On September 22, 2009, the Food and Drug Administration (FDA), under authority granted by the Family Smoking Prevention and Tobacco Control Act, prohibited cigarettes from containing any “characterizing flavor,” including candy, fruit, and alcohol flavors.¹

This prohibition extends to flavored cigarettes and flavored cigarette “component parts,” such as their “tobacco, filter or paper.”² However, the prohibition exempts the flavors of menthol and tobacco and does not apply to non-cigarette tobacco products.

Flavored tobacco products appeal to youth, who are an enticing target market.

The Tobacco Control Legal Consortium has created this series of legal technical assistance guides to serve as a starting point for organizations interested in implementing certain tobacco control measures. We encourage you to consult with local legal counsel before attempting to implement these measures.³ For more details about the following policy considerations, please contact the Consortium.
Although the FDA and its scientific advisory committee have conducted two in-depth studies of menthol as a characterizing flavor in cigarettes, the agency has not indicated that a regulation of menthol is on the horizon.\(^4\) In addition, the FDA’s regulation asserting jurisdiction over non-cigarette tobacco products — also known as its “deeming regulation” — does not extend the flavor restriction to non-cigarette tobacco products.\(^5\) As a result, menthol cigarettes remain on the market, as do many other flavored tobacco products, such as electronic cigarettes, cigars, smokeless tobacco, hookah tobacco (“shisha”), little cigars, and dissolvable tobacco products (e.g., strips and orbs), as well as flavored component parts (e.g., blunt wraps). Federal law allows state and local governments to regulate the sale of tobacco products, including flavored tobacco products and their component parts.

Studies show that flavored tobacco products appeal to youth,\(^6\) who are an enticing target market for the tobacco industry. Research suggests that most smokers try cigarettes before turning 18\(^7\) and that most teens start with flavored tobacco products.\(^8\) Tobacco users (particularly youth) may mistakenly assume that flavored tobacco products are safer than other tobacco products.\(^9\) The presence of flavors such as menthol in tobacco products might also make it more difficult for adult tobacco users to quit.\(^10\)
On July 28, 2017, the FDA announced a comprehensive regulatory plan for tobacco products that prioritizes restrictions on kid-attractive flavors, including menthol, and establishes a cohesive agency-wide approach to nicotine. In the meantime, given the significant threat to public health that flavored tobacco products pose, many local and state governments are considering ways to regulate their sale, pricing, marketing and advertising. This guide provides pointers that local and state health departments, communities and policy makers might want to consider in drafting and implementing policies that regulate flavored tobacco products.

**Policy Options**

- **Sales restrictions.** Some state and local governments have passed laws that restrict the sale of various flavored tobacco products. Providence, Rhode Island and Boston, Massachusetts, for example, prohibit the sale of flavored, non-cigarette tobacco products (including electronic cigarettes), with exceptions for menthol, wintergreen, mint, or tobacco-flavored products. New York City has enacted restrictions on the sale of flavored tobacco products other than cigarettes, with exceptions for electronic cigarettes and menthol, mint, wintergreen, or tobacco-flavored products. The tobacco industry has challenged the New York City and Providence ordinances but both have been upheld by federal appeals courts as valid exercises of local authority to regulate the sale and distribution of tobacco products. Moreover, the state of Maine has restricted the sale of flavored cigars. (See the Consortium’s chart, U.S. Sales Restrictions on Flavored Tobacco Products, which contains more examples of select U.S. jurisdictions where the sale of flavored tobacco products is restricted.)

Communities might also consider prohibiting sales of flavored tobacco products at certain locations such as stores within a certain distance of schools or other youth-oriented facilities, gas stations, convenience stores, pharmacies or grocery stores. Chicago, for example, passed an ordinance prohibiting the sale of flavored tobacco products, including menthol products, within 500 feet of certain city schools. Again, as with any sales prohibition, proponents should be able to show that these restrictions serve a legitimate government interest (e.g., by reducing youth access to tobacco products in the community).

- **Advertising and promotion restrictions.** Any community considering regulating tobacco ads needs to be aware of the First Amendment, which extends some protection to commercial speech, and the Federal Cigarette Labeling and Advertising Act (FCLAA), which limits the ability of state and local governments to place restrictions on the content of cigarette advertisements or promotions. Communities may be able to restrict the advertising or promotion of flavored tobacco products in several ways.
The advertising of flavored tobacco products is often targeted at shoppers inside, outside, and on the property of convenience stores, drug stores, gas stations, and other retail sales outlets. To prevent children from being exposed to advertising and self-service racks, communities could consider restricting the placement of in-store tobacco advertisements. General restrictions on the quantity or size of signs that may appear in store windows or on sidewalks outside retail stores might also help reduce tobacco advertising, along with other kinds of advertising.\textsuperscript{20} Such regulations need to be drafted carefully to avoid the risk of legal challenges related to First Amendment concerns.\textsuperscript{21}

- **Graphic warnings.** Another way to regulate flavored tobacco products in the retail environment is to require tobacco retailers to place graphic warning signs at or near the point of sale to warn of the dangers of tobacco use. These signs should make clear that the warnings are issued by the government — not the tobacco industry or retailers — to counter potential arguments that the government is compelling speech in violation of the First Amendment.\textsuperscript{22}

- **Restricting product access.** Communities seeking to restrict how products are distributed or sold could require all flavored tobacco products to be sold via face-to-face transactions, thus prohibiting vending machines and self-service racks. Such regulations need to be drafted carefully to avoid the risk of legal challenges related to First Amendment concerns.\textsuperscript{23}

- **Regulating tobacco product pricing.** Studies have suggested that the more tobacco products cost, the less likely youth are to start or keep smoking.\textsuperscript{24} Consequently, local and state governments can consider regulating retail value-added promotions and other marketing techniques for flavored tobacco products. For example, some communities restrict and even prohibit price discounts provided by tobacco manufacturers or retailers, such as multi-pack offers (e.g., buy two packs, get one free), product giveaways, samples, or point redemption schemes.\textsuperscript{25} Another price regulation option is to increase taxes on flavored tobacco products, or to ensure that taxes on non-cigarette products are equivalent to taxes on cigarettes.\textsuperscript{26}

**Policy Elements**

Well-crafted restrictions on flavored tobacco products are explicit about what they cover, and how communities will implement and enforce them. Here are a few elements found in such policies:

- **Timely findings and clear statements of purpose:** Findings are brief statements of fact or statistics that outline the issue being addressed, support the need for the policy, and help clarify the policy goal. Regulations on the sale, marketing and advertising of flavored tobacco products typically include evidence showing how the products create a problem within the community or state (e.g., documentation about the disproportionate use of flavored
tobacco products by youth or how flavored products impede adult cessation efforts), and explain how the policy is designed to address this problem.

If a policy is challenged in court, a good set of findings can help to support it. For example, findings can explain that the local government’s authority to enact the policy comes from its responsibility to protect public health and welfare, and can explain how the policy furthers those goals.

- **Clear definitions and concise language:** Avoid confusion about what constitutes a “flavored tobacco product” by clearly defining critical terms. Because the Family Smoking Prevention and Tobacco Control Act prohibits the manufacture and sale of flavored cigarettes (except menthol and tobacco-flavored), be careful that the combination of the local law and the federal law will leave no gaps in covered products. For example, draft the definition of “tobacco product” broadly so it encompasses menthol cigarettes as well as flavored cigars, little cigars, electronic cigarettes, spit/chewing tobacco, dissolvable tobacco products, tobacco lozenges, and other emerging smokeless products. Also, because descriptions such as “mellow” or “arctic” can imply a flavor, and because testing for actual flavoring may be difficult or expensive, consider regulating all products that are marketed as having a distinguishable, distinctive or characterizing flavor or smell.
• **Clear scope of regulation:** Under the Family Smoking Prevention and Tobacco Control Act, the FDA (and not state or local governments) has the power to regulate tobacco product standards. Although prohibiting the sale of a certain type of product, such as a flavored tobacco product, does not set a product standard, the tobacco industry has argued that such a law does resemble a product standard. As a result, a restriction on the sale of flavored tobacco products — often enacted to protect youth or to support adult quit attempts by reducing the number of locations where the products are available — might be easier to defend if it allows the products to be sold by a narrow class of businesses, such as limited types of adult-only facilities.

• **Robust enforcement options:** Regulating the advertising, promotion and sale of flavored tobacco products can be challenging unless clear procedures are established, including reasonable penalty provisions. Ensure that the penalties proposed are appropriate and legal within the jurisdiction and that they are sufficient to cover all administrative expenses. Use clear terms to specify what behavior is prohibited and to whom the policy applies. It may be useful for the enforcement agency to maintain an updated list of all products determined to violate the ordinance. Also carefully consider the means by which products are determined to be flavored (perhaps including chemical testing) and who will bear the costs associated with such determinations.

Effective enforcement of these policies often includes coordination among different enforcement agents, such as law enforcement agencies and administrative agencies, and adherence to consistent procedures throughout a community. The penalties section of the policy should clearly identify when people can be found in violation of the policy, and the penalties or fines imposed for first, second and subsequent violations. Ideally, this section would be part of a licensing system that would include a licensing suspension for a third violation and revocation for additional violations. Consider whether the ordinance will specify the assessment of re-inspection fees against repeat violators of the ordinance.

• **Well-planned implementation process:** Establish a process for publicizing the policy and educating the community, as well as procedures for receiving, tracking and responding to complaints. Make sure to set a realistic date for the policy to take effect, so responsible authorities have sufficient time to establish the necessary procedures for implementation and enforcement, and to notify affected business owners of their obligations under the policy. For instance, it may be helpful to create educational materials for distribution to tobacco retailers informing them of the ordinance’s key provisions, explaining how existing inventories may be treated (and allowing time for existing inventories to be depleted), and providing them an opportunity to ask questions.
Policy Challenges

State and local governments have the authority to pass, implement and enforce laws that regulate the sale of tobacco products, and they can do so in a way that addresses local concerns. Still, due to the tobacco industry’s interest in protecting its profits, even the most carefully drafted local tobacco regulation cannot avoid all risk of legal challenge. Communities considering measures to regulate flavored tobacco products should keep in mind that policies need to be drafted carefully and precisely, with an eye on potential legal issues, such as preemption, and that broad sweeping policies may be more vulnerable to legal challenge than narrow local policies.29

Also, communities considering raising taxes on flavored tobacco products will need to address criticism that tax increases have a disproportionate impact on people in poorer communities, where tobacco use rates are high, and that increased taxation serves only to create greater economic hardship. The counterpoint is that a tobacco product tax is not a tax on a necessity and the public health goals justifying the increased taxation of tobacco products far outweigh the potential for economic harm.
Select Legislation and Policies

Below are examples of flavored tobacco product regulations and legislation around the U.S. If you consider adapting any language from these policies, take care to ensure the provision in question is practical and legal in your jurisdiction. Please note that the Consortium does not endorse or recommend any of the following policies. These examples are included simply to illustrate how various jurisdictions have approached similar issues.30

<table>
<thead>
<tr>
<th>Policy Type</th>
<th>Organization/Jurisdiction</th>
<th>Statute/Regulation/Directive</th>
<th>Select Excerpt of Law</th>
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<tbody>
<tr>
<td>Prohibits manufacture, marketing &amp; sale of flavored cigarettes</td>
<td>Food &amp; Drug Administration</td>
<td>Family Smoking Prevention and Tobacco Control Act § 907: Tobacco Product Standards (codified at 21 U.S.C. § 387g)</td>
<td>... a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural ... a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke.</td>
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<td>Restricts sale of flavored tobacco products, including menthol, within 500 ft. of city middle and high schools</td>
<td>Chicago, Ill., Code §§ 4-64-098, 4-64-180(b) (2016): Flavored Tobacco Products</td>
<td>“Flavored tobacco product” means any tobacco product that ... imparts a characterizing flavor. As used in this definition, the term “characterizing flavor” means a distinguishable taste or aroma, other than the taste or aroma of tobacco, imparted either prior to or during consumption of a tobacco product, including, but not limited to, tastes or aromas of menthol, mint, wintergreen, chocolate, vanilla, honey, cocoa, any candy, any dessert, any alcoholic beverage, any fruit, any herb, and any spice; provided, however, that no tobacco product shall be determined to have a characterizing flavor solely because of the use of additives or flavorings or the provision of ingredient information.</td>
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<td>Restricts sale of flavored cigars</td>
<td>Maine</td>
<td>Me. Stat. tit. 22, § 1560-D (2017): Flavored cigars</td>
<td>“Characterizing flavor” means a distinguishable taste or aroma of candy, chocolate, vanilla, fruit, berry, nut, herb, spice, honey or an alcoholic drink that is imparted to tobacco or tobacco smoke either prior to or during consumption. “Characterizing flavor” does not include a taste or aroma from tobacco.... Except as provided in subsection 5-A, a person may not sell or distribute or offer to sell or distribute in this State any flavored cigar unless the cigar is a premium cigar.... Any flavored cigar that the Attorney General determined had no characterizing flavor or was otherwise exempt under former subsection 5 is exempt from the prohibition on flavored nonpremium cigars in subsection 2 so long as no material change is made to the cigar’s flavoring, packaging or labeling subsequent to the Attorney General’s determination.</td>
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<tr>
<td>Prohibits sale of many flavored tobacco products except in certain adult-only venues</td>
<td>New York City</td>
<td>N.Y.C. Admin. Code, Title 17-713 to 17-718: Regulation of the sale of herbal cigarettes and flavored tobacco products (link instructions: click on “ADC” to find the Administrative Code)</td>
<td>“Flavored tobacco product” means any tobacco product or any component part thereof that contains a constituent that imparts a characterizing flavor.... “Characterizing flavor” means a distinguishable taste or aroma, other than the taste or aroma of tobacco, menthol, mint or wintergreen, imparted either prior to or during consumption of a tobacco product or component part thereof, including, but not limited to, tastes or aromas relating to any fruit, chocolate, vanilla, honey, candy, cocoa, dessert, alcoholic beverage, herb or spice; provided, however, that no tobacco product shall be determined to have a characterizing flavor solely because of the use of additives or flavorings or the provision of ingredient information.... It shall be unlawful for any person to sell or offer for sale any flavored tobacco product except in a tobacco bar.31</td>
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<tr>
<td>Prohibits sale of many flavored tobacco products except in certain adult-only venues</td>
<td>Providence, Rhode Island</td>
<td>Providence, R.I., Code, §§ 14-308 to 14-310</td>
<td>“Flavored tobacco product” means any tobacco product or any component part thereof that contains a constituent that imparts a characterizing flavor.... “Characterizing flavor” means a distinguishable taste or aroma, other than the taste or aroma of tobacco, menthol, mint or wintergreen, imparted either prior to or during consumption of a tobacco product or component part thereof, including, but not limited to, tastes or aromas relating to any fruit, chocolate, vanilla, honey, candy, cocoa, dessert, alcoholic beverage, herb or spice ... provided, however, that no tobacco product shall be determined to have a characterizing flavor solely because of the use of additives or flavorings or the provision of ingredient information.... It shall be unlawful for any person to sell or offer for sale any flavored tobacco product to a consumer, except in a smoking bar.</td>
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<tr>
<td>Prohibits sale of many flavored tobacco products in all locations</td>
<td>Sherborn, Massachusetts</td>
<td>Sherborn Board of Health Regulation Restricting the Sale and Use of Tobacco and Nicotine Delivery Products</td>
<td>[“Flavored Tobacco Product and Flavored Nicotine Delivery Product” means any tobacco product or nicotine delivery product including e-cigarettes defined herein, or component part thereof that contains a constituent that has or produces a characterizing flavor [excluding tobacco, menthol, mint or wintergreen]. A public statement, claim or indicia made or disseminated by the manufacturer of a tobacco product or nicotine delivery product, including e-cigarettes as defined herein, or by any person authorized or permitted by the manufacturer to make or disseminate public statements concerning such product, that such product has or produces a characterizing flavor shall constitute presumptive evidence that the product is a flavored tobacco product or nicotine delivery product, including e-cigarettes as defined herein.... No person shall sell or distribute or cause to be sold or distributed any flavored tobacco or nicotine delivery product.</td>
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Other Helpful Resources

The Consortium’s parent organization, the Public Health Law Center, has webpages containing information on federal regulation of tobacco products, as well as tobacco product regulation at the state and local levels. Our site also provides several resources on regulating flavored tobacco products, including pages devoted to flavored and menthol tobacco products, as well as e-cigarettes. Our site also has resources related to tobacco product advertising, marketing, and pricing. In addition, the Campaign for Tobacco-Free Kids has information on flavored tobacco products, including dissolvables.

Contact Us

Please feel free to contact the Tobacco Control Legal Consortium at publichealthlawcenter@mitchellhamline.edu with any questions about the information included in this guide or to discuss local concerns you may have about implementing any of these policies.

This publication was prepared by the Tobacco Control Legal Consortium, a program of the Public Health Law Center at Mitchell Hamline School of Law, St. Paul, Minnesota. The Public Health Law Center provides information and legal technical assistance on issues related to public health. The Center does not provide legal representation or advice. This document should not be considered legal advice.

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Endnotes

1 Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31 § 102, 123 Stat. 1776 (codified as amended in 2009 in scattered sections of 15 U.S.C. and 21 U.S.C.). According to the Act: “a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke.” 21 U.S.C. § 387g(a)(1)(A) (2017). See also Flavored Tobacco, Food & Drug Admin., https://www.fda.gov/tobaccoproducts/labeling/productsingredientscomponents/ucm2019416.htm (last updated Apr. 14, 2017).

2 Ctr. For Tobacco Products, Food & Drug Admin., Guidance to Industry and FDA Staff: General Questions and Answers on the Ban of Cigarettes that Contain Certain Characterizing Flavors 1 (2d ed.) (2009), https://www.fda.gov/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm183228.htm.
3 The information contained in this document is not intended to constitute or replace legal advice. When available, laws referenced in this document are cited with a link to a publicly accessible database and the year in which that law was last reviewed in the database. Laws without links reference the year of last review in Westlaw.


8 Bridget K. Ambrose et al., Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014, 314 J. Am. Med. Ass’n 1871 (2015), http://jamanetwork.com/journals/jama/fullarticle/2464690 (“The majority of youth ever-users reported that the first product they had used was flavored, including 88.7% of ever hookah users, 81.0% of ever e-cigarette users, 65.4% of ever users of any cigar type, and 50.1% of ever cigarette smokers. For past 30-day youth tobacco use, the overall proportion of flavored product use was 79.8% (95% CI, 77.3%-82.3%) among users of any product and 89.0% among hookah users, 85.3% among e-cigarette users, 71.7% among users of any cigar type, and 59.5% among cigarette smokers.”).


14 U.S. Smokeless Tobacco Mfg. Co. v. City of New York, 708 F.3d 428 (2d Cir. 2013); Nat’l Ass’n of Tobacco Outlets, Inc. v. City of Providence, 731 F.3d 71 (1st Cir. 2013).


17 See Chicago, Ill., Code §§ 4-64-098, 4-64-180(b) (2016), http://library.amlegal.com/nxt/gateway.dll/Illinois/chicago_il/title4businessesoccupationsandconsumerpr/chapter4-64tobaccodealers?ftemplates$fn=default.html&m3=0$vid=amlegal:chicago_il$anc=JD_4-64-010. The ordinance exempts retail tobacco stores.


22 New York City adopted a requirement that cigarette retailers display signs graphically depicting the adverse health effects of smoking, but a federal court struck down this ordinance as violating the preemption clause of the Federal Cigarette Labeling and Advertising Act. 23-34 94th St. Grocery v. N.Y.C. Board of Health, 685 F.3d 174 (2d Cir. 2012). However, because that case turned on preemption relative to cigarettes, it would not be directly relevant to an ordinance requiring point-of-sale warnings depicting the health effects of non-cigarette tobacco products. In addition, the court said that cigarette graphic warnings, if done differently, could be valid.


27 If it is not politically feasible to prohibit the sale of menthol cigarettes, and only flavored non-cigarette tobacco products are targeted by the local law, make sure that the language is precise so that products such as little cigars are not inadvertently exempted as well.


29 See, e.g., Point-of-Sale Strategies, supra note 18, at 12-14.

30 See also U.S. Sales Restrictions on Flavored Tobacco Products, supra note 16.

31 The Second Circuit Court of Appeals noted that “there are only eight tobacco bars in New York City, all of which are in Manhattan and none of which sells flavored smokeless tobacco,” but upheld the ordinance nonetheless. 708 F.3d 428, 432, 436 (2013).

32 The ordinance originally included the language “and concepts such as spicy, arctic, ice, cool, warm, hot, mellow, fresh, and breeze.” However, a federal district court found this language to be unconstitutionally vague and struck it from the ordinance. See Nat’l Ass’n of Tobacco Outlets, Inc. v. City of Providence, No. 12-96-ML, 2012 WL 6128707, *8 (D.R.I. Dec. 10, 2012).