

III. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations, and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for a particular committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within the 60 days, the Commissioner of Food and Drugs will select the nonvoting member to represent industry interests.

IV. Application Procedure

Individuals may self nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Contact information, a current curriculum vitae, and the name of the committee of interest should be sent to the FDA contact person (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process).

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees, and therefore encourages nominations of appropriately qualified candidates from these groups. Specifically, in this document, nominations for nonvoting representatives of industry interests are encouraged from device manufacturing industry.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14 relating to advisory committees.

Dated: November 28, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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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 Block Grant Synar Report Format, FFY 2014-2016—(OMB No. 0930-0222)—Revision

Section 1926 of the Public Health Service Act [42 U.S.C. 300x-26] stipulates that funding Substance Abuse Prevention and Treatment Block Grant (SABG) 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. This section 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, 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 SABG, the Secretary must make a determination that the state has maintained compliance with these requirements. If a determination is made that the state is not in compliance, penalties shall be applied. Penalties ranged from 10 percent of the Block Grant in applicable year 1 (FFY 1997 SABG Applications) to 40 percent in applicable year 4 (FFY 2000 SABG Applications) and subsequent years. 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, the Republic of Palau, the Federated States of Micronesia, and the Republic of the Marshall Islands.

Regulations that implement this legislation are at 45 CFR 96.130, are approved by OMB under control number 0930-0163, and require that each state submit an annual Synar report to the Secretary describing their progress in complying with section 1926 of the PHS Act. The Synar report, due December 31 following the fiscal year for which the state is reporting, 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. SAMHSA's Center for Substance Abuse Prevention will request OMB approval of revisions to the current report format associated with Section 1926 (42 U.S.C. 300x-26). 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. All of the information required in the new report format is already being collected by the states. Specific changes are listed below:

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 a new response option (“Issues regarding the age or gender balance of youth inspectors”) since this is a common challenge reported by states.

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 Government 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 Government 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 Government 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.

ANNUAL REPORTING BURDEN

45 CFR Citation	Number of respondents ¹	Responses per respondents	Total number of responses	Hours per response	Total hour burden
Annual Report (Section 1—States and Territories) 96.130(e)(1–3)	59	1	59	15	885
State Plan (Section II—States and Territories) 96.130(e)(4,5)96.130(g)	59	1	59	3	177
Total	59				1,062

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

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 2–1057, One Choke Cherry Road, Rockville, MD 20857 *OR* email a copy to Summer.King@samhsa.hhs.gov. Written comments must be received before 60 days after the date of the publication in the **Federal Register**.

Summer King,
Statistician.

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2012–0003; Internal Agency Docket No. FEMA–B–1273]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice lists communities where the addition or modification of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or the regulatory floodway (hereinafter referred to as flood hazard determinations), as shown on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports, prepared by the Federal Emergency Management Agency (FEMA) for each community, is appropriate because of new scientific or technical data. The FIRM, and where applicable, portions of the FIS report, have been revised to reflect these flood hazard determinations through issuance of a Letter of Map Revision (LOMR), in accordance with Title 44, Part 65 of the Code of Federal Regulations (44 CFR part 65). The LOMR will be used by

insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings. For rating purposes, the currently effective community number is shown in the table below and must be used for all new policies and renewals.

DATES: These flood hazard determinations will become effective on the dates listed in the table below and revise the FIRM panels and FIS report in effect prior to this determination for the listed communities.

From the date of the second publication of notification of these changes in a newspaper of local circulation, any person has ninety (90) days in which to request through the community that the Deputy Associate Administrator for Mitigation reconsider the changes. The flood hazard determination information may be changed during the 90-day period.

ADDRESSES: The affected communities are listed in the table below. Revised flood hazard information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at www.msc.fema.gov for comparison.

Submit comments and/or appeals to the Chief Executive Officer of the community as listed in the table below.

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) Luis.Rodriguez3@fema.dhs.gov; or visit the FEMA Map Information Exchange (FMIX) online at www.floodmaps.fema.gov/fhm/fmx_main.html.

SUPPLEMENTARY INFORMATION: The specific flood hazard determinations are not described for each community in

this notice. However, the online location and local community map repository address where the flood hazard determination information is available for inspection is provided.

Any request for reconsideration of flood hazard determinations must be submitted to the Chief Executive Officer of the community as listed in the table below.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR part 65.

The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

These flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. The flood hazard determinations are in accordance with 44 CFR 65.4.

The affected communities are listed in the following table. Flood hazard determination information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at www.msc.fema.gov for comparison.