

**Substance Abuse Prevention and Treatment Block Grant
Synar Report Format, FFY 2014-2016**

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 Substance Abuse Prevention and Treatment Block Grant (SABG), 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 05/31/2013. The annual Synar report is due by regulation not later than December 31 of the fiscal year for which the state is requesting SABG funding.

States applying for SABG 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 annual, 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 SABG 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) 2014-2016.

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 (see Section 2); both outcomes will facilitate consistent, credible, and efficient monitoring of Synar compliance across the states. These changes do not affect the burden estimate (see Section 15).** 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 accompanying materials for FY **2014-2016** is in Attachment **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 SABG 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 SABG 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. All of the information required in the new report format is already being collected and reported by the state.

Clarification Changes

To decrease the need for supplemental questions and reporting, additional instruction has been included in 4 portions of the report.

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

Question 1c: Changes to State law – This question, which was formerly Question 1d, asks about changes to state youth access to tobacco laws and has been edited to include an option for changes to state law concerning vending machines. The former Question 1c, which contained detailed information about types of changes to vending machine laws has been eliminated due to the fact that the Family Smoking Prevention and Tobacco Control Act, which gives the Food and Drug Administration (FDA) the authority to regulate tobacco products, banned vending machines in youth accessible locations as of June 2010, making it unlikely that states that have not done so already will enact similar state laws. However, there are three U.S. jurisdictions not subject to federal law that may still enact vending machine restrictions and can report this information in the new Question 1c.

Questions 5a, 5b, and 5d: Enforcement Agencies, Evidence of Enforcement and Frequency of Enforcement – These questions have been clarified so it is clear that they refer to enforcement of state youth access laws, and not federal youth access laws.

In Section II (Intended Use), the following clarification change is being made:

Question 3 – State Challenges: This question includes two new response options (“Issues regarding the age balance of youth inspectors” and “Issues regarding the gender balance of youth inspectors”) since these are common challenge reported by states. While CSAP had originally recommended adding one new response option, the recommended response option was split into two based on feedback received during the sixty day comment period.

In Appendix B (Synar Survey Sampling Methodology), the following clarification is being made:

Question 4 – Vending machine inclusion in Synar Survey – This question, which asks if vending machines are included in the Synar survey and the reasons for their elimination if they are not included, includes a new response option (“State has a contract with the FDA and is actively enforcing the vending machine requirements of the Family Smoking Prevention and Tobacco Control Act”). This new option is included because federal law bans vending machines in youth accessible locations and states that are contracted with the FDA to enforce this provision are not required to include vending machines in their Synar surveys.

In Appendix C (Synar Survey Inspection Protocol), the following change is being made:

Question 1 – Synar Survey Protocol – This question, which asks about aspects of the state’s Synar survey protocol (including whether buys are consummated or unconsummated, whether youth inspectors carry identification, whether adult inspectors enter the outlet with the youth, and whether youth inspectors are compensated), has been edited to remove the option for “Not specified in protocol” since all states are required to submit Synar protocols that include these items. Additionally, a requirement for states to provide a narrative explanation has been included for those states who choose the response option “Permitted under specified circumstances.”

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 the addition of clarifying questions, 2) reduce the need for State Project Officers to ask additional 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:

Questions 4d-g – Coordination with Agency that Receives the FDA State Enforcement Contract – These close-ended questions ask the state to list the agency that is under contract to the FDA to enforce federal youth access laws, to describe the relationship between the state's Synar program and this agency, and to identify if the state uses data from the FDA enforcement inspections for the Synar survey. They have been added to replace the previously open-ended Question 5g, which required a narrative response. These close-ended questions will focus state responses.

In Appendix B (Synar Survey Sampling Methodology), the following changes are being made:

Questions 9a-b – Synar Survey Estimation System Sample Size (SSES) Calculator – These questions, which ask if the state used the SSES sample size calculator and if so, if they used the state or stratum level calculator, will eliminate the need for State Project Officers to ask these clarifying questions during the review process. This revision also eliminates the need for those states who use the SSES sample size calculator to manually list the sample size formulas.

Question 10b – Stratum Level Information – This question, which asks states who used the stratum level calculator to provide the stratum level information, eliminates the need for State Project Officers to ask this clarifying question during the review process.

In Appendix C (Synar Survey Inspection Protocol), the following change is being made:

Questions 4a-b – Type of Tobacco Products – These questions, which ask the state to define the type of tobacco products requested during Synar inspections and to describe the protocol for tobacco type selection, have been added to Appendix C. They have been added to provide additional information about state Synar protocols, which is frequently requested by partner agencies and can also be used to target technical assistance.

There are no changes to Forms 1-5 or Appendix D.

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 Block Grant Application System (WebBGAS). States and jurisdictions are also required to provide one hard copy of the ASR complete with the signature of the Governor or his or her designee to SAMHSA's Office of Financial Resources, 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 SABG 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

A Federal Register notice soliciting public comment on this collection of information was published on December 4, 2012 (Vol. 77, pages 71805-71807) and two comments were received (Attachment C). One respondent stated that they had reviewed the Federal Register notice and had nothing to add. The second respondent suggested that one of the response options to Question 3 of Section II be split into two. This change has been made.

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 copies of the annual report must 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	Total number of responses	Hours per response	Total burden	Cost per Hour	Total Cost
Annual report (Section I – States and Territories) 96.130(e) (1-3)	59	1	59	15	885	\$25	\$22,125
State Plan (Section II– States and Territories)	59	1	59	3	177	\$25	\$4,425

96.130(e) (4, 5); 196.130(g)							
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 the 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 \$220,000. This includes staff costs associated with reviewing state reports for completeness and compliance, written correspondence, and other administrative activities, as well as contract costs for statistical review of state survey results.

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 SABG. 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 SABG 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.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

This information collection does not involve statistical methods.

List of Attachments

<u>Attachment</u>	<u>Description</u>
A	FFY 2014-2016 Annual Synar Report Format
B	Instructions to States for Completing the Annual Synar Report Questionnaire
C	Public Comment