

An Overview of the Synar Provision: History, Impact of Tobacco 21 Legislation, and Recommendations

Background on Synar:

In 1992, Congress enacted the Alcohol, Drug Abuse, and Mental Administration Reorganization Act (102-321) that included a provision referred to as the Synar Amendment, which required 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) 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. A compliance rate below 80 percent would result in penalization of a State's SAPT Block Grant allocation of up to 40 percent. 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 SAPT Block Grant – State alcohol and drug agencies – to specifically support Synar implementation and enforcement activities.



FDA's Role:

The U.S. Food and Drug Administration (FDA) within the Department of Health and Human Services (HHS) 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 States or third-party vendors to support compliance checks and enforcement. These resources are not necessarily allocated to the State alcohol and drug agency.

Impact of federal Tobacco 21 law on Synar:

The fiscal year 2020 appropriations package (P.L. 116-94) was enacted in December 2019 and included provisions that raised the minimum age of legal tobacco access from 18 to 21. The final law does the following:

- **Maintains Synar but increases the age for tobacco access from 18 to 21.**
- **Maintains FDA's jurisdiction over tobacco** and maintains FDA's contracts to States and third-party vendors for compliance checks and enforcement.
- **Creates a mandatory 3-year implementation period** where no penalties can be levied for Synar non-compliance.
 - The Secretary of Health and Human Services (HHS) may add an additional 2 years to this transition period with no penalties.
- **Outlines three pathways for States that are out of compliance:**
 - *Alternative Penalty:* 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 SAPT Block Grant allocation per each percentage point over compliance rate goal (known for years as the "alternative penalty").
 - *Negotiated Agreement:* State may agree to a negotiated agreement for a corrective action plan approved by the Secretary and in accordance with guidelines by the Secretary.
 - *10 Percent Cut to SAPT Block Grant:* State is penalized an amount equal to no more than 10 percent of the State's SAPT Block Grant allocation (instead of up to 40 percent, which was the previous penalty).
- **Authorizes \$18.5 million per year for 5 years (FY 2020-FY 2024)** for transition 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. The legislation did not describe precisely which State agency would receive and manage the funds.
 - These funds were not appropriated in FY 2020 nor in FY 2021.
- **Notes that the Secretary of HHS shall provide technical assistance to States**, ensure that SAMHSA and FDA 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)."
 - This CFR references regulatory requirements for retailers under FDA's compliance program.
 - Implications of this provision: There is an opportunity for more coordination and alignment between work under FDA and work under SAMHSA/Synar.



Implementation efforts in 2020:

- The COVID-19 pandemic impacted Synar implementation in 2020.
 - Public health interventions to address COVID-19, such as social distancing and wearing a face mask, created challenges for States related to Synar implementation. In addition, States noted difficulties conducting their “Coverage Study” which involves confirming a list of all retailers that sell tobacco. This list then serves as the source for States to generate an accurate approach to sampling for their compliance checks.
- SAMHSA releases “[Revision to Guidance](#)” on June 12, 2020:
 - Document interprets no need to revisit the 20 percent compliance rate because the statute did not specifically reference a change.
 - Notes that the SAPT Block Grant set-aside funds may now be used to comply with updated Synar provisions.
 - Notes that States must begin to conform to guidance in the document and complete their transition “three years from the issuance of this document”.
- SAMHSA sends letter to State alcohol and drug agencies (SSAs) on August 28, 2020 regarding Synar and COVID-19:
 - Provides guidance on Synar implementation given challenges related to COVID-19.
 - Reiterates that States must submit Synar Annual Reports per statutory requirement, however, States are encouraged to describe challenges such as the COVID-19 pandemic that may have caused incomplete actions.
 - Grants States a one-year extension for coverage study. States seek extension through Government Project Officer (GPO).

Opportunities for action:

- NASADAD recommends work between the Association and SAMHSA to consider opportunities for technical assistance related to Synar. This could include re-establishing an annual Synar conference.
- NASADAD encourages regular communication between the FDA, NASADAD, and State alcohol and drug agencies.
- NASADAD will encourage 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.
- In addition, coordination with the Centers for Disease Control and Prevention (CDC) would be beneficial given the work of the Office of Smoking and Health (OSH) and other CDC operational divisions.
- Congress should be aware of the benefits of fully funding, in FY 2022, the \$18.5 million authorization for transition grants to State alcohol and drug agencies to help support implementation and compliance with the updated Synar requirements.