



Regulating E-Cigarettes

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.¹ For more details about these policy considerations, please contact the Consortium.

Electronic Cigarettes (E-Cigarettes)

Electronic nicotine delivery systems (“electronic cigarettes” or “e-cigarettes”) are products often shaped like cigarettes, cigars or pipes that are designed to deliver nicotine or other substances to a user in the form of a vapor. Typically, e-cigarettes consist of battery-powered heating elements and replaceable cartridges that contain nicotine or other chemicals, and an atomizer that, when heated, converts the contents of the cartridge into a vapor that a user inhales.

First marketed in China in 2004, these products are now available around the world, thanks largely to Internet sales and aggressive marketing claims promoting the safety, convenience and cost-effectiveness of e-cigarettes over conventional cigarettes. E-cigarette manufacturers also claim that because their products are non-combustible and emit a vapor rather than secondhand smoke they can be legally used where traditional tobacco products are banned. While [proponents of e-cigarettes](#), including [some](#) in the public health community, view them as less hazardous alternatives to combustible cigarettes, others see them as gateway products to tobacco abuse and nicotine addiction and support their restriction or even removal from the market. Those in favor of regulating the product point out that e-cigarette cartridges are available in a variety of flavors that appeal to youth (such as bubblegum, chocolate and mint), and can be purchased at mall kiosks, where young people often congregate, as well as online, where safeguards against youth access can be breached more easily than in face-to-face purchases.



Public health authorities generally agree on the need for further scientific study to confirm the products’ unproven safety claims.² The [Food and Drug Administration](#) (FDA) and many leading public health organizations have expressed concern about the

lack of clinical studies on the potential health risks posed by e-cigarettes and the way these products are marketed without appropriate health warnings or legal age restrictions. In recent years, litigation between the FDA and e-cigarette manufacturers stemming from concerns about the safety and regulatory status of these products resulted in a temporary ban on the import of e-cigarettes into the United States.³ Today, as discussed below, federal policy regarding the regulation of e-cigarettes is in transition. This brief guide provides pointers for communities and policy makers to consider when drafting or implementing laws or policies that regulate e-cigarettes.

Policy Options

Public health organizations support regulating e-cigarettes for several reasons, such as: reducing youth initiation to nicotine and tobacco products, protecting the health of all users, and promoting the enforcement of smoke-free laws. There are several policy options that can advance these public health goals.

Regulating Sale. As discussed below, the FDA is developing a strategy to regulate e-cigarettes containing tobacco as tobacco products. State and local governments are not prevented from regulating the sale of tobacco products.⁴ For example, a government could prohibit the sale of such products anywhere within its jurisdiction, prohibit the sale of such products to minors, require these products to be kept behind the counter, or allow these products to be sold only in places adults are permitted to enter.

Regulating Marketing. State and local governments have an interest in protecting the public from false or misleading claims about any product. Prohibiting e-cigarette manufacturers and retailers from making unsubstantiated marketing claims about the safety and benefits of these products is in the best interest of public health. Every state and some local governments have laws in place to control misleading product claims, and these laws may be enforceable against some e-cigarette marketing efforts. For instance, state consumer protection and unfair trade practices statutes typically prohibit false or misleading advertising about products sold within the state. State and local governments may also be able to consider options designed to limit the targeted marketing of e-cigarettes to minors. While commercial speech concerns can be a part of such a policy consideration,⁵ thought should be given to how e-cigarettes are promoted in a community and whether restrictions can be placed on those efforts. Notably, a law prohibiting the sale of e-cigarettes would also be likely to substantially reduce the marketing of these products.

Regulating Use. Proponents of e-cigarettes claim these products are safer to use than traditional tobacco products, and do not expose bystanders to the risk of secondhand smoke.⁶ Yet concern about the lack of scientific data on e-cigarettes has caused a growing number of state and local governments to prohibit their use in various public places—often under existing or new smoke-free laws. The goal of such legislation is generally to minimize the use of products that pose unknown health risks – particularly unregulated products that deliver powerful drugs, such as nicotine, to the user. Another legislative goal is to prevent confusion in the enforcement of smoke-free laws caused by

the perception that e-cigarette smokers (also known as “vapers”) are actually smoking conventional cigarettes. Omitting e-cigarettes from smoke-free laws could cause conventional smokers to assume that smoking is permitted and nonsmokers might become needlessly concerned at what they see as a violation of a smoke-free law.

Policy Elements

Regardless of the type of policy effort pursued to regulate e-cigarettes, each policy shares a few common elements, such as:

- **Clear definitions and concise language:** To avoid confusion about what constitutes an e-cigarette, make sure your definitions are explicit about what they cover and broad enough to anticipate future product innovations. This eliminates ambiguity if new products are released that are similar to e-cigarettes but do not fall under a narrow definition.
- **Robust enforcement options:** Enforcing restrictions on the sale, marketing and use of e-cigarettes can be challenging unless clear procedures are established, including a reasonable penalty and appeal process. Effective enforcement of these policies often includes coordination among different enforcement agencies and consistent procedures throughout a community.
- **Well-planned implementation process:** Establish a process for publicizing the policy and educating the community, as well as procedures for receiving, tracking and following up on complaints. Make sure you set a realistic date for the policy to take effect.

Policy Challenges

One of the most controversial issues affecting the regulation of electronic cigarettes has been debate over their status as either drug delivery (e.g., smoking cessation) devices or tobacco products. The regulatory status of e-cigarettes was at the heart of recent litigation between the FDA and e-cigarette manufacturers, including *Sottera Inc. v. Food & Drug Administration*.⁷ Under the [Family Smoking Prevention and Tobacco Control Act](#) (Tobacco Control Act), the FDA has authority to regulate “any product made or derived from tobacco that is intended for human consumption.” The brands of e-cigarettes being marketed most widely today do not contain tobacco, but most often do contain nicotine extracted from tobacco.⁸ Between 2008 and 2010, the FDA determined that certain e-cigarettes were unapproved drug/device combination products, comparable to nicotine patches, which the agency has regulated for years under the drug and device provisions of the federal [Food, Drug and Cosmetic Act](#) (FDCA).

In December 2010, the U.S. Court of Appeals for the D.C. Circuit issued a decision in *Sottera*, stating that e-cigarettes and other products “made or derived from tobacco” are not “drugs,” “devices,” or combination products, unless they are marketed for therapeutic purposes – and that the FDA can regulate them as tobacco products under the Tobacco

Control Act. On April 25, 2011, the FDA [announced](#) it will not appeal the court's decision and that it is now developing a strategy to regulate e-cigarettes containing tobacco as tobacco products under the Tobacco Control Act. For the latest federal information about regulating e-cigarettes, visit the FDA's website at <http://www.fda.gov>.

As with any tobacco product, state and local policies restricting the sale and marketing of e-cigarettes may be subject to legal challenges, such as Commercial Speech or Commerce Clause claims.⁹ Policies regulating the use of e-cigarettes may also be challenged in court, particularly since e-cigarette restrictions are often included in smoke-free laws, requiring drafters to redefine "smoking" to include the use of not only cigarettes, cigars, pipes and other traditional tobacco products, but also e-cigarettes. Communities may want to consider a comprehensive approach that targets similarly addictive gateway products on the market now or in the future (such as nicotine water or lobelia e-cigarettes).

Select Legislation and Policies

Below are a few examples of tobacco control policies that include provisions regulating the sale, marketing or use of e-cigarettes.¹⁰ Many of these provisions are included in smoke-free laws. Local and state governments might also want to consider other legislative avenues or regulatory options, such as pricing strategies.

If you consider adapting any language from the following policies, take care to ensure the provision in question is practical and legal in your jurisdiction. Please note that the Tobacco Control Legal Consortium does not endorse or recommend any of the following policies. These examples are included simply to illustrate how various jurisdictions have defined and regulated these products.

Locality/State	Policy Name	Text of Policy
Minnesota	<u>Tobacco Modernization and Compliance Act of 2010, Minn. Stat. § 609.685</u>	<p>Regulates sale of e-cigarettes and imposes criminal penalties for the sale of nicotine or <u>lobelia</u> delivery products, including e-cigarettes, to minors.</p> <p>"Whoever sells to a person under the age of 18 years a product containing or delivering nicotine or lobelia intended for human consumption, or any part of such a product, that is not tobacco as defined by section 609.685, is guilty of a misdemeanor for the first violation. Whoever violates this subdivision a subsequent time within five years of a previous conviction under this subdivision is guilty of a gross misdemeanor."</p> <p>Definition: A nicotine delivery device is "a product containing or delivering nicotine or lobelia intended for human consumption, or any part of such a product, that is not tobacco as defined by section 609.685."</p>

New Hampshire	<u>An Act Prohibiting the Sale of E-Cigarettes to Minors, Chap. 0113</u>	Prohibits sale of e-cigarettes and liquid nicotine to minors, distribution of free samples of such products in a public place, and use of such products on grounds of any public educational facility. Definition: “ <i>E-cigarette</i> means any electronic smoking device composed of a mouthpiece, a heating element, a battery, and electronic circuits that provides a vapor of pure nicotine mixed with propylene glycol to the user as the user simulates smoking. This term shall include such devices whether they are manufactured as e-cigarettes, e-cigars, ore-pipes, or under any other product name.”
New Jersey	<u>New Jersey Smoke-Free Air Act, P. L. 2009, Chap. 182</u>	Prohibits the smoking of tobacco products and the use of electronic smoking devices in all enclosed indoor places of public access and workplaces. Definition: “ <i>Electronic smoking device</i> means an electronic device that can be used to deliver nicotine or other substances to the person inhaling from the device, including, but not limited to, an electronic cigarette, cigar, cigarillo, or pipe.”
Utah	<u>Utah Code § 76-10-101, 104, 105, 111</u>	Regulates sale, gift, or distribution of e-cigarettes by manufacturer, wholesaler, or retailer. Definition: “ <i>Electronic cigarette</i> means any device, other than a cigarette or cigar, intended to deliver vapor containing nicotine into a person’s respiratory system.”
Suffolk County, New York	<u>A Local Law Banning the Sale of E-Cigarettes to Persons Under the Age of 19, Local Law No. 29-2009</u>	Prohibits the sale of e-cigarettes to minors and “the use of e-cigarettes and like products in public places where traditional forms of smoking are already allowed.” Definition: “ <i>E-cigarette</i> shall mean any electronic device composed of a mouthpiece, heating element, battery and electronic circuits that provides a vapor of liquid nicotine and/or other substances mixed with propylene glycol to the user as he or she simulates smoking. This term shall include such devices whether they are manufactured as e-cigarettes, e-cigars, e-pipes or under any other product name.”
Organizations		
Americans for Nonsmokers’ Rights	<u>Model Ordinance</u>	Findings: “Unregulated high-tech smoking devices, commonly referred to as electronic cigarettes, or ‘e-cigarettes,’ closely resemble and purposefully mimic the

Prohibiting
Smoking in All
Workplaces and
Public Places

act of smoking by having users inhale vaporized liquid nicotine created by heat through an electronic ignition system. After testing a number of e-cigarettes from two leading manufacturers, the Food and Drug Administration (FDA) determined that various samples tested contained not only nicotine but also detectable levels of known carcinogens and toxic chemicals, including tobacco-specific nitrosamines and diethylene glycol, a toxic chemical used in antifreeze. The FDA's testing also suggested that "quality control processes used to manufacture these products are inconsistent or non-existent." ("Summary of results: laboratory analysis of electronic cigarettes conducted by FDA," *Food and Drug Administration (FDA)*, July 22, 2009; <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm173146.htm>.) E-cigarettes produce a vapor of undetermined and potentially harmful substances, which may appear similar to the smoke emitted by traditional tobacco products. Their use in workplaces and public places where smoking of traditional tobacco products is prohibited creates concern and confusion and leads to difficulties in enforcing the smoking prohibitions."

Definition: "*E-cigarette* means any electronic oral device, such as one composed of a heating element, battery, and/or electronic circuit, which provides a vapor of nicotine or any other substances, and the use or inhalation of which simulates smoking. The term shall include any such device, whether manufactured, distributed, marketed, or sold as an e-cigarette, e-cigar, e-pipe, or under any other product name or descriptor."

Other Helpful Resources

The Americans for Nonsmokers' Rights website contains the latest news, reports and related [resources on e-cigarettes](#). For guidance and regulatory information about e-cigarettes, check the Food and Drug Administration's [website on e-cigarettes](#). For a different perspective on e-cigarettes, visit the website of the [American Association of Public Health Physicians](#).

Contact Us

Please feel free to contact the [Tobacco Control Legal Consortium](#) with any questions about the information included in this guide or to discuss local concerns you may have about implementing such a policy regulating e-cigarettes.

¹ The information contained in this document is not intended to constitute or replace legal advice.

² American Heart Assoc. et. al., *Policy Guidance Document Regarding E-Cigarettes* (April 9, 2010) (this document was released prior to the final decision in *Soterra Inc. v. Food & Drug Admin.*, but contains useful information about e-cigarettes from major public health organizations).

³ The Food and Drug Administration took enforcement action against several e-cigarette manufacturers for violations of the Federal Food, Drug, and Cosmetic Act (FDCA), including unsubstantiated claims and poor manufacturing practices. For information about the litigation between the FDA and e-cigarette manufacturers, as well as legal documents related to the enforcement actions taken by the FDA regarding these products, visit the FDA's e-cigarette website at <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm172906.htm>.

⁴ Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (codified, in relevant part, at 15 U.S.C.A. §§ 1333-34 and 21 U.S.C.A. § 301 *et seq.* (2010)) (preserving local and state authority to regulate the sale of tobacco products).

⁵ See Tobacco Control Legal Consortium, *Restricting Tobacco Advertising – Tips and Tools* (2011).

⁶ Proponents claim that e-cigarettes emit an odorless vapor made of water and harmless chemicals rather than the hazardous secondhand smoke of combustible cigarettes.

⁷ *Sottera, Inc. v. Food & Drug Admin.*, 627 F.3d 891 (D.C. Cir. 2010).

⁸ Generally, the nicotine in electronic cigarettes is “derived from natural tobacco plants.” However, it is not entirely clear whether that is true of all electronic cigarettes currently on the market, or whether it will be true of future products. Furthermore, not all electronic cigarettes contain nicotine; some contain comparable chemicals such as lobelia. Letter from Michael M. Levy, Jr., Director, Division of New Drugs and Labeling Compliance, Food & Drug Administration, to William P. Bartkowski, President, Ruyan American, Inc. (Sept. 8, 2010), available at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm225181.htm>.

⁹ See Tobacco Control Legal Consortium publications on Commercial Speech and Commerce Clause issues in the regulation of tobacco products on its website section, Federal Regulation of Tobacco Products, at <http://publichealthlawcenter.org/topics/special-collections/federal-regulation-tobacco-collection>.

¹⁰ Several other states are considering legislation to regulate the sale and use of e-cigarettes and a growing number of countries, such as Australia, Canada, Brazil, Israel, Mexico and Hong Kong, have imposed marketing restrictions on these products. Also, back in 2008, the [World Health Organization](#) announced that it does not consider e-cigarettes an effective nicotine-replacement therapy and that these products need to undergo toxicity analyses and “operate within the proper regulatory framework.”

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