the page that specifically addresses the States' Synar data.

Questions 4 and 4a: Responsible Agency - The addition of the word, "prevention", and the

deletion of the word, "Control", corrects a long incorporated error in the phrasing of this question. The intent of the question is to identify the State Agency responsible for general tobacco prevention (the Agency responsible for tobacco control is already requested in Question 3), and then to clarify how the State Agency responsible for Synar (tobacco control) collaborates with the agency it identifies as having this responsibility for general tobacco prevention.

Question 5b: Evidence of Enforcement - This table is revised to remove the "Not Applicable" and "Not Available" Columns (and the respective Totals Column). These changes not only greatly simplify this table; they call on the State to provide enforcement data that is certainly available in all States. The data relating to License Suspensions, however, may not be available in a State without tobacco retailer licensing, in which case that State is now instructed to simply write in "N/A". In addition, enforcement data in the form of fines for tobacco sales violations represents a minimum penalty which can be "reasonably expected" to lower the State's retailer violation rate. Although historically accepted as a proxy for this requirement, a citation in and of itself and without data to clarify its adjudication and therefore impart an actual penalty to a violating retailer, does not technically represent "evidence" of enforcement that the Synar Amendment and its implementing Regulations require. Allowing States to report its fine data as "Not Applicable" or even "Not Available" is not consistent with the Synar Amendment, its implementing Regulations, or the Congress' intent for Synar. Therefore, SAMHSA has removed these columns as options.

Questions 5d & 5e: Enforcement's Risk of Bias to Synar Survey - These two questions are added to address the Synar requirement that States minimize bias to their Synar survey process and results. This is a special concern when a State combines its enforcement effort with its Synar survey process. It is incumbent on the State to minimize the risk that retailers notify other retailers that inspections are in progress, thereby allowing for an artificially low estimate of the true statewide tobacco retailer violation rate. These questions are frequently a part of State Project Officer questions that are supplemental to the State's original report. It is necessary to include them in the formal and original Annual Synar Report Questionnaire for States to address this bias requirement of Synar. As a result of incorporating these two additional questions into the original ASR, the need for follow-up questions to the State is reduced.

Question 9b: Number of Youth Inspectors - This piece of instruction is added to increase the integrity of data reported throughout the ASR. There have been frequent discrepancies between numbers reported in SSES and that reported in the body of the ASR Questionnaire (Question 9).

In Section II (Intended Use), the following changes are being made with respect to the Annual Synar Report:

Question 3: State Challenges to Complying with Synar Requirements - SAMHSA proposes that the following phrase is added, "and propose a plan for each, or indicate the State's need for TA related to each relevant challenge:" This addition incorporates SAMHSA's goal to facilitate its formal State Noncompliance Prevention Plan. The goal of this change and this plan is to prompt the State to begin noncompliance prevention activities early in the hope of avoiding the finding of a retailer violation rate that forces the Secretary of the Department to find the State

out of compliance and so subject the State to an extreme penalty: By regulation, 40% of its entire SAPT Block Grant, or, as has been provided every year since 2000, an Alternative Penalty could still cost millions of dollars from the State budget.

Appendix A / Form 5: Inspector Characteristics - 14 year-old youth inspectors are removed from this table to address this recommendation from the 2001 GAO Report on SAMHSA's National Synar Program. This change also addresses the subsequent and related revision to the new Synar Standard Terms and Conditions to begin with the FFY 2008 ASR.

Appendices B & C: Sampling Design & Inspection Protocol - In spite of instructions provided in various contexts, many States continue to modify these appendices without SAMHSA's advance approval. This short paragraph of instruction is designed to minimize the need for SPO questions to supplement the ASR.

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 regulations. For the FFY 2008 Annual Synar Report (ASR), SAMHSA plans to make the ASR Questionnaire for States and Jurisdictions available in the Agency's electronic SAPT Block Grant Application System (BGAS). States and Jurisdictions will still need to provide a 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. The Synar report format and software (Synar Survey Estimation System - SSES) are used to facilitate State and Jurisdictional reporting of statistical requirements related to the regulations. For States and Jurisdictions choosing not to use BGAS for submitting the ASR, a CD-ROM containing the report will continue to be accepted. The Synar report format and software provide the States and Jurisdictions with a standard format for reporting Synar data and many States and Jurisdictions have revised their data collection efforts to correspond to this format for reporting on the Synar requirements and to facilitate the ease of importing data from a previous year's Synar report and other Statespecific MIS data. CSAP anticipates that approximately forty States and Jurisdictions will submit their Synar reports electronically for the period 2008-2010.

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. 72, No. 85, pages 24591-92 on May 3, 2007, and no comments were received.

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>
Duplication and distribution	1 week
Review for completeness	2 weeks
Review for regulatory compliance	4 weeks
Process report approval for SAI'T award	1 week

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	Sec. 26 of the PHS Act (42 USC 300x-26] 45 C. R. Part 96.130: Tobacco Regulations re: SAPT Block Grants 45 C.F.R. 96.122(d): Specifies the due date for the Synar Report
B	Proposed FFY 2008-2010 Annual Synar Report Format (Clean Copy)
C	Proposed FFY 2008-2010 Annual Synar Report Format (Marked Copy)
D	GAO-02-74 Reducing Youth Access to Tobacco, November 2001
E	Instructions to States for Completing the Annual Synar Report Questionnaire (Marked Copy)
F	Sample Synar Alternative Penalty (Section 214 - 2004)