

A Strategic Partnership

The Food and Drug Administration's (FDA) Tobacco Retail Compliance Inspection Contracts and the Substance Abuse and Mental Health Services Administration's (SAMHSA) Synar Program

In July 1992, the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act (P.L. 102-321) became law, which includes the Synar amendment (section 1926) aimed at decreasing youth access to tobacco.

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) became law granting the Food and Drug Administration (FDA) authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. Currently the law applies to cigarettes, smokeless tobacco and cigarette tobacco.

SAMHSA and FDA are collaborating to ensure that their separate programs work together to help reach the shared goal of reducing youth access to, and use of, tobacco products.

Overview of Programs	
FDA's Tobacco Retail Compliance Inspection Contracts	SAMHSA's Synar Program
<p>The Tobacco Control Act authorizes FDA to contract, where feasible, with States, the District of Columbia, five U.S. Territories (American Samoa, Commonwealth of the Northern Mariana Islands, Guam, Puerto Rico, and the U.S. Virgin Islands), and American Indian Tribes to assist with inspections of retail establishments.</p> <p>Section 102 of the Tobacco Control Act required FDA to re-issue its 1996 final regulation restricting the sale and distribution of cigarettes and smokeless tobacco products. The rule contains provisions designed to limit young people's access to tobacco products, as well as restrictions on marketing to curb the appeal of these products to minors. The youth access and advertising regulations took effect on June 22, 2010 (21 C.F.R. Part 1140).</p>	<p>The Synar regulation is applicable to the 50 States, the District of Columbia, and eight U.S. Territories (American Samoa, Commonwealth of the Northern Mariana Islands, Federated States of Micronesia, Guam, Marshall Islands, Palau, Puerto Rico, and the U.S. Virgin Islands). It is not applicable to American Indian Tribes.</p> <p>The Synar regulation requires States and U.S. Territories (as a condition of receiving their full Substance Abuse Prevention and Treatment Block Grant (SAPT BG) awards) to:</p> <ul style="list-style-type: none"> • Have in effect a law prohibiting any manufacturer, retailer, or distributor of tobacco products from selling or distributing such products to any individual younger than age 18; • Enforce this law; • Conduct annual, unannounced inspections of retail tobacco outlets in a way that provides a valid probability sample of tobacco sales outlets accessible to minors; • Negotiate interim target rates and a date to achieve a noncompliance rate of no more than 20 percent; and • Submit an annual report detailing State and Territorial activities to enforce its law.



Differences between the FDA's Tobacco Retail Compliance Inspection Contracts and SAMHSA's Synar Program

FDA	SAMHSA
<p>Among other things, the FDA's reissued regulation restricts youth access to cigarettes and smokeless tobacco by:</p> <ul style="list-style-type: none"> • Prohibiting retailers from selling cigarettes, roll-your-own tobacco, smokeless tobacco, or cigarette tobacco to any person younger than age 18; • Requiring retailers to examine photographic identification of anyone under the age of 27 who attempts to purchase these products; and • Banning vending machines and self-service displays, except in facilities where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time. 	<p>The Synar regulation requires States to enact State laws making it illegal for retailers to sell tobacco products to minors.</p> <p>These State laws are not required under the Synar regulation to include a photo identification requirement or a ban on vending machines and self-service displays.</p>
<ul style="list-style-type: none"> • All compliance check inspections completed under the FDA contracts are for enforcement purposes, and violations may lead to Warning Letters, Civil Money Penalties, or other enforcement options. • There is no requirement that compliance check inspections conducted under the FDA contracts be conducted at a statistically representative sample of tobacco outlets, although FDA requires its contractors to conduct inspections in a variety of different locations, outlet types, and communities, including minority communities as directed by Section 105 of the Tobacco Control Act. 	<ul style="list-style-type: none"> • The Synar regulation requires States to assess compliance with State youth access laws via a statistically valid survey of youth-accessible tobacco retailers. Inspections completed for purposes of the Synar survey may include a State-level enforcement component, or they may not. • The Synar regulation requires States to enforce State youth access laws, but explicitly forbids States from using Substance Abuse Prevention & Treatment Block Grant (SAPT BG) money to fund enforcement.
<ul style="list-style-type: none"> • The FDA regulation does not include a specific performance target. 	<ul style="list-style-type: none"> • The Synar regulation sets a performance target (States must prove that the retailer violation rate is 20 percent or less via the statistically valid survey described above) and an incentive to comply (potential loss of SAPT BG funds).



Relationship between SAMHSA's State Synar Program and the FDA's Tobacco Retail Compliance Contracts

Category	Description
Use of Inspection Data	States and U.S. Territories that are awarded FDA contracts may use data from FDA compliance check inspections for Synar reporting as long as the inspections are completed at the retail tobacco outlets randomly sampled for the Synar survey. Specifically, FDA recommends that the contractor offer the State Synar Program the option of having a portion of the compliance check inspections conducted under the FDA contract completed at those retail tobacco outlets randomly sampled for the Synar survey.
Option to Combine Inspections	If the contractor chooses to conduct FDA compliance check inspections at those outlets randomly selected for the Synar sample or for other tobacco enforcement efforts, the compliance check inspections must follow FDA's protocol and must be conducted by the FDA-commissioned inspectors.
Funding	FDA funds cannot be used to support any contractor work beyond the FDA inspectional requirements (e.g., filling out the Synar form or other inspection forms, or obtaining and completing additional evidence for a charge specific to State, Territorial, or local law).
Implementation Plan	FDA contractors that wish to use FDA inspection data toward Synar reporting should discuss their plans with their FDA representative. They must also inform their SAMHSA/Center for Substance Abuse Prevention (CSAP) State Project Officer of their intention and work with him/her to make any needed changes to Appendix B or Appendix C of the Annual Synar Report, if applicable.
Vending Machines	The FDA regulation restricts the sale of cigarettes and smokeless tobacco from vending machines. If FDA has contracted with a State to enforce this provision, that State is no longer required to include vending machines in their annual Synar surveys. States should contact their SAMHSA/CSAP State Project Officer for more information.

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State Enforcement	States and U.S. Territories that choose to use data from FDA compliance check inspections toward Synar reporting must continue to show evidence of enforcement of State youth access laws in order to meet Synar regulation requirements.
Retailer Violation Rate	As a requirement of the Synar regulation, States will continue to be held accountable for meeting or achieving a retailer violation rate below the 20 percent target. Because of this performance target, States will need to continue conducting ancillary youth tobacco access prevention activities, such as merchant education and community mobilization, to help reduce the retailer violation rate.
Confidentiality of FDA Inspection Data	In States that maintain separate FDA and Synar programs, individuals commissioned by the FDA may share general information about the FDA regulations with other agencies, but may not share information about specific sites being inspected, or the outcomes of those inspections, until a final determination of compliance or non-compliance has been made and posted to the FDA website. Information on all completed FDA inspections can be found in a database searchable by State, city, zip code, retailer name, decision type, and decision date at: http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm232109.htm . State Synar programs may wish to use this data to identify retailers and/or geographic areas that need additional retailer education and follow-up enforcement inspections.

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