

FEDERAL TOBACCO 21: THE LAW OF LAND

In December 2019, Congress passed a \$1.37 trillion spending bill that included a provision to raise the minimum legal sales age for all tobacco products from 18 to 21 nationwide. Upon the President's signature on December 20, 2019, the age change became effective immediately.

- It is now a violation of federal law for any retailer to sell any nicotine or tobacco products to anyone under the age of 21.
- FDA will oversee enforcement of the minimum legal sales age at 21.
- There are no exemptions for sales to members of the military who are under 21.
- The law does not phase-in age restrictions (i.e., there is no "grandfathering") of those who are currently 18, 19 or 20.
- The law does not preempt cities, counties or states from passing and enforcing their own age restriction laws and does not preempt Tobacco 21 laws already in place in cities, counties and states, except that no military or grandfathering exemptions are granted.
- The law penalizes retailers for selling tobacco products to youth, not those attempting to purchase, although many states and cities retain purchase, use and possession (PUP) laws.
- The law does not require that states pass laws to raise their sales age to 21, but it does require states to demonstrate that their retailers are complying with the law. If not, the state eventually risks losing some portion of their federal substance abuse grant funding.
- This law does not address flavored tobacco or nicotine products in any way, although on January 2, 2020, the FDA issued an enforcement policy on unauthorized flavored cartridge based e-cigarettes: <u>https://www.fda.gov/media/133880/download</u>

Federal Tobacco 21 Law FAQ

1. What was the Tobacco 21 landscape prior to the Federal Legislation?

Over 540 local jurisdictions and 19 states had passed a Tobacco 21 law.

2. Where can I find the Federal Tobacco 21 Legislation?

The bill is available at the link provided below and the Tobacco 21 provisions begin on page 1492:

https://docs.house.gov/billsthisweek/20191216/BILLS-116HR1865SA-RCP116-44.PDF

3. What does the Federal Tobacco 21 bill do?

• Amends the Federal, Drug, and Cosmetic Act 906(d) to include a new subsection, 906(d)(5), which states: "Minimum Age of Sale -- It shall be unlawful for any retailer to sell a tobacco product to any person younger than 21 years of age."

Note: This amendment makes it clear that the retailer is responsible, rather than the sales clerk or youth purchaser.

- Amends Federal, Drug and Cosmetic Act 906(d)(3)(ii) to restrict the FDA from establishing a minimum legal sales age above age 21.
- FDA will continue to enforce the minimum legal sales age. The law does not increase fines/penalties for violations.
- Amends the Public Health Services Act Sec. 1926 (42 U.S.C. 300x-26) (the Synar Amendment) with respect to grant monies, enforcement, implementation, and compliance rates (discussed more in depth in Question 5).
- Enables the Secretary of Health and Human Services to promulgate regulations for tobacco product sales to increase the minimum age of sale from 18 to 21 and update the ID verification age from 27 to 30.
- The law provides grant funding to the states to assist in obtaining retailer compliance, but federal funds are meant to "supplement" state-funded tobacco control efforts not "supplant" state funding to that effect.
- Health and Human Services will provide technical assistance to the states.
- No exemptions or phase in were included, including no military exemption or grandfathering of age groups.
- The law does not preempt states or localities from passing their own age restriction laws.
- Congress appropriated \$18.5 million in grant money available to support states in their transition, with a sunset period until September, 2024.

NOTE: This summary does not include every change to current law based on the Tobacco 21 provisions of the spending bill but rather serves as an overview. The bill language in full can be found in the link in Answer 2 (above).

4. When is Federal Tobacco 21 effective?

The age change became effective immediately, according to the Food and Drug Administration: "On December 20, 2019, the President signed legislation to amend the Federal Food, Drug, and Cosmetic Act, and raise the federal minimum age of sale of tobacco products from 18 to 21 years. It is now illegal for a retailer to sell any tobacco product – including cigarettes, cigars and e-cigarettes – to anyone under 21. FDA will provide additional details on this issue as they become available."

Retailers can visit the FDA website for guidance:

https://www.fda.gov/tobacco-products/compliance-enforcement-training/retail-sales-tobaccoproducts

NOTE: The legislation enables the Secretary of Health and Human Services to promulgate rules to carry out the new law no later than 180 days after the date of enactment of the Act. The Secretary is required to publish the final rule to update the regulations under Chapter 9 of the Federal Food, Drug, and Cosmetic Act to carry out the amendments, to update all references to persons under 18, and to update the relevant age verification requirements to require age verification for individuals under the age of 30. This final rule will take effect no later than 90 days after the date on which the final rule is published.

5. What is 'Synar' and how does the Federal bill amend Synar?

The original Synar Amendment, named for the Oklahoma Senator who introduced the amendment, required, among other things, states to adopt state laws setting the tobacco sale age at 18 in order to receive their Substance Abuse Prevention and Treatment Block (SAPTB) grant money. However, that part of the Synar amendment was repealed in the new legislation, and states are not required to pass their own laws to update their tobacco sales age to 21. States will still need to demonstrate compliance with the federal age of 21 as a condition of the grant. Specifically, under 42 U.S.C. 300x-26, a funding agreement for the SAPTB under Section 1921 requires the states involved to (1) annually conduct random, unannounced inspections to ensure that retailers do not sell tobacco products to individuals under the age of 21, and (2) report such findings to the federal government annually. If states do not demonstrate a compliance rate determined by the Secretary, they risk losing up to 10% of their SAPTB monies.

The new law grants a 3-year grace period following enactment to come into compliance with the reporting and enforcement requirements before the Secretary may withhold any funds, with a further 2-year period for the Secretary to exercise discretion in enforcement.

6. Does the Federal Tobacco 21 law include a Military Exemption?

No. The Federal Tobacco 21 law does not exempt anyone from the age requirement. It is now illegal for retailers to sell tobacco product to anyone under the age of 21.

7. What does this mean for states and localities that have a military exemption in their Tobacco 21 laws? Does this Federal law overturn all military exemptions that are currently in effect?

The Federal Tobacco 21 law does not exempt anyone or group from the age restriction requirements. States and cities that exempt members of the military from their Tobacco 21 laws are in violation of federal law. In other words, because the federal law does not have a military exemption, all such sales to persons under 21, regardless of military status, are illegal.

8. Can a law exempting the military from the new age of sale of 21 be enacted before the federal law starts to be enforced?

No. The federal law became effective when it was signed by President Trump. The law does not have a military exemption. Therefore, sales to any persons under the age of 21, including military personnel, are illegal. *States cannot authorize something that is illegal under federal law.*

9. Does the Federal Tobacco 21 law include a phase-in period?

No. Per the FDA website, the law is effective immediately and it is illegal for a retailer to sell tobacco products to persons under the age of 21.

10. Is there more to be done? Should my state/city continue to pass Tobacco 21 laws independently?

Yes, absolutely! In many states and cities, outdated and uninformed youth access laws remain on the books. Many of these laws were written and lobbied for by the tobacco industry. These antiquated laws consistently place penalties on youth rather than the retailer who profits from sales, and many lack real enforcement mechanisms or penalties that deter bad behaviors. Even with a federal Tobacco 21 law, there is much work that needs to be done around age restriction laws at a state and local level.

The federal Tobacco 21 law does not preempt states and localities from adopting their own Tobacco 21 laws. In fact, changes to the Synar Amendment require states, as a condition of their grant funding, to demonstrate compliance with the federal age of 21. Specifically, under 42 U.S.C. 300x-26, a funding agreement for the SAPTB under Section 1921 requires the states involved to (1) annually conduct random, unannounced inspections to ensure that retailers do not sell tobacco products to individuals under the age of 21, and (2) report such findings to the federal government annually. If states do not demonstrate a compliance rate determined by the Secretary, they risk losing up to 10% of their SAPTB monies. *Therefore, the federal law inherently encourages state and local action*. Moreover, state and local enforcement will help improve the effectiveness of a Tobacco 21 law.

States and localities should continue passing policies at the local and state level to make their age restriction laws align with federal law. Effective sales regulations also include requiring a tobacco retail license, mandating a minimum number of compliance checks, and updating their penalty structure to incentivize compliance.

Again, states and cities are not preempted from passing or enforcing their own Tobacco 21 laws. Therefore, in locations that already have Tobacco 21, we recommend continued enforcement. In locations that do not have a Tobacco 21 law, we recommend updating laws and enforcing the new age.

11. What are the penalties for youth who are caught trying to purchase or those who are using tobacco products?

The federal law does not place any penalties for youth who are caught attempting to purchase, purchasing, or using tobacco products. However, state and local laws often place a penalty on youth for such activity. We recommend you monitor your local and state laws for these provisions.

If your jurisdiction does place a penalty on the youth for purchase, use, or possession of tobacco products, we recommend that the jurisdiction update its laws to align with federal standards that place the penalties on the retailers, not the youth purchaser.

12. What are the penalties for selling to those under 21?

The FDA enforces the minimum legal sales age contracting with the states or a third party to conduct compliance checks at retail locations. Maximum penalties for violating regulations issued under Section 906(d) of the Food, Drug, and Cosmetic Act, including the restrictions on the sale and distribution of covered tobacco products in 21 CFR part 1140, are set forth at Section 103(q)(2) of the Tobacco Control Act and have since been adjusted for inflation. The penalty structure is available at:

https://www.fda.gov/tobacco-products/compliance-enforcement-training/ctp-compliance-enforcement

The first time a retailer with an approved training program violates the regulations issued under Section 906(d) of the FD&C Act, FDA will send the retailer a Warning Letter. The maximum civil money penalty amounts for such retailers range from \$292 (for a second violation within a 12-month period) to \$11,698 (for a sixth or each subsequent violation at the same retail location within a 48-month period).ⁱ

The FDA may also pursue a *No-Tobacco-Sale Order* (NTSO) against retailers that have a total of five or more repeated violations of certain restrictions within 36 months. Retailers are prohibited from selling regulated tobacco products at the specified location during the period of the NTSO.ⁱⁱ Per guidance from the FDA, "Repeated violations" is defined to mean "at least 5 violations of particular requirements over a 36-month period at a particular retail outlet that constitute a repeated violation."ⁱⁱⁱ In addition, states and localities may have their own age restriction enforcement mechanism. These programs vary by state and we recommend you research your own jurisdiction to learn about your state or locality's age restriction enforcement program.

13. Did flavored e-cigarettes become illegal with this new law?

No. This legislation does not prohibit or restrict the sale of flavored products. **On January 2, 2020, the FDA issued an enforcement policy on unauthorized flavored cartridge based e-cigarettes:** <u>https://www.fda.gov/media/133880/download</u>

Note: Prior to this legislation and under the authority granted by the Family Smoking Prevention and Tobacco Control Act, the FDA prohibited cigarettes from containing any "characterizing flavor," including candy, fruit, and alcohol flavors. This regulation was not impacted by the new legislation. Please consult your state and local laws as some jurisdictions have prohibited the sale of (or further restricted) flavored tobacco products.

Disclaimer: The information presented is not legal representation or advice, is not to be acted on as such, may not be current and is subject to change. This information is for educational purposes only. If you require legal advice or a legal opinion, we encourage you to consult with legal counsel.

¹ The Civil Money Penalty amounts listed in this guidance reflect the amounts listed in the statute. FDA is required to update these amounts annually to reflect inflation by the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. No. 101-410, 104 Stat. 890 (1990) (codified as amended at 28 U.S.C. 2461 note 2(a)), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of the Bipartisan Budget Act of 2015, Pub. L. No. 114-74, November 2, 2015). For the most up-to-date amounts, please see 45 CFR §102.3 or the CTP website at: http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm232109.htm

^{II} Products, Center for Tobacco. "Tobacco Compliance & Enforcement." U.S. Food and Drug Administration, FDA, https://www.fda.gov/tobaccoproducts/compliance-enforcement-training/ctp-compliance-enforcement.

^{III} Department of Health and Human Services, Food and Drug Administration Center For Tobacco Products, "Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers (Revised), Guidance for Industry." Published Dec. 2016, available at <u>https://www.fda.gov/media/80888/download</u>, FDA understands this to mean that there is a "repeated violation" if: There are at least five violations of requirements issued under Section 906(d) of the FD&C Act at a particular outlet; Each of the five violations represents the second or subsequent violation of a particular requirement; and Each of the five violations occurs within 36 months.