

**Substance Abuse Prevention and Treatment Block Grant
Synar Report Format, FFY 2017-2019**

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 05/31/2016. 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) 2017-2019.

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 3 portions of the report.

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

Question 1b: Changes to state law – This question asks about changes in state laws that impact the state’s protocol for conducting Synar inspections and has been edited to include an option for

changes to state law concerning changes in the definition of tobacco products. Many states are changing the definition of tobacco products in their state laws to include electronic nicotine delivery systems, which would impact the types of products that could be included in Synar surveys.

Question 1c: Changes to state law – This question asks about changes to state youth access to tobacco laws and has been edited to include an option for changes to state law concerning additional product categories to their youth tobacco access law. While some states have changed the definition in the state law to include electronic nicotine delivery systems, smokeless tobacco, and other tobacco products, other states have added these products as additional product categories in addition to tobacco products.

Question 2: Describe how the Annual Synar Report and the state plan were made public prior to submission of the ASR. This question asks states to describe how they make their ASR public prior to submission. States have been asked to provide a web address and the date the ASR was posted to that web address if they choose to post the ASR on an agency website. The ASR format has been clarified to provide a separate text box to enter both of these pieces of information.

Questions 4d-f – 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. This question has been edited to include skip logic and response options if a state does not have a current contract with the FDA.

Questions 5b, 5c, 5d, 5e, 5f: 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 or local youth access laws. In addition, these questions have been re-ordered (but the wording has not been changed) to improve logical flow of the questions. In addition, question 5e has been edited to include separate response options to allow states to describe each of the additional activities listed in the question stem to encourage states to describe each of those activities fully.

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

Question 3 – State Challenges: This question asks states to identify and describe their challenges in implementing the Synar program. This question has been edited to include separate response options to allow states to describe each of the challenges listed in the question stem to encourage states to describe each of the challenges fully and to make targeted technical assistance requests.

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

Title: The title of this Appendix has been edited to reflect that it is the summary of the state's inspection protocol and that the Appendix itself is not detailed enough to serve as the entirety of

the state's inspection protocol.

Questions 4– 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 edited to separate the options of including small cigars and cigarillos and to add the option of including electronic nicotine delivery systems or electronic cigarettes.

Questions 5a and b– The previous question 5 has been separated into two sections to provide ensure states are able to fully describe the methods used to recruit, select and train adult supervisors for the survey separately from the methods used to recruit, select, and train youth inspectors.

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:

Question 6: Changes to the sampling methodology – This question asks states if their sampling methodology has changed from the previous year. If there has been a change, a sub-question has been added to document how that change was communicated to SAMHSA. Since this change requires prior approval, a state who has not received prior approval will have the opportunity to discuss the process that was used to determine a change needed to be made.

Question 9: Changes to the inspection protocol – This question asks states if their inspection protocol has changed from the previous year. If there has been a change, a sub-question has been added to document how that change was communicated to SAMHSA. Since this change requires prior approval, a state who has not received prior approval will have the opportunity to discuss the process that was used to determine a change needed to be made. Existing questions 9a, 9b, and 9c have been renumbered to account for this new sub-question.

In Appendix B (Synar Survey Sampling Methodology), the following changes are 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. Because many states have a contract with the FDA and is actively enforcing the vending machine requirements of the Family Smoking Prevention and Tobacco Control Act, some states that include vending machines in their sampling protocols do not sample any because there are few eligible vending machines remaining on their list frame. A second part has been added to this question to determine how vending machines are sampled.

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 28, 2015 (Vol. 80, page 80782) and five comments were received.

- One respondent indicated that SAMHSA should correct the mailing address for hard copies, though it was determined that hard copy submissions are no longer required and this instruction has been deleted. In addition this respondent indicated that language be

added to Questions 6a, 8a and b, and 9. These changes were made.

- One respondent corrected time periods listed in questions 2, 5, and 6, and also provided changes to language in question 6a and 9a. These changes were made.
- One respondent indicated that it was unclear what was expected under subquestions 6 and 9. These will be clarified in the instructions. This respondent also commented on the amount of burden that was associated with completing the report and that burden could be reduced if the report format was easier to use. SAMHSA is taking this comment into account.
- Two respondents commented that they agreed with the proposed changes.

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)	59	1	59	15	885	\$25	\$22,125

96.130(e) (1-3)							
State Plan (Section II– States and Territories) 96.130(e) (4, 5); 196.130(g)	59	1	59	3	177	\$25	\$4,425
Total	59		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 2017-2019 Annual Synar Report Format
B	Instructions to States for Completing the Annual Synar Report Questionnaire
C	Public Comment