

Oregon Premium Retail Tobacconists Association, represented by Suzanne Kelso, President
February 7, 2017

Who we are: Members of the Oregon Premium Retail Tobacconists Association are brick and mortar, small, family owned, premium tobacconists, selling predominantly premium cigars and pipe tobacco. Approximately 75 locations around the state, employing approximately 300 people.

Our goal: State level retail licensing for the sale of tobacco administered by the Department of Revenue. Create a database of all retailers to be shared with Oregon Health Authority for use in federal and state inspections. Coordinate inspections to minimize disruptions to small businesses in Oregon.

Fee Structure: Fee of \$25/year for initial license application and subsequent annual renewals, payable to the Department of Revenue.

History of our Involvement: We met with Legislative Counsel and Senator Monnes Anderson in September 2016. Our input has not been integrated.

Inspection funding: The FDA not only allows, but encourages, that the federal funding for inspections be used to satisfy both federal and state requirements. The FDA entered into contract with OHA for tobacco inspections. \$492,000 in 9/2015 that expired in 10/2016. The funding has been available since 2010. Over \$221 million has been awarded. Over \$7 million to Washington alone. **Why are Oregon businesses being asked to pay when federal resources are available? No additional funding is needed via the licensing fee.**

Current Required Inspections of Tobacco Retailers in Oregon:

Dept. of Revenue, SYNAR, FDA, OHA (grid attached) – SYNAR Retailer Violation Rate FFY 2016 - 5.8% (attached)
OHA is contracted to perform Synar and FDA inspections (until 10/16), and FDA funding allows use with all inspections

We support efforts to restrict the sale of tobacco products to adults only. There are already at least SIX existing laws in Oregon that address this goal in addition to Federally Regulated Restrictions.

- ORS 163.575 – prohibits the sale of tobacco products to minors.
- ORS 167.400 prohibits the possession of tobacco products by minors.
- ORS 167.401 prohibits the purchase by minors.
- ORS 431A.175 prohibits distribution to minors.
- ORS 167.407 prohibits locations of the product.
- **ORS 431A.183 requires random inspections of sellers of tobacco**

In summary: It is our opinion the licensing bill should be restricted to addressing the need to know WHO is selling tobacco products. The database can then be shared for the enforcement of all existing laws above. **We do not need new regulations, only the enforcement of existing law.** The resources are already available. **Please do not burden small businesses further with redundant inspections and fees.**

Attachments:

FDA Tobacco Retail Inspection Contracts

Oregon's Retail Tobacco Inspection Programs – OHA document

Department of Revenue Cigarette and Tobacco Products Inspection Process

FDA – A Strategic Partnership specifically allowing FDA funds to be used for Synar testing

FDA – Strategic Partnership: FDA, Synar, State and Local Retail Tobacco Enforcement. **FDA “intends to contract with all jurisdictions who wish to do so”, and specially allowing FDA funds to “support enforcement actions under state law”.**

[en Español \(http://esp.fda.gov/TobaccoProducts/default.htm\)](http://esp.fda.gov/TobaccoProducts/default.htm)

FDA Tobacco Retail Inspection Contracts

FDA issues contracts to assist with compliance check inspections of retail establishments to help enforce the Youth Access and Advertising Regulations that took effect on June 22, 2010. FDA has a goal of establishing a contract, where feasible, with every U.S. State and Territory, but some States and Territories, for a variety of reasons, have been unable to do so. Therefore, FDA has awarded contracts to third- party entities that are able to hire commissionable inspectors to do compliance check inspections of tobacco retailers in those states and territories where FDA has not been able to contract with a state agency. FDA has further expanded this program by awarding retail inspection contracts to Tribes to conduct retail inspections within their jurisdictions. In addition, FDA may also conduct its own investigations using FDA personnel.

Jurisdiction	Contractor	Date of Initial Award	Date of Most Recent Award	Most Recent Award Amount	Total Awarded To Date*
Alabama	Alabama Department of Public Health	6/24/2010	9/30/2016	\$1,645,400.00	\$9,613,825.26
Alaska	Information Systems and Networks Corporation	9/4/2014	7/26/2016	\$450,675.23	\$1,290,480.31
American Samoa	American Samoa Department of Human and Social Services	6/18/2014	4/27/2016	\$191,509.00	\$574,555.00
Arizona	Arizona Department of Health Services	9/10/2010	9/30/2016	\$611,225.00	\$4,102,041.31
Arkansas	Arkansas Tobacco Control Board	8/30/2010	9/30/2016	\$836,101.00	\$5,398,354.01

California	California Department of Public Health	9/8/2011	5/4/2016	\$4,334,123.00	\$18,263,658.00
Colorado	Colorado Department of Public Health and Environment	8/30/2010	9/13/2016	\$1,172,020.76	\$7,316,271.28
Connecticut	Connecticut Office of Mental Health and Addiction Services	7/6/2011	4/18/2016	\$1,197,334.00	\$5,332,522.00
Delaware	Information Systems and Networks Corporation	9/19/2016	9/19/2016	\$451,370.59	\$451,370.59
Delaware	#Delaware Department of Safety and Homeland Security	7/13/2011	7/14/2014	\$169,908.63	\$657,398.17
Florida	Information Systems and Networks Corporation	4/1/2014	7/28/2016	\$2,214,564.75	\$6,388,398.51
Georgia	Georgia Department of Revenue	9/12/2011	2/25/2016	\$643,818.86	\$2,765,255.88
Guam	Guam Department of Administration	9/19/2012	9/12/2016	\$249,572.05	\$1,080,056.05
Hawaii	Hawaii Department of Health	9/15/2011	9/30/2016	\$386,608.00	\$1,767,801.04
Idaho	Idaho Department of Health and Welfare	9/10/2010	9/30/2016	\$1,066,494.00	\$4,488,387.00
Illinois	Illinois Liquor Control Commission	8/10/2010	5/12/2016	\$1,272,489.26	\$6,412,991.06

Indiana	Indiana Alcohol and Tobacco Commission	8/3/2011	9/15/2015	\$878,349.13	\$4,891,657.59
Iowa	Iowa Department of Commerce, Alcoholic Beverages Division	9/22/2011	5/19/2016	\$494,296.81	\$2,848,671.38
Kansas	Kansas Department of Revenue, Alcoholic Beverage Control	9/9/2010	8/23/2016	\$456,448.61	\$3,265,264.21
Kentucky	Commonwealth of Kentucky, Public Protection and Regulation Cabinet	6/27/2011	4/26/2016	\$723,211.51	\$3,416,764.84
Louisiana	****Louisiana Department of Revenue and Taxation	9/7/2011	6/12/2013	\$313,172.50	\$1,479,186.50
Louisiana	Information Systems and Networks Corporation	9/30/2014	9/30/2016	\$714,660.36	\$2,045,303.36
Maine	Maine Department of the Attorney General	6/15/2010	9/30/2016	\$565,564.47	\$4,576,234.20
Maryland	Maryland Department of Health and Mental Hygiene	7/29/2010	9/30/2016	\$1,043,337.00	\$5,676,215.00
Massachusetts	Massachusetts Department of Public Health	6/15/2010	5/4/2016	\$983,082.31	\$5,251,113.93
Mescalero Apache Tribe	Mescalero Apache Tribe	9/15/2016	9/15/2016	\$23,898.60	\$23,898.60
Michigan	Michigan Department of Community Health	8/8/2011	5/2/2016	\$1,426,668.00	\$6,782,479.00

Minnesota	Minnesota Department of Human Services	6/29/2011	7/6/2016	\$801,120.96	\$3,887,540.76
Mississippi	Mississippi Attorney General's Office, Alcohol and Tobacco Enforcement Unit	6/24/2010	9/30/2016	\$840,506.00	\$6,359,633.50
Missouri	Missouri Department of Mental Health	8/30/2010	9/30/2016	\$642,630.00	\$4,267,602.00
Montana	Montana Department of Public Health and Human Services	9/21/2012	4/20/2016	\$179,697.00	\$708,014.00
Nebraska	Information Systems and Networks Corporation	7/29/2014	7/28/2016	\$469,093.62	\$1,341,007.66
Nevada	#### Information Systems and Networks Corporation	8/12/2014	8/12/2014	\$457,853.89	\$457,853.89
New Hampshire	New Hampshire Liquor Commission	9/8/2011	9/8/2016	\$245,346.20	\$1,100,881.40
New Jersey	New Jersey Department of Health and Senior Services	7/13/2011	9/1/2016	\$1,725,098.00	\$7,122,439.00
New Mexico	%%%% New Mexico Department of Human Services	9/27/2011	3/30/2016	\$347,257.48	\$2,692,329.71
New York	Information Systems and Networks Corporation	7/7/2014	7/7/2016	\$1,611,124.01	\$4,720,098.69

North Carolina	North Carolina Department of Health and Human Services, Division of Mental Health	9/7/2011	3/1/2016	\$1,205,930.00	\$5,328,876.00
North Dakota	Information Systems and Networks Corporation	5/12/2014	5/12/2016	\$335,511.00	\$964,129.94
Northern Mariana Islands	%% Northern Mariana Islands Department of Commerce	9/21/2012	4/1/2015	\$396,856.29	\$1,203,383.80
Ohio	Information Systems and Networks Corporation	9/16/2016	9/16/2016	\$2,089,184.96	\$2,089,184.96
Ohio	##Ohio Department of Mental Health and Addiction Services	9/28/2011	9/24/2014	\$1,062,280.54	\$3,766,559.41
Oklahoma	Oklahoma Alcoholic Beverage Laws Enforcement Commission	9/14/2011	9/30/2016	\$402,517.00	\$2,177,234.14
Oregon	###Information Systems and Networks Corporation	7/16/2014	7/16/2014	\$737,649.66	\$737,649.66
Oregon	%%%Oregon Health Authority	9/1/2015	9/1/2015	\$492,766.60	\$492,766.60
Pennsylvania	Pennsylvania Department of Health	7/29/2010	9/30/2016	\$1,006,442.00	\$5,491,799.42
Puerto Rico	*****Puerto Rico Department of Health	9/20/2012	6/25/2014	\$638,444.00	\$1,340,007.00

Puerto Rico	Information Systems and Networks Corporation	9/4/2015	7/26/2016	\$878,311.32	\$1,739,396.77
Rhode Island	Rhode Island Department of Behavioral Healthcare, Developmental Disabilities and Hospitals	6/17/2011	3/29/2016	\$498,569.00	\$3,337,762.00
Rincon Band of Luiseno Indians	Rincon Band of Luiseno Indians	9/14/2016	9/14/2016	\$11,645.00	\$11,645.00
Seminole Tribe of Florida	%Seminole Tribe of Florida Inc.	9/19/2014	9/19/2014	\$297,112.00	\$297,112.00
Shoshone-Bannock Tribes	Shoshone-Bannock Tribes	9/19/2014	9/13/2016	\$12,902.00	\$97,523.26
South Carolina	South Carolina, Alcohol and Other Drug Abuse Services	9/20/2012	5/4/2016	\$2,232,415.08	\$6,067,589.20
South Dakota	Information Systems and Networks Corporation	5/12/2014	5/12/2016	\$309,602.93	\$902,440.05
Tennessee	Tennessee Department of Agriculture, Regulatory Services Division	6/24/2010	9/30/2016	\$370,111.00	\$2,042,109.00
Texas	Texas Department of State Health Services	8/2/2011	8/1/2016	\$1,531,878.00	\$6,199,687.00
U.S. Virgin Islands	Information Systems and Networks Corporation	6/27/2014	6/27/2016	\$176,589.56	\$514,171.68
Utah	**Utah Department of Health	9/13/2011	5/15/2013	\$288,563.47	\$841,174.44

Utah	Information Systems and Networks Corporation	9/30/2014	9/30/2016	\$267,654.94	\$771,002.94
Vermont	Vermont Department of Liquor Control	2/28/2013	9/6/2016	\$326,987.00	\$1,581,421.71
Virginia	Virginia Department of Alcoholic Beverage Control	8/10/2011	2/12/2016	\$1,152,089.92	\$6,457,651.69
Washington	Washington State Liquor Control Board	9/10/2010	8/31/2016	\$1,379,075.07	\$7,227,833.61
Washington D.C.	***District of Columbia Government	7/13/2011	5/15/2013	\$288,124.00	\$884,144.00
Washington D.C.	Information Systems and Networks Corporation	4/27/2015	4/14/2016	\$221,351.86	\$438,365.64
West Virginia	West Virginia Department of Health and Human Resources	8/24/2011	5/31/2016	\$831,261.00	\$4,747,850.00
Wisconsin	Wisconsin Department of Health Services	7/19/2011	5/10/2016	\$923,155.79	\$3,923,253.18
Wyoming	Information Systems and Networks Corporation	6/27/2014	6/27/2016	\$275,700.68	\$794,484.89
Total					\$221,521,109.88

* Total Awarded includes modifications made during the course of the contract that may be separate from the annual award.

** The contract with the Utah Department of Health expired on 8/31/14.

*** The contract with the District of Columbia Government expired on 7/12/14.

**** The contract with the Louisiana Department of Revenue and Taxation expired on 9/14/14.

***** The contract with the Puerto Rico Department of Health expired on 3/29/15.
The contract with the Delaware Department of Safety and Homeland Security expired on 7/8/2015.
The contract with the Ohio Department of Mental Health and Addiction Services ended on 7/8/2015.
The contract with Information Systems and Networks Corporation for Oregon expired on 7/15/15.
The contract with Information Systems and Networks Corporation for Nevada expired on 8/11/15.
% The contract with the Seminole Tribe of Florida expired on 3/29/16.
%% The contract with the Northern Mariana Islands Department of Commerce expired on 9/30/2016.
%%% The contract with the Oregon Health Authority ended on 10/19/16.
%%%% The contract with the New Mexico Department of Human Services ended on 10/21/16.

<u>More in Retail</u> (/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Retail/default.htm)
<u>Retailer Education Materials</u> (/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Retail/ucm237741.htm)
<u>Retailer Overview of FDA Regulations for Selling Tobacco Products</u> (/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Retail/ucm205021.htm)
<u>Retailer Regulations and Guidance</u> (/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Retail/ucm237759.htm)
<u>Retailer Training and Enforcement</u> (/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Retail/ucm249332.htm)
<u>Tobacco Retailer Warning Letters</u> (/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Retail/ucm316432.htm)

Tobacco Retailer Inspections in the State of Oregon

	SAMHSA's Synar Program	Oregon's Tobacco Retailer Compliance Inspections	FDA's Tobacco Retail Compliance Inspection Contracts
Where?	Annual, unannounced inspections of retail tobacco outlets in a way that provides a valid probability sample of tobacco sales outlets accessible to minors. Results of the Synar Survey are reported annually to SAMHSA, resulting in Oregon's Retailer Violation Rate (RVR) as reported in SAMHSA's Annual Synar Reports.	Annual, unannounced inspections of retail tobacco outlets. Approximately 1,500 of the estimated 3,000 tobacco retailers receive a compliance visit during the annual inspection period.	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.
When?	Random, unannounced inspections	Random, unannounced inspections	Year round
Why?	The Synar regulation sets a performance target (States must prove that the retailer violation rate is 20% or less via the statistically valid survey described above) and an incentive to comply (potential loss of SAPT BG funds).	AMH contracts with the Oregon State Police to conduct inspections, as required by ORS 181.428 (State Police Tobacco Law Enforcement Fund) and ORS 181.430 (Department to administer program to enforce laws discouraging use of tobacco products by minors).	The FDA regulation does not include a specific performance target.
Additional Resources	www.samhsa.gov/synar	www.oregon.gov/oha/amh/pages/prevention.aspx	<p>Compliance information: www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm</p> <p>Inspection database: http://www.accessdata.fda.gov/scripts/occe/inspections/occe_insp_searching.cfm</p> <p>Email: TobaccoIndustryQuestions@fda.hhs.gov</p>

SSES Table 2 (Synar Survey Results by Stratum and by OTC/VM)

STATE: OR
FFY: 2016

Samp Stratum	Var Stratum	Outlet Frame Size	Estimated Outlet Population Size	Number of PSU Clusters Created	Number of PSU Clusters in Sample	Outlet Sample Size	Number of Eligible Outlets in Sample	Number of Sample Outlets Inspected	Number of Sample Outlets in Violation	Retailer Violation Rate(%)	Standard Error(%)
All Outlets											
1	1	2,711	2,572	N/A	N/A	935	887	881	51	5.8%	
Total		2,711	2,572			935	887	881	51	5.8%	0.6%
Over the Counter Outlets											
1	1	2,711	2,572	N/A	N/A	935	887	881	51	5.8%	
Total		2,711	2,572			935	887	881	51	5.8%	0.6%
Vending Machines											
1	1	0	0	N/A	N/A	0	0	0	0	0.0%	
Total		0	0			0	0	0	0	0.0%	0.0%

Oregon's Retail Tobacco Inspection Programs

	State-level Inspections			Local Inspections & Enforcement
	Enforcement Inspections*	FDA Inspections	Synar Inspections	
Why	Required as a part of the Synar Amendment, but not funded with federal dollars.	Required under the Family Smoking Prevention and Tobacco Control Act.	Federally mandated under the Synar Amendment, which requires enforcement of laws which ban the sale of tobacco to minors.	Ensure compliance with local ordinances.
Who	Managed by Public Health Division (PHD). Inspections conducted by retired Oregon State Police (OSP) Troopers, as OSP employees.	Managed by Public Health Division. Inspections conducted by Food and Drug Administration (FDA) commissioned inspectors.	Managed by Public Health Division (PHD). Inspections conducted by retired Oregon State Police (OSP) Troopers, as PHD employees.	Managed by local governments. Inspections conducted as identified by local ordinance.
What	Random/unannounced minor decoy inspections of a random sample of known tobacco retailers statewide.	Minor decoy and advertising & labeling inspections of tobacco retailers statewide.	Random/unannounced minor decoy inspections of a random sample of known tobacco retailers statewide.	Inspections of tobacco retailers in the jurisdiction of the ordinance/law.
How many	Approximately 1,500 inspections conducted annually from a pool of approximately 2,700 non-age-restricted tobacco outlets.	Federal law requires that at least 25% of all known retailers are inspected annually, but numbers vary yearly. Approximately 3,700 tobacco outlets currently known.	Approximately 500-900 inspections conducted annually from a pool of approximately 2,700 non-age-restricted tobacco outlets.	Dependent on local ordinance/law requirements. May include all outlets or just non-age-restricted outlets.
Inspection types	Minor decoy inspections using 16-year old youth and inspections to ensure compliance with labeling and packaging standards.	Minor decoy inspections using 16-17-year-old youth; and Advertising and Labeling inspections to ensure compliance with FDA regulations.	Minor decoy inspections using 16-year-old youth.	Dependent on local ordinance/law requirements.
Penalties	Greek cited for endangering the welfare of a minor. Minimum fine of \$200, maximum fine of \$2,000. Presumptive fine is \$435. Additional civil penalties may be assessed to the store owner.	Graduated penalties beginning with a warning letter to the owner, to civil penalties of up to \$11,000 for a 6th offense within a 48 month period. The FDA may also issue a No-Tobacco-Sale Order (NTSO) for repeated violations.	Citations are not issued during Synar inspections. However, the State of Oregon could face the loss of alcohol and drug prevention and treatment funding if sales rates are above 20%.	Determined by local ordinance/law or by using state statute. State or federal violations may effect local tobacco retail license.
Use	Primary source of data for sales to minors. Large sample size. All program aspects (method, implementation, and penalties) are administered by the Public Health Division.	Supplemental source of data for sales to minors. Large sample size. The Public Health Division does not administer penalties; FDA directly administers.	Supplemental source of data for sales to minors. Smaller sample size. No penalties to retailers.	Data can be used to meet the enforcement requirement of the Synar Amendment and supplement state enforcement inspections.

+ Department of Revenue

Oregon Department of Revenue (/DOR/Pages/index.aspx) / Programs (/DOR/programs/Pages/default.aspx) / Businesses (/DOR/programs/businesses/Pages/default.aspx) / Cigarette and tobacco products inspection process

Cigarette and tobacco products inspection process

Our field agents conduct cigarette and other tobacco tax inspections at retail outlets. Upon entering a business, an agent will:

- Present a business card as identification.
- Ask to speak with the owner or manager.
- Explain the purpose of the visit.
- Ask to examine cigarettes and tobacco products. When possible, an employee of the business should be present when back rooms are inspected.
- Ask to examine receipts and invoices for cigarettes and tobacco products.
- Issue a Demand to Examine Books and Records in the event that receipts or invoices aren't available. Responses can be faxed, mailed, or reviewed in person during a follow-up visit at the agent's discretion.

Recordkeeping Requirements

You must maintain invoices for all cigarette purchases. The invoices must show:

- The seller's name and address;
- The date of sale; and
- The quantity and description of cigarettes sold.

You must maintain invoices for all tobacco product purchases. The invoices must show:

- The license number of the distributor;
- A certified statement that all taxes have been or will be paid;
- The seller's name and address;
- The purchaser's name and address;
- The date of sale; and
- The quantity and description of tobacco products sold.

Cigarette seizures

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.

Continued on next page



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.

Contact Us 1-877-CTP-1373
 AskCTP@fda.hhs.gov • www.fda.gov/tobacco
 FDA Center for Tobacco Products
 9200 Corporate Blvd • Rockville, MD 20850-3229





State and FDA Coordination

- FDA inspection results may be used to meet a State's Synar obligations
- FDA inspection results may also be used to support enforcement actions under state law
- Therefore, a retailer may be subjected to enforcement from both the state or local government as well as the FDA



FDA Inspection Contracts

- FDA awards contracts not grants
- Funding for CTP's inspections come from user fees paid by manufacturers and importers of tobacco products
- Cost Reimbursement Contracts
 - Reimbursed only for actual expenses incurred for the inspection program
 - Awarded as one year contracts with option years



Inspections

The Tobacco Control Act, among other things:

- Authorizes FDA to contract with States, Territories and Tribes, to the extent feasible, to carry out inspections of tobacco retailers within that area to ensure compliance with the laws and regulations

