An Overview of the Synar Provision:

History, Impact of Tobacco 21 Legislation, and Recommendations

Background

Congress enacted the *Alcohol, Drug Abuse, and Mental Administration Reorganization Act* (Public Law No: 102-321) in 1992 that included a provision referred to as the Synar Amendment. The Amendment aimed to decrease youth tobacco use by requiring States and Territories to enact and enforce laws prohibiting the sale or distribution of tobacco products to individuals under the age of 18.

In 1996, the Substance Abuse and Mental Health Services Administration (SAMHSA), within the Department of Health and Human Services (HHS), issued a regulation giving further guidance to States related to Synar implementation and enforcement. The regulation required States to conduct annual, unannounced inspections of tobacco retailers that provide a probability sample of the accessibility of tobacco products to minors under the age of 18. States had to meet at least an 80 percent compliance rate of retailers refusing tobacco sales to minors. States that have a retail violation rate (RVR) of 20 percent or more resulted in penalization up to 40 percent of a State's Substance Abuse Prevention and Treatment (SAPT) Block Grant.

Over time, Congress worked with the Administration to offer an alternative penalty that was significantly less than the 40 percent marker but required the State to generate funds to remedy the violation. No federal funding was ever provided to the managers of the Substance Use Prevention, Treatment, and Recovery Services (SUPTRS) Block Grant (previously Substance Abuse Prevention and Treatment [SAPT] Block Grant) – State alcohol and drug agencies – to specifically support Synar implementation and enforcement activities.

Impact of Federal Tobacco 21 Law on Synar

Tobacco 21 legislation was included in a larger fiscal year 2020 appropriations package (P.L. 116-94) that was enacted in December 2019. The final law:

- **Maintained Synar but increased the age for tobacco access from 18 to 21.**
- **Maintained FDA's jurisdiction over tobacco** and maintained FDA's contracts to States and third-party vendors for compliance checks and enforcement.
- **Created a mandatory 3-year transition and implementation period** where no penalties could be levied for Synar noncompliance.
  - The Secretary of HHS could add an additional 2 years to this transition period with no penalties.
- **Authorized $18.5 million per year for 5 years (FY 2020-2024)** for grants to States to ensure compliance with the new approach to Synar. If the Secretary of HHS determines a State "is prepared to meet, or has met" Synar requirements, the allowable uses of the transition grants expand to include "tobacco cessation activities, strategies to prevent the use of tobacco products by individuals under the age of 21…" or allowable uses under Synar.
  - These funds were never appropriated.
- **Required the Secretary of HHS to provide technical assistance to States,** required SAMHSA and FDA to coordinate the technical assistance, and that the technical assistance provided to States is "…consistent with applicable regulations for retailers under part 1140 of title 21, Code of Federal Regulations (CFR)."

FDA's Role – The U.S. Food and Drug Administration (FDA) plays an important role in regulating the sale of tobacco products. The FDA's Center for Tobacco Products (CTP) authorizes the sale of new and modified risk tobacco products with marketing orders, which are granted based on the product's risks to the population as a whole. Additionally, the FDA directs federal resources through contracts to some States or third-party vendors to support compliance checks and enforcement. These resources are not necessarily allocated to the State alcohol and drug agency.

  - This CFR references regulatory requirements for retailers under FDA's compliance program.
- **Outlined three pathways for States found to be out of compliance.**
  - *Alternative Penalty*: A State may certify to HHS that it will commit additional State funds to Synar activities. The amount would equal 1 percent of the State's SUPTRS Block Grant allocation per each percentage point over the compliance rate goal (known for years as the "alternative penalty").
  - *Negotiated Agreement*: A State may agree to a negotiated agreement for a corrective action plan approved by the Secretary and in accordance with guidelines set by the Secretary.
  - *10 Percent Cut to SUPTRS Block Grant*: A State would be penalized an amount equal to no more than 10 percent of the State's SUPTRS Block Grant allocation (instead of up to 40 percent, which was the penalty in the original statute).

Implementation Efforts – 2020-2021

The COVID-19 pandemic created significant challenges to implementing the Synar amendment in 2020 and the following years. Public health interventions such as social distancing, business closures, and wearing a face mask created obstacles for States in routinely conducting compliance checks. In addition, States noted difficulties conducting their "Coverage Study," which involves confirming a list of retailers that sell tobacco. This list then serves as the source for States to generate an accurate approach to sampling for their compliance checks.

On June 12, 2020, SAMHSA released a "Revision to Guidance" (since removed from SAMHSA's webpage) that clarified a State must keep their RVR to 20 percent or less. States could also begin using funding from the prevention set-aside within the SUPTRS Block grant to fund compliance efforts.

On August 28, 2020, SAMHSA sent a letter to State alcohol and drug agencies that provided guidance on Synar implementation given the challenges related to the COVID-19 pandemic. The guidance reiterated that States were required to submit Synar Annual Reports per statutory requirement, however, States were encouraged to describe challenges, such as the pandemic, that may have caused incomplete actions. States were able to seek an extension.

Implementation Efforts – 2022-2023

On June 13, 2022, SAMHSA sent a revised letter to State alcohol and drug agencies indicating that Synar penalties could be enforced in December 2023 for the period of performance from January 1, 2023-September 30, 2023, consistent with the three-year compliance transition period included in the 2020 omnibus (the Consolidated Appropriations Act of 2020; P.L. 116-93).

On November 22, 2023, SAMHSA Assistant Secretary for Mental Health and Substance Use notified SSAs that the HHS Secretary approved an additional two-year transition period where no penalties will be assessed. States were briefed that they are expected to complete the transition to comply with the Tobacco 21 guidance revisions in their Synar program by December 20, 2024. The new period of performance was established to be January 1, 2025, through September 30, 2025. In December 2025, States found to be out of compliance with Synar would choose one of the three pathways referenced above. All States also had to submit an action plan to SAMHSA that identified their current compliance efforts, remaining barriers to compliance, a plan of action for identifying barriers, and the kind of technical assistance needed from SAMHSA and partners to achieve compliance.

Opportunities for Action

1. NASADAD recommends continued work between the Association and SAMHSA to promote opportunities for technical assistance related to Synar. This could include re-establishing an annual Synar conference.
2. NASADAD encourages regular communication between SAMHSA, FDA, NASADAD, and State alcohol and drug agencies.
3. NASADAD encourages SAMHSA and FDA to partner in order to coordinate and leverage their efforts related to tobacco control. In turn, this partnership may help reduce any duplicative efforts and enhance effectiveness.
4. NASADAD encourages coordination with the Centers for Disease Control and Prevention (CDC) given the work of the Office of Smoking and Health (OSH) and other CDC operational divisions.
5. NASADAD is highlighting the benefits of fully funding the $18.5 million authorization for grants to State alcohol and drug agencies to help support implementation and compliance with the updated Synar requirements.
6. NASADAD is also highlighting the benefits of extending the authorization of the $18.5 million for 5 more years.