

Introduction to Tobacco Control

Introduction

This guide is meant to provide a high-level overview of the tobacco control landscape at both the federal and state levels. Each jurisdiction in Maryland has additional local laws that are not included in this guide. Please reach out individually to your local health department or the Legal Resource Center for Public Health Policy (LRC) for county-specific questions.

This guide is not intended to serve as legal advice; you should always confer with your county attorney or Assistant Attorney General on any legal questions. If you have any questions about the materials in this guide—or any questions about tobacco regulation—feel free to contact the LRC at (410) 706-0842 or publichealth@law.umaryland.edu.

Federal Regulation of Tobacco Products and Important Federal Actors

The term "tobacco product" is defined in § 201(rr) of the Food, Drug, and Cosmetic Act as "any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product." The Family Smoking Prevention and Tobacco Control Act (TCA) provides the U.S. Food and Drug Administration (FDA) with the authority to regulate tobacco products. The Center for Tobacco Products (CTP) at the U.S. FDA is responsible for carrying out the provisions of the TCA.

According to the U.S. Constitution's Supremacy Clause, federal law is the "supreme Law of the Land" and supersedes laws passed by lower forms of government.² However, the TCA does preserve some authority for state, local, and tribal governments to regulate tobacco:

- Laws relating to or prohibiting the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products by individuals of any age;
- Information reporting to the state;
- Measures relating to fire safety standards for tobacco products; and
- Local taxation of tobacco products.

As discussed in the state regulation section of this resource, the high Court in Maryland has limited local regulation of tobacco in this state.

Family Smoking Prevention and Tobacco Control Act (TCA)

In 2009, President Barack Obama signed the TCA into law. The TCA grants the U.S. FDA authority to regulate the manufacture, distribution, and marketing of tobacco products. At that time, the only regulated types of tobacco products included cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco; however, the TCA gave the U.S. FDA the power to deem other tobacco products subject to its authority. In 2016, the U.S. FDA used this authority to publish the "Deeming Rule." This rule extended the U.S. FDA's authority to cover cigars, hookah tobacco, pipe tobacco, electronic smoking devices/vapes, and other tobacco products (OTP).

¹ 21 CFR § 1100.3 (2024) https://www.ecfr.gov/current/title-21/chapter-I/subchapter-K/part-1100

² Article VI, Clause 2 https://constitution.congress.gov/browse/essay/artVI-C2-1/ALDE 00013395/

What does the TCA do?

- Restricts tobacco marketing and sales to anyone under 21;
- Requires ID check of anyone under 27 before making a sale;
- Requires warning labels on tobacco products and advertisements;
- Requires disclosure of ingredients;
- Preserves state, local, and tribal authority;
- Ensures that "modified risk" claims are supported by scientific evidence;
- Prevents tobacco products from being sold in vending machines unless in an adult-only facility;
- Prohibits free samples except for smokeless tobacco at a qualified adult-only facility;
- Prohibits free gifts with purchase;
- Determines whether a product can be marketed as modified risk tobacco products;
- Sets minimum package sizes;
- Stops tobacco companies from sponsoring any athletic or entertainment events using an identifiable logo;
- Prohibits clove cigarettes and flavored cigarettes, cigarette tobacco, and roll your own tobacco, other than menthol;
- Prevents selling cigarettes in packages less than 20;
- Requires premarket tobacco product approval for many tobacco products

What does the CTP at U.S. FDA do?

- Conducts inspections, including undercover buys, to ensure compliance with the TCA
 - o Violations result in warning letters, civil money penalties, or no-tobacco-sale orders
 - Inspections are conducted by FDA Commissioned Officers who are state and local public health officials who have been given the authority to perform FDA work. They are state and local employees who act on behalf of the FDA.
- Investigates reports of potential tobacco product violations. Complaints may be submitted by:
 - Completing an online complaint, available at https://www.accessdata.fda.gov/scripts/ptvr/index.cfm;
 - Calling CTP's toll-free number at 1.877.CTP.1373;
 - Emailing CTPCompliance@FDA.hhs.gov; or
 - Completing and mailing a paper complaint, available at https://www.fda.gov/media/85811/download. The complaint can be mailed to:

Food and Drug Administration Center for Tobacco Products Document Control Center

Building 71, Room G335

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

- Reviews premarket tobacco product applications (PMTA) for new tobacco products and issues marketing orders if approved for sale at retail:
 - Any tobacco product not commercially marketed in the U.S. as of February 15, 2007, is considered a new product, and manufacturers must submit a PMTA to the U.S. FDA.
 - All applications for newly covered products pursuant to the Deeming Rule were due September 9th, 2020.
 - Because millions of products were submitted for review, the FDA has been unable to make decisions on all applications.

- Even though only products marketed with an FDA marketing order are considered legally sold, the FDA has opted not to enforce this provision against manufacturers and retailers for products that have applications properly pending before the FDA.
- A list of tobacco products with marketing orders is accessible at www.fda.gov/searchtobacco

What are Synar inspections?

In 1992, Congress enacted the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act which includes an amendment aimed at decreasing youth access to tobacco. This amendment, named for its sponsor, Congressman Mike Synar of Oklahoma, requires all states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and six Pacific Island Jurisdictions to enact and enforce laws prohibiting the sale or distribution of tobacco products to individuals under age 18 (now 21). States must prove that the retailer violation rate is 20 percent or less each year to receive their full Substance Use Prevention, Treatment, and Recovery Services Block Grant award from the Substance Abuse and Mental Health Services Administration's (SAMHSA). To make this determination, SAMHSA contracts with the Maryland Department of Health to act on behalf of the federal government and conduct state enforcement checks to a predetermined number of tobacco retailers in each county every year. No more than 20 percent of those checks can result in a violation of the law. These checks and this program are unrelated to U.S. FDA enforcement.

In fiscal years 2014 and 2015 Maryland became the first state to exceed the 20 percent retailer violation rate (24.1 percent and 31.4 percent, respectively). In response, Maryland launched the Responsible Tobacco Retailer Initiative (www.NoTobaccoSalesToMinors.com), which brought together local, community, and state partners to educate retailers on youth tobacco sales laws and increase enforcement of these laws. The Initiative was successful, and retailer violation rates dropped to 10.8 percent initially in 2016. In recent years, the retailer violation rate has begun to increase in Maryland, as well as dozens of other states. This is believed to be due to the lack of enforcement during the COVID-19 pandemic and national emergency.

State Regulation of Tobacco Products and Important Maryland Actors

The Master Settlement Agreement

In the mid-1990s, Maryland and most other states sued the largest cigarette companies for deceptive practices in making and marketing cigarettes. Some of these practices included deliberately making cigarettes more addictive and deadly while intentionally misrepresenting the risks. The states sought court orders modifying the companies' marketing practices and money damages to pay for increased medical costs caused by tobacco-related diseases. In 1998, the companies and states entered into a comprehensive settlement of all these claims, requiring the companies to change their marketing practices and pay billions of dollars to the states over time. This settlement is called the Tobacco Master Settlement Agreement (MSA). The MSA requires cigarette companies to pay approximately \$6 billion to the states collectively every year. Their payments will continue in perpetuity, meaning that the companies will pay for as long as they sell cigarettes anywhere in the United States. Maryland receives 2.26% of the companies' annual settlement payment; all of which goes into the Cigarette Restitution Fund (CRF) which is used to fund the Tobacco Use Prevention and Cessation Program and the Cancer Prevention, Education, Screening, and Treatment Program.

Maryland Department of Health (MDH)

The Center for Tobacco Prevention and Control (CTPC) at MDH is the administrator of the CRF and funds all 24 local health departments and other state partners to complete tobacco prevention and control activities. They work with community partners, state agencies, healthcare entities, resource centers, and local health departments to implement proven strategies to protect Maryland residents from tobacco-related death and disease.

Alcohol, Tobacco, and Cannabis Commission (ATCC)

The Alcohol and Tobacco Commission (ATC) was an independent commission established through the passage of HB1052 (2019) and became effective in January 2021. The law created the Commission, Office of the Executive Director, and the Field Enforcement Division. The ATC consisted of five people who were appointed to a five-year term by the Governor of Maryland with the advice and consent of the Senate.

On May 3, 2023, the ATC evolved into the Alcohol, Tobacco, and Cannabis Commission (ATCC) following the enactment of HB556 (2023). The ATCC is comprised of seven people who are appointed for a five-year term by the Governor of Maryland, with the advice and consent of the Senate. The ATCC also includes ex-officio members from MDH and the Maryland State Police. The ATCC regulates the alcohol and tobacco industries in Maryland and collaborates with the Maryland Cannabis Administration in managing the medical and retail cannabis sectors. As it relates to tobacco, the ATCC has authority to reprimand, suspend, or revoke a license if a retailer is found out of compliance with Maryland law.

ATCC Enforcement- Sales to Underage Persons

If convicted of a criminal violation for selling a tobacco product to a person under age 21, twice in a twelve-month period, the ATCC is required to suspend a retailer's license for up to 90 days and upon a third conviction up to 180 days. For a subsequent conviction, the ATCC must revoke the license.

If a retailer violates local or state civil statutes or the TCA, by selling tobacco products to underage persons twice in twelve months, the ATCC will accept referrals and schedule a hearing to determine whether action will be taken on the license. However, it is not required to suspend or revoke the license. The ATCC's detailed guidance is available at https://content.govdelivery.com/attachments/MDCOMP/2024/05/02/file_attachments/286629 7/TCB-24-002-Updated.pdf.

ATCC Enforcement: Flavored Cartridge-Based and Disposable ESDs

In January 2020, the U.S. FDA announced that it would be prioritizing its enforcement against companies manufacturing and selling cartridge-based ESDs. In response, the Office of the Comptroller, the tobacco regulatory agency in Maryland at the time, issued a bulletin announcing that the office would be prioritizing enforcement of cartridge-based and disposable ESDs with flavors other than tobacco or menthol. Citing its authority pursuant to Business Regulation §16.7-207(a)(5), a license to sell ESD products in Maryland may be subject to disciplinary action if a licensee does not comply with local, state, or federal law. Because no flavored ESD product had yet been granted an FDA marketing order, all contemporary products on the market were technically being sold illegally, and the Comptroller opted to take action.

Agents from the Comptroller's Field Enforcement Division immediately conducted product inspections to ensure compliance with this change. When the ATCC took over as regulatory agency in 2021, they began to enforce this directive which is still in effect. If you see flavored cartridge-based and disposable ESDs being sold in Maryland, you can report it to the ATCC. The full bulletin is available at

https://atcc.maryland.gov/Documents/Publications/Tobacco Tax Bulletins/bl tt77.pdf.

State Preemption

Preemption occurs when a higher level of government limits or eliminates the power of a lower level government to regulate certain issues. Local jurisdictions in Maryland have limited authority to pass and enforce local tobacco laws because of Maryland's high court decision in *Altadis U.S.A. v. Prince George's County, Maryland*. In 2009, the Prince George's County Council passed an ordinance regulating the packaging of cheap cigars. The cigar industry sued Prince George's County and in 2013, the Maryland Court of Appeals (now the Maryland Supreme Court) found that local governments are preempted from enacting laws relating to cigar packaging. This decision has been interpreted broadly, and local governments have hesitated to enact laws relating to the sale and distribution of all non-vape tobacco products. The decision fundamentally altered the legal landscape in Maryland. Jurisdictions have been hesitant to propose laws regulating the sale and use of tobacco products for fear of lengthy and expensive legal challenges. Furthermore, some jurisdictions have stopped enforcing local laws that existed prior to the *Altadis* decision. This issue has been taken up with the Maryland General Assembly on multiple occasions but has yet to be corrected.

Relevant Maryland Laws

Maryland laws are listed in the Maryland Code which is available for free at https://govt.westlaw.com/mdc/Index?contextData=%28sc.Default%29&transitionType=Default. Searching on the website is relatively intuitive. For example, to search "Business Regulation Article, Title 16.5," first click on the Business Regulation Article and then scroll down to click on Title 16.5.

A list of state and local laws are also available at www.mdtobaccolaws.org and additional information is available on the MDH website at

https://health.maryland.gov/notobaccosalestominors/Pages/home.aspx.

Maryland Clean Indoor Air Act of 2007 (CIAA)

Codified in the Maryland Code, Health-General Article, §§ 24-501 et seq., the CIAA prohibits smoking and vaping (including hemp and cannabis) in virtually all indoor workplaces to "preserve and improve the health, comfort, and environment of the people of Maryland by limiting exposure to environmental tobacco smoke." The law provides for fair and consistent statewide protection from exposure to secondhand smoke and vape in indoor settings.

Specifically, people are not allowed to smoke or vape in:

- Government-owned mass transportation;
- An indoor place of employment;

An indoor area open to the public which is defined as an indoor area or a portion of an
indoor area accessible to the public by either invitation or permission or an indoor area
of any establishment licensed or permitted under the Alcoholic Beverages and Cannabis
Article for the sale or possession of alcoholic beverages.

There are a few exceptions to the CIAA. A person can smoke in:

- Private residences unless being used by a person who is licensed to provide childcare;
- Private vehicles unless being used for the public transportation of children or as part of health care or childcare transportation;
- A hotel or motel room as long as the total percent of smoking rooms does not exceed 25%;
- A retail tobacco business in which the primary activity is the retail sale of tobacco
 products and accessories and the sale of other products is incidental (incidental is
 interpreted as approximately 25%, however, MDH is working to clarify this meaning);
- Any facility of a manufacturer, importer, wholesaler, or distributor of tobacco products or of any tobacco leaf dealer or processor in which employees of the manufacturer, importer, wholesaler, distributor, or processor work or congregate;
- A research or educational laboratory for the purpose of conducting scientific research into the health effects of tobacco smoke

Local Health Departments may enforce the provisions of the CIAA. The <u>Maryland Department of Health</u> provides guidance on how to file a complaint.

Licenses

Any tobacco product retailer in Maryland is required to obtain a license issued by the Clerk of Courts for the county where the business is located.

The provisions governing the requisite cigarette license can be found in the <u>Maryland Code</u>, <u>Business Regulation Article</u>, <u>Title 16</u>. The clerk issues a license to act as a retailer to each qualified business. Each business location needs a separate license. The license fee is \$300.

The provisions governing other tobacco products (OTP) licenses can be found in the Maryland Code, Business Regulation Article, Title 16.5. OTP includes cigars, premium cigars, pipe tobacco, chewing tobacco, snuff, snus, filters, rolling papers, pipes, and hookahs. OTP does not include cigarettes, electronic smoking devices, or U.S. FDA-approved smoking cessation drugs/devices. A person can get an OTP retailer license or a tobacconist license. An OTP retailer is a person who sells OTP to consumers or holds OTP for sale to consumers. A tobacconist is an OTP business that derives at least 70 percent of its revenues, measured by average daily receipts, from the sale of OTP and tobacco–related accessories; this is commonly associated with hookah bars and premium cigar shops. The clerk issues a license to act as an OTP retailer or tobacconist to each qualified business. Each business location needs a separate license.

The provisions governing electronic smoking device (ESD) licenses can be found in the <u>Maryland Code</u>, <u>Business Regulation Article</u>, <u>Title 16.7</u>. An ESD is a device that can be used to deliver aerosolized or vaporized nicotine to an individual inhaling from the device, this includes an electronic cigarette, an electronic cigar, an electronic cigarillo, an electronic pipe, an electronic

hookah, a vape pen, vaping liquid and any component, part, or accessory. An ESD retailer is a person that sells ESDs to consumers, holds ESDs for sale to consumers, or distributes sample ESDs to consumers in the state when allowed. A vape shop vendor is an ESD business that sells ESDs and related accessories to consumers on the premises of its place of business. The clerk issues a license to act as an ESD retailer or vape shop vendor to each qualified business. Each business location needs a separate license. The license fee is \$300. If a person is already licensed under Title 16 or 16.5 the person does not need a separate license under 16.7 to sell ESDs. An ESD retailer is a person that sells ESDs to consumers, holds ESDs for sale to consumers, or distributes sample ESDs to consumers in the state when allowed. A vape shop vendor is an ESD business that sells ESDs and related accessories to consumers on the premises of its place of business. The clerk issues a license to act as an ESD retailer or vape shop vendor to each qualified business. Each business location needs a separate license. The license fee is \$300. If a person is already licensed under Title 16 or 16.5 the person does not need a separate license under 16.7 to sell ESDs.

Civil and Criminal Offenses

A local health department has the authority to civilly enforce or use law enforcement to criminally cite a retailer for selling a tobacco product to a person under age 21. Local health departments are at liberty to choose which type of citation to use but the same transaction/offense may not be prosecuted as both civil and criminal offenses.

Civil Citations (Maryland Code, Health-General Article, §§ 24-305 (ESD) and 24-307 (tobacco products))

- The sale of a tobacco product to a person under age 21 is punishable by:
 - o First Offense: Fine of up to \$300
 - Second Offense: Fine of up to \$1,000 (if within 24 months of a prior violation)
 - Additional Offenses: Fine of up to \$3,000 (if within 24 months of a prior violation)
- The owner/licensee is responsible for the civil penalty whether or not they made the illegal sale. Therefore, citing the clerk is futile and the licensee should be cited accordingly.
- Other "persons" may also be cited if they distribute these products commercially, even if they are not licensed.
- The ATCC advises sending a referral to pursue administrative license violations against a tobacco retailer following at least two (2) documented sales to individuals under 21 that occurred at the same licensed location within 12 months.

Criminal Offenses (Maryland Code, Criminal Article, § 10-107)

- The sale of tobacco products to those under age 21 may be a criminal misdemeanor, punishable by:
 - o First Offense: Fine of up to \$500
 - Second Offense: Fine of up to \$1,000 (if within 24 months of first violation)
 - o Additional Offenses: Fine of up to \$3,000 (if within 24 months of a prior violation)
- The owner, licensee, or both may be cited criminally and/or responsible for money penalties.

Taxation

Different tobacco products are taxed at different rates. The tobacco tax rates are found in the Maryland Code, Tax-General Article, § 12-105.

Cigarettes	\$5.00 for each package of 20 cigarettes
	25 cents for each cigarette in a package of more than 20 cigarettes
OTP except cigars	60% of the wholesale price of the product
Cigars	70% of the wholesale price of the cigar
Premium cigars	15% of the wholesale price of the premium cigar
Pipe tobacco	30% of the wholesale price of the pipe tobacco

Product Placement

All tobacco products except for premium cigars, including cigarettes, cigars, ESDs, snus, nicotine pouches, etc., are required to be located behind a counter in an area accessible only to the licensed retailer and employees of the licensed retailer. This provision does not apply to licensed tobacconists.

ID Checks

A retailer cannot sell any tobacco product to a person under 21 and the person making the sale is required to check the purchaser's government-issued ID if the purchaser is under 30 before selling the product in a direct face-to-face exchange.

This document was developed by the Legal Resource Center for Public Health Policy in consultation with the Maryland Department of Health.