

The Tobacco Control Act: How does the Synar Program Fit In?

What does the Tobacco Control Act do?

- On June 22, 2009, the President signed the Family Smoking and Tobacco Control Act (Tobacco Control Act) into law.
- The Tobacco Control Act grants the Food and Drug Administration (FDA) important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.
- Section 102 of the Tobacco Control Act requires FDA to issue, with certain modifications, its 1996 final regulation restricting the sale and distribution of cigarettes and smokeless tobacco products (August 28, 1996, 61 FR 44396 at 44615 to 44618). 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.

What does the Synar Amendment and its implementing regulation do?

- The Synar Regulation requires States to:
 - 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 (SAMHSA required that each State reduce its retailer violation rate (RVR) to 20 percent or less by FFY 2003); and
 - Submit an annual report detailing State activities to enforce its law.
- The Synar regulation is applicable to the 50 States, the District of Columbia and eight U.S. Territories. It is not applicable to tribes.

How do the access restrictions in FDA's re-issued tobacco regulation differ from the Synar regulation?

- The Tobacco Control Act requires FDA to re-issue a regulation, with certain amendments, that FDA promulgated in 1996 restricting the sale, distribution, promotion, and advertising of cigarettes and smokeless tobacco to protect children and adolescents. Among other things, the FDA regulation will restrict youth access to cigarettes and smokeless tobacco by:
 - Prohibiting retailers from selling cigarettes or smokeless tobacco to any person younger than age 18

- Requiring retailers to examine photographic identification from anyone under the age of 27 who attempts to purchase cigarettes or smokeless tobacco
- 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.

The Synar regulation requires States to enact State laws making it illegal for retailers to sell tobacco products to minors. These State laws do not need to include a photo identification requirement or a ban on vending machines and self-service displays.

- 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 an enforcement component, or they may not. To the extent feasible, FDA will be enforcing the re-issued 1996 regulation by contracting with the States, territories, and tribes to conduct inspections of retail facilities. Enforcement actions will be taken against retailers who are found to be in violation of the requirements in the regulation, including issuing Warning Letters and seeking Civil Money Penalties against retailers.
- 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 Substance Abuse Prevention and Treatment Block Grant (SAPT BG) funds). The FDA regulation does not include performance targets or incentives to ensure that retailers comply with the law, but FDA will be conducting an extensive outreach campaign to ensure that retailers understand their responsibilities under the new law and the consequences for violating it.
- The Synar regulation requires States to enforce State youth access laws, but explicitly forbids States from using SAPT BG money to fund enforcement. The Tobacco Control Act requires FDA to enter into contracts with the States, to the extent feasible, to conduct enforcement inspections of retailers for compliance with the Tobacco Control Act. This means that FDA will be commissioning and training State officials to conduct inspections of retail establishments to assess compliance with requirements of the re-issued 1996 rule, including compliance with the access restrictions described above.

What does passage of the Tobacco Control Act mean to SAMHSA's Synar Program?

- The Tobacco Control Act does not pre-empt the Synar regulation or State or local youth access laws that are in addition to, or more stringent than, the access provisions in the Tobacco Control Act. As a result, the Synar regulation will remain in effect, as will any existing State or local youth access laws that are at least as stringent as the FDA requirements.
- As a requirement of the Synar regulation, States will continue to be required to conduct representative surveys of tobacco retailers each year to determine their

compliance with State youth access laws. If inspections conducted by States for FDA produce a census of or a representative sample of enforcement inspections being conducted in States each year, States may report the FDA enforcement results (or a sub-set of them, as appropriate) as their State-wide retailer violation rate. States that have contracted with FDA and wish to take advantage of this option must inform their 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.

- As a requirement of the Synar regulation, States will continue to be held accountable to meeting or exceeding the 20% retailer violation rate 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.
- The FDA regulation prohibits the sale of cigarettes and smokeless tobacco from vending machines in facilities unless the retailer ensures that no children are present, or can enter, at any time. If FDA has contracted with a State to enforce this provision, that State would no longer be required to include vending machines in their annual Synar surveys. More information about this will be forthcoming from SAMHSA over the next year. Please note that States that currently include vending machines in their Synar surveys will need to continue to do so for the Synar inspections conducted in FFY 2010 and reported in the FFY 2011 Annual Synar Report.