

DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION
CENTER FOR SUBSTANCE ABUSE PREVENTION
ROCKVILLE, MD 20857

REVISION TO GUIDANCE

DATE: June 12, 2020

ADDRESSEES: SINGLE STATE AUTHORITIES
STATE SUBSTANCE ABUSE PREVENTION AGENCIES
STATE SYNAR COORDINATORS

SUBJECT: Revision to SAMHSA’s Synar Guidance on Tobacco Regulation for the Substance Abuse Prevention and Treatment Block Grant, in Response to PL 116-94 Appropriations Bill signed into law on December 20, 2019, which Increased the Minimum Age for Purchasing Tobacco Products from 18 to 21.

BACKGROUND: In July 1992, Congress enacted the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act (PL 102-321), which includes an amendment to Section 1926 of the Public Health Service Act (42 U.S.C. 300x-26) aimed at decreasing youth access to tobacco. This amendment, named for its sponsor, Congressman Mike Synar of Oklahoma, requires States (that is, all States, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and six Pacific jurisdictions) to enact and enforce laws prohibiting the sale or distribution of tobacco products to individuals under the age of 18. States must comply with the Synar Amendment in order to receive their full Substance Abuse Prevention and Treatment Block Grant (SABG) awards.

On January 19, 1996, SAMHSA published “Tobacco Regulation for Substance Abuse Prevention and Treatment Block Grants” in the Federal Register, amending 45 C.F.R. Part 96 to add section 96.130 – State Law Regarding the Sale of Tobacco Products to Individuals Under the Age of 18 – known as the Synar regulation. SAMHSA subsequently issued and revised guidance documents, providing instructions to States on compliance rate goals, use of funds, State reporting requirements, conforming amendments, and penalties.

Public Law 116-94, signed on December 20, 2019, supersedes this legislation and increased the minimum age for tobacco sales from 18 to 21. PL 116-94 also amends section 906(d) of the Federal Food, Drug,

and Cosmetic Act of 1938, the General Provisions Respecting Control of Tobacco Products, raising the federal minimum age for sale of tobacco products from 18 to 21 years and instructing the Food and Drug Administration to make conforming changes to regulations regarding sale and distribution of tobacco products to carry out the amendments made by Public Law 116-94. These conforming changes include increasing the minimum age of sale for tobacco products from 18 to 21 years of age, increasing the minimum age for age verification by means of photographic identification from under the age of 27 to under the age of 30, and increasing the minimum age of individuals that may be present or permitted to enter facilities that maintain vending machines or self-service displays that sell tobacco products from 18 years to 21 years of age.

In accordance with Public Law 116-94, this Revision to Guidance document updates previously issued SAMHSA guidance in 2011 as it relates to compliance rate goals, use of funds, state reporting requirements, conforming amendments and penalties. This Tobacco 21 Revision to Guidance document also outlines the three-year transition period for implementation and compliance.

**GUIDANCE
REVISIONS:**

Compliance Rate Goals

The Compliance Rate Goals outlined in Implementing the Synar Regulation (revised 2011), requires that "...each State reduce its [Retail Violation Rate] RVR to 20 percent or less..." A violation is defined as "The fraction (or percentage) of tobacco-selling outlets in a State that are accessible to minors and sell tobacco to them. The objective of the Synar survey is to estimate this rate using sampling techniques and survey inspection."

PL 116-94 does not change the compliance rate goal of 20 percent or less. However, the definition of a violation is expanded to include tobacco-selling outlets in a State that are accessible to anyone under the age of 21.

Use of Funds

The Synar regulation states that "States may not use the Block Grant to fund the enforcement of their statute, except that they may expend funds from the primary prevention set-aside of their Block Grant allotment under 45 CFR 96.124(b)(1) for carrying out the administrative aspects of the requirements, such as the development of the sample design and the conducting of the inspections." [45 CFR 96.130(j)].

This Revision to Guidance document clarifies that the prevention set-aside may be used to fund revisions to States' Synar programs to comply with PL 116-94.

State Reporting Requirements

The State Reporting Requirements in *Implementing the Synar Regulation* (revised 2011) outlines that “States are required to report their sampling methodology and results of the annual Synar survey as a part of the Annual Synar Report no later than December 31.” This includes the State’s sampling methodology, Synar survey results, Synar inspection report, and the Synar inspection protocol.

This Revision to Guidance document does not change the requirement to submit an Annual Synar Report, but does require that States revise their methodology, inspection reports, and inspection protocols, to include the revised age requirements (under 21). In addition, the Synar survey results must now include results for sales to youth and young adults under the age of 21.

Conforming Amendments

SAMHSA’s guidance on *Implementing the Synar Regulation* explains that, in order for States to be in compliance with the Synar regulations, States must “Enact a law prohibiting any manufacturer, retailer, or distributor of tobacco products from selling or distributing such products to any individual under age 18.”

PL116-94 removes the requirements for enacting State Laws. Therefore, States do not need to demonstrate a change in State Law to maintain compliance with Synar. However, SAMHSA’s guidance further requires that States “Enforce underage access laws to a degree that reasonably can be expected to reduce the illegal sale of tobacco products to individuals under age 18.” PL116-94 increases the minimum age to 21. Therefore, States are expected to enforce underage access to reduce the illegal sale of tobacco products to individuals under the age of 21.

Penalty

SAMHSA’s guidance on *Implementing the Synar Regulation* explains, “Failure to comply with the requirements of the Synar Regulation can result in a State losing up to 40 percent of its Federal Block Grant funds for substance abuse prevention and treatment.” Revisions to the definition of compliance are outlined above, including enforcement to reduce illegal sales to individuals under the age of 21, completing annual reporting requirements, demonstrating a Retail Violation Rate of 20 percent or less.

PL-116-94 revises the penalty to up to 10 percent of the Substance Abuse Prevention and Treatment Block Grant, and codifies a negotiated alternate penalty. Instead of taking the 10 percent penalty, States that are found out of compliance (report a Retail Violation Rate above 20 percent) may elect to submit a corrective action plan to the Assistant

Secretary for Mental Health and Substance Use within 90 days of receipt of notice that they are not in compliance with the Synar regulations, which outlines strategies they will take to reduce the Retail Violation Rate to 20 percent or less. States may not use Substance Abuse Prevention and Treatment Block Grant funds to pay for these activities, and must find alternate sources of funds to cover these costs.

CITATIONS IN LAW:

Section 1926 of the Public Health Service Act (42 U.S.C. 300x-26)
Further Consolidated Appropriations Act, 2020 (PL 116-94)

CITATIONS IN REGULATIONS:

“Tobacco Regulation for Substance Abuse Prevention and Treatment Block Grants” by the Substance Abuse and Mental Health Services Administration (SAMHSA) (61 FR 1492, Jan. 19, 1996); 45 C.F.R. §96.130.

“Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products” (81 FR 28974 May 10, 2016)

“Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents” (75 FR 13225, March 19, 2010).

CITATIONS IN GUIDANCE:

Implementing the Synar Regulation, Sample Design Guidance, published 2011.

EFFECTIVE DATE:

States are expected to begin transitioning their Synar programs to conform to the guidance revisions outlined in this document immediately, and complete their transitions within three years from the issuance of this document.

During this three-year period, SAMHSA will not enforce penalties for Retail Violation Rates in excess of 20 percent. However, states are expected to continue to meet the expectations of the law, including reporting.

INQUIRIES TO:

Substance Abuse Prevention Grant Project Officers

/Elinore F. McCance-Katz/

Elinore F. McCance-Katz, M.D., Ph.D.
Assistant Secretary for Mental Health and
Substance Use