



Regulating Electronic Cigarettes and Similar Devices

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.

Overview

Electronic cigarettes or electronic nicotine delivery systems (e-cigarettes) are battery-powered devices, often resembling cigarettes, cigars or pipes, designed to deliver nicotine or related substances to users in the form of an aerosol.² Over the last few years, these products have changed dramatically in their appearance and enjoyed a boom in popularity, thanks in part to a dramatic increase in marketing efforts. E-cigarette advertising often mirrors the cigarette advertisements of a generation ago, using celebrity endorsements that emphasize sex appeal, rugged individualism and overall coolness while promoting e-cigarettes as a less harmful, more convenient and cost-effective alternative to conventional tobacco products. Many public health organizations and policymakers are concerned about their safety and impact on public health due, in part, to the lack of manufacturing standards and ingredient disclosure requirements.³ While the federal government recently began the process of exercising its regulatory authority over e-cigarettes through the issuance of a proposed deeming regulation, the regulation in its current form would not provide a comprehensive regulatory structure. In addition, it could be several years before the regulation is finalized. Until that time, e-cigarettes will continue to be manufactured without federal regulatory oversight or quality controls, and can be broadly promoted, advertised and sold without appropriate health warnings and, in some jurisdictions, without legal age restrictions.



Recently, a growing number of state and local governments have taken steps to regulate the sale, price, and use of e-cigarettes to protect the public's health, reduce youth initiation to nicotine and tobacco products, and promote enforcement of tobacco-free laws.⁴ This guide



provides a few options and pointers for communities and policy makers to consider when drafting or implementing laws or policies that regulate e-cigarettes. Given the rapidity with which the e-cigarette market is growing, this publication may be updated regularly.

Background

Product Description. E-cigarettes typically consist of a battery-powered heating element, a cartridge that contains liquid nicotine or other chemicals, and an atomizer that, when heated, converts the contents of the cartridge into an aerosol that the user inhales.⁵ The two primary categories of e-cigarettes are closed systems, in which prefilled cartridges are used, and open systems, which allow the user to add solution manually to a refillable tank. Open systems have experienced the most dramatic growth in recent months.⁶ In 2004, when e-cigarettes first entered the market in China, they were shaped like cigarettes, cigars or pipes and the liquid or gel heated in the cartridge contained nicotine. Over the last decade, however, as the e-cigarette market has expanded, product designs and ingredients have also evolved, making it difficult to arrive at any standard definition. Today, e-cigarettes come in hundreds of brands, including rechargeable and disposable models, and a variety of shapes mimicking common household products, such as flash drives, pens, and lipstick. Depending on the brand, most e-cigarette cartridges contain tobacco-derived nicotine, humectants to produce the aerosol (for example, propylene glycol or glycerol), and flavorings.⁷ Because e-cigarettes are not subject to manufacturing standards, the quality and content of ingredients varies among brands, as do the level and concentration of nicotine in e-liquid. In fact, some e-liquid is marketed as nicotine-free and, as a result, may not be covered by laws that only regulate tobacco products.

Growing Market. E-cigarettes were first sold primarily over the Internet and in shopping mall kiosks, but are also now widely available in brick-and-mortar establishments across the U.S., such as convenience stores, gas stations, retail tobacco stores and, increasingly, in standalone e-cigarette shops. Sales of e-cigarettes in the U.S. have risen dramatically from approximately \$20 million in 2008, to \$1.7 billion in 2013.⁸ Some Wall Street analysts speculate that sales of e-cigarettes might even overtake those of conventional cigarettes within the next ten years.⁹ As an indication of the tobacco industry's interest in this rapidly growing market, several of the largest tobacco companies, such as Lorillard, R.J. Reynolds and Altria, have either acquired e-cigarette companies or are marketing their own electronic cigarettes.¹⁰ Significantly, as e-cigarette sales have risen, product costs have dropped, making e-cigarettes far more affordable than conventional cigarettes.¹¹ The relatively low cost of e-cigarettes is one factor that makes these products appealing to youth, who tend to be particularly price-sensitive.¹²

Health Risks. The [U.S. Food and Drug Administration](#) (FDA) and many leading public health organizations generally agree on the need for further scientific study to assess unproven safety claims about e-cigarettes and to determine the overall public health impact of e-cigarette use.¹³ Potentially harmful constituents have been documented in some e-cigarette cartridges, including diethylene glycol, genotoxins, animal carcinogens,¹⁴ and diacetyl, a butter flavoring known to cause serious lung damage to factory workers who manufacture microwave popcorn.¹⁵ The nicotine in e-cigarettes, as in all tobacco products, is highly addictive, can be toxic in high doses, and has immediate bio-chemical effects on the brain and body.¹⁶ The Surgeon General cautions

that nicotine may harm developing fetuses, and may negatively impact adolescent brain development.¹⁷ Given unregulated production processes, the type and concentration of product ingredients, including nicotine, varies among e-cigarette brands. For example, e-cigarette cartridges typically contain between 6 and 24 mg of nicotine per milliliter, but in some brands, the nicotine level can be much higher.¹⁸ Moreover, testing has shown that the nicotine content labeling on these products is not always accurate.¹⁹ In addition, much is still unknown about the health effects of e-cigarette aerosol on both the user and those in close proximity who are exposed to the secondhand aerosol.²⁰ Large-scale epidemiologic research is needed to determine whether these products promote cessation and help smokers quit or whether they promote experimentation, initiation or dual use of tobacco products and perpetuate addiction to nicotine.²¹

Because of the many questions about the safety and public health impact of e-cigarettes, public health professionals are concerned about their growing popularity, particularly among youth.²² E-cigarettes and refill cartridges are advertised on radio, on TV, and in magazines, are distributed in bars, in nightclubs, at festivals, and at racecar and other events,²³ and are widely available online, where safeguards against youth access can be breached more easily than in face-to-face purchases.²⁴ Moreover, e-liquid comes in thousands of flavors, including kid-friendly fruit and candy flavors such as bubblegum, gummi bear, and watermelon²⁵ – flavors that federal law prohibits in conventional cigarettes.²⁶ Evidence of the growing popularity of e-cigarettes among youth is supported by findings from the National Youth Tobacco Survey, conducted by the Centers for Disease Control and Prevention (CDC), which show that the percentage of e-cigarette use among middle and high school students doubled from 2011 to 2012, and that 1.8 million middle and high school students said they had tried e-cigarettes in 2012.²⁷ As a measure of concern about the lack of manufacturing requirements and sales and marketing restrictions on e-cigarettes, forty-one Attorneys General sent the FDA a letter in September 2013, urging the agency to regulate e-cigarettes to safeguard minors from nicotine addiction and other potential health effects of e-cigarettes.²⁸

Federal Regulation. On April 25, 2014, the FDA released its proposed deeming regulation that would treat e-cigarettes as a tobacco product for certain purposes. However, the proposed regulation is subject to change and likely will not be finalized for at least a year. Even after the rule is finalized, implementation of certain provisions may take up to three more years.²⁹ Some of the key provisions of the proposed regulation would restrict minors from purchasing e-cigarettes, prohibit free samples and require ingredient disclosure and premarket review of new products, but it would not regulate many of the policy areas identified in this document. Some policy options which the FDA has the authority to regulate, such as requiring that products be kept behind the counter, were not included. Other regulatory options, such as including e-cigarettes in smoke-free laws or levying taxes, are beyond the authority of the FDA. Therefore, clean air and taxation policies would need to be enacted at the state and local levels, and many other health-promoting policies could be implemented on the state and local level much sooner than federal regulations will be in place.

Policy Options

Public health organizations support regulating e-cigarettes for several reasons, including reducing youth initiation to nicotine and tobacco products, protecting the health of all users,

preserving clean air, and promoting the enforcement of smoke-free (and tobacco-free) laws. Several policy options can advance these public health goals.

- **Regulating Sale.** As discussed above, the FDA recently issued a preliminary deeming regulation that would regulate e-cigarettes as tobacco products. The deeming regulation would not prohibit state and local governments, if they have sufficient authority, from also regulating them as tobacco products.³⁰ For example, a government could consider prohibiting the sale of such products anywhere within its jurisdiction, prohibiting the sale of such products to minors, requiring these products to be kept behind the counter in stores, requiring e-cigarette stores and “vaping lounges” to be licensed as tobacco retailers, or allowing these products to be sold only in places where minors are not permitted to enter. Also, a state or local government could consider prohibiting the sale of certain products, such as flavored e-cigarette liquid.
- **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 certain 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 want to consider, in conjunction with a law prohibiting sales to minors or to all consumers, options designed to limit the targeted marketing of e-cigarettes to minors. While there are some limits to restrictions on commercial speech,³¹ governments might want to work with legal counsel to consider how e-cigarettes are promoted in a community and the extent to which restrictions can be placed on those efforts.

- **Regulating Price.** Yet another option that state and local governments might consider is regulating price. One politically feasible option is to prohibit the distribution of all free samples of e-cigarettes and related products. Although the [Family Smoking Prevention and Tobacco Control Act](#) (Tobacco Control Act) restricts tobacco manufacturers from distributing free samples of “cigarettes, smokeless tobacco or other tobacco products,”³² this prohibition currently does not extend to free samples of electronic cigarettes. As mentioned above, free samples are a component of the proposed deeming regulation, but there is no certainty regarding when or if this regulation will become finalized at the federal level. Prohibiting free samples, as well as prohibiting the use of coupons, rebates or other discounting practices, are other ways state and local governments might regulate the price of e-cigarettes.³³ In addition, all states and those localities with taxing powers can consider imposing a tax on e-cigarettes and related products to help the state or locality offset health expenses and costs related to tobacco control programs or enforcement, collect revenue, and keep the prices of these products high, reducing consumption, particularly among youth.

- **Regulating Use.** Because e-cigarettes emit an aerosol rather than secondhand smoke, many existing smoke-free – and some tobacco-free – laws or policies, as currently written, do not restrict the use of these products in public or in places of employment. Thus, e-cigarettes often are used in places where the use of combustible tobacco products is prohibited, undermining state and local efforts to promote and protect clean air. Proponents of e-cigarettes claim these products are safer to use than conventional tobacco products, and do not expose bystanders to the risk of secondhand smoke.³⁴ Recent scientific research has shown some negative health effects related to secondhand exposure to e-cigarette aerosol which has caused a growing number of state and local governments to prohibit their use in various public places and places of employment—often under existing or new smoke-free laws.³⁵ The goal of such legislation generally is to minimize the use of unregulated products that pose unknown health risks to the user or to bystanders.

Such laws serve another important legislative goal: to support enforcement of existing smoke-free laws. Users of e-cigarettes may appear to be smoking combustible cigarettes, and might cause confusion for those in charge of enforcing a smoke-free law. Omitting e-cigarettes from the restrictions imposed by smoke-free laws could cause smokers of conventional products to assume that smoking is permitted. It may also cause nonsmokers to become needlessly concerned at what they see as a violation of a smoke-free law. Moreover, many public health professionals are concerned that permitting e-cigarettes to be used in traditionally smoke-free areas renormalizes “smoking-like behavior,” and can result in higher youth initiation rates and a slower decline in adult cessation rates.³⁶

- **Regulating Packaging.** The ingestion of e-cigarette liquid by children has become a significant health risk. A recent study by the CDC showed that calls to poison control centers due to the ingestion of e-cigarette liquids increased from one per month in September 2010 to approximately 215 per month in February 2014, with children under the age of five comprising most of the victims.³⁷ Governments may consider requiring that e-cigarettes and e-cigarette liquids be sold in child-resistant packaging to minimize the risk of accidental poisoning.
- **Regulating Disposal.** Improperly disposed of e-cigarette cartridges, batteries and related devices could result in nicotine exposure to children, adults, and animals, the contamination of soil and water, and other adverse impacts on the environment. States and communities might want to consider adopting policies that require environmentally responsible disposal of e-cigarette waste.

Policy Elements

Regardless of the type of policy effort pursued to regulate e-cigarettes, all strong policies share a few common elements, such as:

- **Clear definitions and concise language:** To avoid confusion about what constitutes an e-cigarette, definitions should explicitly state what they cover, yet be broad enough to

anticipate future product innovations. This eliminates ambiguity which might arise if new products or components are similar to those already in existence but may not fall under a narrow definition. For example, when e-cigarettes were first introduced they looked like cigarettes, but now they take a variety of forms. As another example, definitions that only cover products that contain tobacco-derived nicotine can be limiting and can make enforcement difficult. Many cartridges are interchangeable, and e-cigarettes can be used to inhale not only tobacco-derived nicotine, but also synthetic nicotine and other substances. A broad definition should cover all of these variations.

When drafting definitions, it is important to consider the range of products intended to be captured, the specific activity to be addressed, the existing laws within the particular jurisdiction and the political environment. Definitions should be easy for the average person to understand and tailored to each situation. For example, when writing a sales restriction law, it might be helpful to include language that exempts products approved by the FDA for sale as tobacco cessation aids and that are being marketed and sold for that purpose.³⁸ However, a clean indoor air law might not benefit from such an exemption.

Drafting Tips: In most circumstances, existing definitions of “tobacco products” in tobacco control laws should be broadened to include e-cigarettes and similar products. In many jurisdictions, it may also be helpful to include a clear, comprehensive definition of e-cigarettes that includes component parts, in addition to, or as a part of, the broadened definition of “tobacco products.” Doing so may help prevent any questions from arising about which products are covered by the law. To ensure that drafting inconsistencies or other problems do not occur, consult with a lawyer familiar with the laws of your jurisdiction, or contact a Consortium attorney.

- **Robust enforcement options:** Enforcing restrictions on the sale, marketing, pricing and use of e-cigarettes can be challenging unless clear procedures are established, including a reasonable penalty and appeals process.³⁹ Effective enforcement of these policies often includes coordination among different enforcement agencies and consistent procedures throughout a community. States could also use existing consumer protection laws to ensure that the public is protected from false claims made about these products.
- **Well-planned implementation process:** A process should be established for publicizing the policy and educating the community, as well as for receiving, tracking and following-up on complaints. It is also important to set a realistic date that the policy will take effect and to communicate that date.

Policy Challenges

One of the most controversial issues affecting the regulation of electronic cigarettes has been the 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 litigation in 2010 between the FDA and e-cigarette manufacturers, most notably in *Sottera Inc. v. Food & Drug Administration*.⁴⁰ Generally, the court in *Sottera* held that the FDA could not regulate

e-cigarettes as drug delivery devices because they were not marketed for therapeutic purposes such as smoking cessation. However, the court held that the FDA could regulate them under its tobacco control authority. Under the Tobacco Control Act, the FDA has the 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 generally contain nicotine extracted from tobacco.⁴¹ It is important to note, however, that any e-cigarettes that are neither made nor derived from tobacco would not be subject to the FDA’s regulatory authority.

As with any tobacco control policies, state and local measures regulating the sale, marketing or price of e-cigarettes may be challenged in the courts by the tobacco industry and its allies, who may argue that those restrictions are preempted by other laws or that they violate specific constitutional provisions.⁴² For example, in 2013 the City of Providence, Rhode Island, successfully fought off a legal challenge to ordinances that prohibit the sale of flavored non-cigarette tobacco products in most locations and prohibit price discounting of tobacco products.⁴³ The industry argued that these ordinances were preempted by federal and state law and violated the First Amendment, but the court did not agree. Moreover, new policies regulating the use of e-cigarettes could be challenged in court simply as a means to dissuade other communities from adopting similar provisions. Public health professionals and policymakers should also be on the lookout for legislation proposed by the industry that purports to regulate e-cigarettes and related devices. While the proposed laws may appear to prevent youth access to e-cigarettes, they often lack the necessary substantive provisions, exempt e-cigarettes from other tobacco product regulations, such as tax laws, or severely limit local authority to regulate e-cigarettes through preemption provisions.⁴⁴

Select Legislation and Policies

In recent years, many state and local governments have wrestled with determining the most effective way to regulate e-cigarettes and the evolving market of related devices.⁴⁵ Below are a few examples of tobacco control policies that include provisions regulating the sale, marketing, price discounting, or use of e-cigarettes.⁴⁶ Local and state governments might also want to consider other legislative avenues or regulatory options.

Before using any language from the following policies, take care to ensure the provision in question is practical and legal in your jurisdiction, including exploring whether the original jurisdiction faced any issues that could affect implementation in your jurisdiction. Please note that the Tobacco Control Legal Consortium does not endorse or recommend any of the following policy approaches. These select examples are included simply to illustrate how various jurisdictions have approached the regulation of these products.

Select State Laws Regulating E-Cigarettes

Locality/State	Policy Name	Text of Policy
Minnesota	Tobacco Modernization and Compliance Act of 2010	Regulates sale of e-cigarettes and imposes criminal penalties for the sale of nicotine or lobelia delivery products, including e-cigarettes, to minors.

[Minn. Stat. § 609.6855](#)

“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.”

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.”

Comment: Section 609.685 contains an expansive definition of tobacco including “any product containing, made, or derived from tobacco that is intended for human consumption, whether chewed, smoked, absorbed, dissolved, inhaled, snorted, sniffed, or ingested by any other means, or any component, part, or accessory of a tobacco product. . . .” The law exempts FDA-approved tobacco cessation products.

[Minn. Stat. § 297F.05 subd. 3](#)

Raises Minnesota’s excise tax on cigarettes and most other tobacco products to 95 percent of the “wholesale sales price.”

Definition. The Minnesota Department of Revenue interprets the tobacco products tax as covering electronic cigarettes. [Revenue Notice #12-10](#).

New Jersey

[New Jersey Smoke-Free Air Act, P. L. 2009, Chap. 182](#)

Prohibits the smoking of tobacco products and the use of electronic smoking devices in all enclosed indoor places of public access and workplaces.

Definition: “*Electronic smoking device* 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.”

North Dakota

[N.D. Cent. Code §23-12-09 \(West 2013\)](#)

Prohibits smoking, including use of e-cigarettes, in all enclosed areas of public places and places of employment, including within twenty feet of entrances, exits, operable windows, air intakes, and ventilation systems of enclosed areas in which smoking is prohibited.

Definition: “*Smoking* means inhaling, exhaling, burning, or carrying any lighted or heated cigar, cigarette, or pipe, or

any other lighted or heated tobacco or plant product intended for inhalation, in any manner or in any form. Smoking also includes the use of an *e-cigarette which creates a vapor, in any manner or any form, or the use of any oral smoking device* for the purpose of circumventing the prohibition of smoking in this Act. . . . *E-cigarette* means any electronic oral device, such as one composed of a heating element and battery or electronic circuit, or both, 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, and e-pipe or under any other product, name, or descriptor.”

Utah [Utah Code § 76-10-101, 104, 105, 111](#) Regulates sale, gift, or distribution of e-cigarettes by manufacturer, wholesaler, or retailer.

Definition: “*Electronic cigarette* means any device, other than a cigarette or cigar, intended to deliver vapor containing nicotine into a person’s respiratory system.”

Vermont [7 V.S.A. § 1012 \(2014 Act 135\)](#) Requires e-cigarette solution to be sold in child-resistant packaging.

Definition: “*Child-resistant packaging*” means packaging that is designed or constructed to be significantly difficult for children under five years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time and not difficult for normal adults to use properly, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time. (2) “*Nicotine liquid container*” means a bottle or other container of a nicotine liquid or other substance containing nicotine which is sold, marketed, or intended for use in a tobacco substitute. The term does not include a container containing nicotine in a cartridge that is sold, marketed, or intended for use in a tobacco substitute if the cartridge is prefilled and sealed by the manufacturer and not intended to be opened by the consumer.

Local Policies

Boston, MA [Boston Public Health Commission Regulation Clean Air](#) Prohibits use of tobacco and e-cigarettes in the workplace, including adjacent outdoor areas.

Definition: E-Cigarette – any electronic device composed of a mouthpiece, heating element, battery and/or electronic

	<p>Works Workplace Smoking and E- Cigarette Use Restrictions</p>	<p>circuits that provides a vapor of liquid nicotine to the user, or relies on vaporization of any liquid or solid. This term shall include such devices whether they are manufactured as e-cigarettes, e-cigars, e-pipes, or under any other product name.</p>
<p>New York City, New York</p>	<p>A Local Law Establishing a Sales Age of 21 for Cigarettes, Tobacco Products & Electronic Cigarettes</p>	<p>Raises the sales age from eighteen to twenty-one years for cigarettes and tobacco products and establishes a sales age of twenty-one years for electronic cigarettes.</p> <p>Definition: “<i>Electronic cigarette</i> means a battery-operated device that contains nicotine and delivers vapor for inhalation. Electronic cigarette shall include any refill, cartridge, and any other component of an electronic cigarette.”</p>
<p>Suffolk County, New York</p>	<p>A Local Law Banning the Sale of E- Cigarettes to Persons Under the Age of 19, Local Law No. 29-2009</p>	<p>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.”</p> <p>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.”</p>
<p>Providence, Rhode Island</p>	<p>No. 42 Ordinance Prohibiting Sale of Flavored Tobacco Products (2012)</p> <p>No. 43 Ordinance Prohibiting Price Discounting of</p>	<p>Prohibits sale or offer for sale of any flavored tobacco product, except in a smoking bar.</p> <p>Definition: “<i>Tobacco product</i> means any product containing tobacco or nicotine, including but not limited to cigars, pipe tobacco, snuff, chewing tobacco, dipping tobacco, bidis, snus, dissolvable tobacco products, and electronic cigarette cartridges; provided, however, that such term shall not include: (1) cigarettes, including those cigarettes subject to the Special Rule for Cigarettes relating to characterizing flavors of the federal Family Smoking and Tobacco Prevention Act (sic); and (2) any product that has been approved by the U.S. Food and Drug Administration, pursuant to its authority over drugs.”</p> <p>*****</p> <p>Prohibits redemption of tobacco product coupons and sale of tobacco products through multi-pack offers or other price discounting methods. The law, which applies to all tobacco products including electronic cigarette cartridges, is located within the city’s local tobacco licensing scheme.</p>

[Tobacco Products \(2012\)](#)

Definition: “Tobacco products” shall mean any substance containing tobacco leaf, including but not limited to cigarettes, cigars, pipe tobacco, snuff, chewing tobacco, dipping tobacco, orbs sticks, dissolvable tobacco products, and electronic cigarette cartridges; provided, however, that “tobacco products” shall not include any product that has been approved by the United States Food and Drug Administration for use as a medical treatment to reduce and eliminate nicotine or tobacco dependence.

Organizations

Americans for Nonsmokers’ Rights

[Model Ordinance Prohibiting Smoking in All Workplaces and Public Places](#)

Findings: “Unregulated high-tech smoking devices, commonly referred to as electronic cigarettes, or ‘e-cigarettes,’ closely resemble and purposefully mimic the 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.’⁴⁷ According to a more recent study, electronic cigarette emissions are made up of a high concentration of ultrafine particles, and the particle concentration is higher than in conventional tobacco smoke. E-cigarettes produce an aerosol or 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. The World Health Organization (WHO) recommends that electronic smoking devices not be used indoors especially in smokefree environments, in order to minimize the risk to bystanders of breathing in the aerosol emitted by the devices and to avoid undermining the enforcement of smokefree laws.”

Definition: “*Electronic Smoking Device* means any product containing or delivering nicotine or any other substance intended for human consumption that can be used by a person to simulate smoking through inhalation of vapor or aerosol from the product. The term includes any such device, whether manufactured, distributed, marketed, or

sold as an e-cigarette, e-cigar, e-pipe, e-hookah, or vape pen, or under any other product name or descriptor.”

Other Helpful Resources

The Tobacco Control Legal Consortium and Public Health Law Center’s website features several [resources on e-cigarettes](#). Other legal centers affiliated with the Consortium, including [ChangeLab Solutions](#) and the New England Law | Boston’s [Center for Public Health and Tobacco Policy](#), have additional resources. For information about federal regulation of e-cigarettes, check the U.S. Food and Drug Administration’s [website on e-cigarettes](#) or the Consortium’s [FDA Tobacco Action Center](#). The Americans for Nonsmokers’ Rights website contains the latest news, reports and related [resources on e-cigarettes](#). A summary of the scientific research on e-cigarettes as of Oct. 2013 is available on the Tobacco-Related Disease Research Program website (see also webcast panel presentations, [E-Cigarettes: The Vapor this Time?](#), Oct. 3, 2013). Other public health organizations, including [Legacy](#) and the [Campaign for Tobacco-Free Kids](#), have material on e-cigarettes on their websites as well.

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.

Last updated: October 2014

Notes

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

² These products are referred to by a variety of names including electronic nicotine delivery systems (ENDS), personal vaporizers (PVs), electronic smoking devices, vapor products and alternative nicotine delivery devices, among others. For the purposes of this publication, the term e-cigarette is intended to capture all of these products. Although the term “aerosol” is used throughout this publication, the term “vapor” is also often used interchangeably when defining or describing these products.

³ See, e.g., Am. Heart Assoc. et al., *Electronic Cigarettes: A Policy Statement From the American Heart Association* (August 2014), available at <http://circ.ahajournals.org/content/early/2014/08/22/CIR.000000000000107.citation>; Am. Acad. Pediatrics, *E-Cigarettes* (2013), available at http://www2.aap.org/richmondcenter/pdfs/ECigarette_handout.pdf. See also Letter from Nat’l Assoc. Attys General to Margaret Hamburg, Comm’r Food and Drug Admin. (Sept. 24, 2013) (urging the FDA to move quickly to issue proposed regulations that will address the advertising, ingredients and sale to minors of e-cigarettes), available at <http://www.naag.org/assets/files/pdf/E%20Cigarette%20Final%20Letter%20%285%29%281%29.pdf>; Letter from Assoc. State and Territorial Health Officials to Margaret Hamburg, Comm’r Food and Drug

Admin. (Oct. 22, 2013) (urging the FDA to take all available measures to regulate “the advertising, ingredients, and sale to minors of electronic cigarettes”).

⁴ See, e.g., Legal Resource Center for Maryland Public Health Law and Policy, *State Electronic Smoking Device Legislation* (2013), available at <http://publichealthlawcenter.org/sites/default/files/resources/UofMaryland-fs-state-e-smokingdevice-legislation-9-2013.pdf> (table summarizing state legislation on electronic smoking devices as of Sept. 12, 2013); American Nonsmokers’ Rights Foundation, *U.S. State and Local Laws Regulating Use of Electronic Cigarettes* (Oct. 1, 2014), available at <http://www.no-smoke.org/pdf/ecigslaws.pdf>.

⁵ Because the user inhales aerosol or vapor, rather than smoke, the use of an e-cigarette is often referred to as “vaping.”

⁶ *Open System Vaporizers Officially Overtake E-Cigs, Top \$1 Billion in Sales for the First-Time Ever*, Marketwatch.com (Sept. 25, 2014), <http://www.marketwatch.com/story/open-system-vaporizers-officially-overtake-e-cigs-top-1-billion-in-sales-for-the-first-time-ever-2014-09-25>.

⁷ Brian A. King et al., *Awareness and Ever Use of Electronic Cigarettes Among U.S. Adults, 2010-2011*, 15 NICOTINE & TOBACCO RESEARCH 1623-7 (2013).

⁸ *E-Cigarette Sales are Smoking Hot, Set to Hit \$1.7 Billion*, CNBC.com (Aug. 28, 2013), <http://www.cnbc.com/id/100991511/print>.

⁹ See, e.g., Melissa Vonder Haar, *Are E-Cigs the Wave of the Future?*, CSP DAILY NEWS, Aug. 13, 2013, <http://www.cspnet.com/category-management-news-data/tobacco-news-data/articles/are-e-cigs-wave-future>.

¹⁰ *Lorillard Inc. Acquires Blu Ecigs*, CSP DAILY NEWS, Apr. 25, 2012, <http://www.cspnet.com/category-management-news-data/tobacco-news-data/articles/lorillard-acquires-blu-ecigs>; *Reynolds Developing New Smokeless Products*, WINSTON-SALEM J., July 29, 2012, http://www.journalnow.com/business/article_cf223198-c21f-5b4e-8e7b-c5fb6190dcad.html; *Marlboro Maker Altria to Sell E-Cigarettes*, L.A. TIMES, June 11, 2013, <http://articles.latimes.com/2013/jun/11/business/la-fi-mo-altria-electronic-cigarette-20130611>.

¹¹ Richard Craver, *Electronic Cigarettes Gaining on Traditional Products*, WINSTON-SALEM J., Dec. 14, 2012, http://www.journalnow.com/business/business_news/local/article_41fa04d6-4655-11e2-95d9-0019bb30f31a.html (“Refill cartridges can be purchased in different sizes and flavors; five-packs typically cost between \$9 and \$18. By comparison, a carton of cigarettes can cost between \$25 and \$50 for most name brands.”)

¹² U. S. DEP’T OF HEALTH & HUMAN SERVS., *PREVENTING TOBACCO USE AMONG YOUTH AND YOUNG ADULTS: A REPORT OF THE SURGEON GENERAL 522-29* (2012), available at <http://www.surgeongeneral.gov/library/reports/preventing-youth-tobacco-use/full-report.pdf>.

¹³ U.S. Food & Drug Admin., *Electronic Cigarettes*, <http://www.fda.gov/newsevents/publichealthfocus/ucm172906.htm> (last visited Oct. 7, 2014).

¹⁴ Nathan Cobb et al., *Novel Nicotine Delivery Systems and Public Health: The Rise of the “E-Cigarette,”* 100 AM. J. PUB. HEALTH, 2340-42 (2010).

¹⁵ Jasper Hamill, *The Health Claims of E-Cigarettes Are Going Up in Smoke*, forbes.com, Aug. 21, 2014, available at <http://www.forbes.com/sites/jasperhamill/2014/08/31/the-health-claims-of-e-cigarettes-are-going-up-in-smoke>.

¹⁶ U.S. DEP’T OF HEALTH & HUMAN SERVS., *HOW TOBACCO SMOKE CAUSES DISEASE: THE BIOLOGY AND BEHAVIORAL BASIS FOR SMOKING – ATTRIBUTABLE DISEASE: A REPORT OF THE SURGEON GENERAL* (2010), available at <http://www.ncbi.nlm.nih.gov/books/NBK53017>; see also U.S. DEP’T OF HEALTH & HUMAN SERVS., *THE HEALTH CONSEQUENCE OF SMOKING: NICOTINE ADDICTION* (1988), available at <http://tobaccodocuments.org/atc/71015953.html>.

- ¹⁷ U.S. DEP'T OF HEALTH & HUMAN SERVS., THE HEALTH CONSEQUENCES OF SMOKING —50 YEARS OF PROGRESS: A REPORT OF THE SURGEON GENERAL (2014), available at <http://www.surgeongeneral.gov/library/reports/50-years-of-progress/full-report.pdf>.
- ¹⁸ Megan Schroeder et al., *Electronic Cigarettes and Nicotine Clinical Pharmacology*, TOBACCO CONTROL (2014), available at http://tobaccocontrol.bmj.com/content/23/suppl_2/ii30.full.
- ¹⁹ Michael Trehy et al., *Analysis of Electronic Cigarette Cartridges, Refill Solutions and Smoke for Nicotine and Nicotine-related Impurities*, 34 J. LIQUID CHROMATOGRAPHY & RELATED TECHNOLOGIES 1442, 1457 (2011).
- ²⁰ See, e.g., Monique Williams et al., *Metal and Silicate Particles Including Nanoparticles are Present in Electronic Cigarette Cartomizer Fluid and Aerosol*, 8 PLoS ONE 3 (e57987) (2013), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3603976>; Tobias Schripp et al., *Does E-Cigarette Consumption Cause Passive Vaping*, 23 INDOOR AIR 25-31 (2013); Americans for Nonsmokers' Rights, *Electronic (e-) Cigarettes and Secondhand Aerosol* (2014), available at <http://no-smoke.org/pdf/ecigarette-secondhand-aerosol.pdf>.
- ²¹ See Am. Heart Assoc. et al., *supra* note 3.
- ²² Letter from Nat'l Assoc. Attys General, *supra* note 3.
- ²³ Anna Edney, *E-Cigarette Marketing Seen Threatened by FDA Scrutiny*, Bloomberg.com, Oct. 16, 2013, <http://www.bloomberg.com/news/print/2013-10-16/e-cigarette-marketing-seen-threatened-by-fda-scrutiny.html>.
- ²⁴ In addition, instructive videos on how to make e-liquid are widely available online, including YouTube and e-cigarette and related product web sites. See, e.g., <http://www.bing.com/videos/search?q=e-liquid+video+instructions&qpv=e-liquid+video+instructions&FORM=VDRE> (examples of videos related to e-liquid (e-juice) and instructions for filling e-cigarette cartridges).
- ²⁵ Matt Richtel, *E-Cigarette Makers Are in an Arms Race for Exotic Vapor Flavors*, N.Y. TIMES, July 15, 2014, available at http://www.nytimes.com/2014/07/16/business/e-cigarette-makers-are-in-an-arms-race-for-exotic-vapor-flavors.html?_r=0.
- ²⁶ Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31 § 102, 123 Stat. 1776 (codified as amended in scattered sections of 5 U.S.C., 15 U.S.C. and 21 U.S.C. (2009)). 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) (2009).
- ²⁷ CTRS. FOR DISEASE CONTROL AND PREVENTION, *Notes from the Field: Electronic Cigarette Use Among Middle and High School Students – U.S., 2011-2012*, 62 MORBIDITY AND MORTALITY WKLY. REP. 729-30 (2013), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6235a6.htm>.
- ²⁸ Letter from Nat'l Assoc. Attys General, *supra* note 3.
- ²⁹ For more specific information related to the deeming regulation, please visit our FDA Tobacco Action Center at <http://publichealthlawcenter.org/topics/tobacco-control/fda-tobacco-action-center>. For the latest federal information about regulating e-cigarettes, visit the FDA's website at <http://www.fda.gov>.
- ³⁰ Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (codified, in relevant part, at 21 U.S.C.A. § 301 *et seq.* (2009) (preserving local and state authority to regulate the sale of tobacco products)).

³¹ See Tobacco Control Legal Consortium, *Restricting Tobacco Advertising – Tips and Tools* (2011), available at <http://publichealthlawcenter.org/sites/default/files/resources/tclc-guide-restricttobadvert-2011.pdf>.

³² Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified as amended in relevant part at 21 U.S.C. §§ 301 *et seq.*); 21 C.F.R. § 1140.16(d)(1).

³³ See, e.g., Tobacco Control Legal Consortium, *Tobacco Coupon Regulations and Sampling Restrictions* (2011), available at <http://publichealthlawcenter.org/sites/default/files/resources/tclc-guide-tobcouponregsandsampling-2011.pdf>.

³⁴ Proponents claim that e-cigarettes emit an odorless vapor made of water and harmless chemicals rather than the hazardous secondhand smoke of combustible cigarettes. See, e.g., Ecigsavings.com, <http://www.ecigsavings.com/electronic-cigarettes/about-electronic-cigarettes> (last visited Oct. 7, 2014).

³⁵ See, e.g., Rachel Grana et al., *Background Paper on E-cigarettes*, Center for Tobacco Control Research and Education, University of California, San Francisco and WHO Collaborating Center on Tobacco Control (Dec. 2013). See also American Nonsmokers' Rights Foundation, *U.S. State and Local Laws Regulating Use of Electronic Cigarettes* (Oct. 1, 2014), available at <http://www.no-smoke.org/pdf/ecigslaws.pdf>.

³⁶ Matt Richtel, *The E-Cigarette Industry, Waiting to Exhale*, N.Y. TIMES, Oct. 26, 2013, available at http://www.nytimes.com/2013/10/27/business/the-e-cigarette-industry-waiting-to-exhale.html?pagewanted=all&_r=0.

³⁷ CTRS. FOR DISEASE CONTROL AND PREVENTION, *Calls to Poison Centers for Exposures to Electronic Cigarettes – United States, September 2010-February 2014*, 63 MORBIDITY AND MORTALITY WKLY. REP. 297-300 (2014), available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6313a4.htm?s_cid=mm6313a4_w.

³⁸ U.S. Food & Drug Admin, *Smoking Cessation Products to Help You Quit*, <http://www.fda.gov/TobaccoProducts/ResourcesforYou/ucm168231.htm> (last visited Oct. 7, 2014). These FDA-approved cessation devices include products such as nicotine gum, patch, nasal spray and inhalers.

³⁹ As just one indication of enforcement challenges, some e-cigarettes sold as non-nicotine products have cartridges that can be replaced with nicotine cartridges or vials of liquid nicotine purchased locally or online. See, e.g., the following e-cigarette websites: Prime Vapor, <http://www.primevapor.com/Flavor-e-cigarette-cartridges-1/zero-nicotine-10> and CloudNine, <http://cloudnine.hillarymilesproductions.com/e-cigarette-reviews/electronic-cigarette-filter-styles-replaceable-flavor-cartridges-compared-to-e-liquid-refillable-cartridges> (last visited Oct. 7, 2014).

⁴⁰ *Sottera, Inc. v. Food & Drug Admin.*, 627 F.3d 891 (D.C. Cir. 2010).

⁴¹ 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. Moreover, not all electronic cigarettes contain nicotine; some contain other 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>.

⁴² 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>. See also Consortium resources on Preemption and Public Health, at <http://publichealthlawcenter.org/topics/other-public-health-law/preemption-public-health>.

⁴³ See *Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence*, 731 F.3d 71 (1st Cir. 2013), available at <http://media.ca1.uscourts.gov/pdf/opinions/13-1053P-01A.pdf> (upholding two 2012 Providence ordinances that restrict sales of flavored non-cigarette tobacco products and prohibit the redemption of tobacco product coupons and other price discounting practices in retail stores and ruling that the laws serve the city's legitimate goal of reducing smoking and other tobacco use and that they do not violate the First Amendment and are not preempted by federal and state law).

⁴⁴ See, e.g., Missouri Senate Bill No. 841, which states that e-cigarettes shall not be taxed as tobacco products, available at <http://www.senate.mo.gov/14info/pdf-bill/tat/SB841.pdf> (last visited Oct. 13, 2014).

⁴⁵ See Legal Resource Center for Maryland Public Health Law and Policy, *supra* note 4.

⁴⁶ 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, Norway, Lebanon, Israel, Mexico, Hong Kong and Singapore, have imposed marketing restrictions on these products. *But see* Andrew Higgins & Matt Richtel, *European Lawmakers Reject Tight Restrictions on E-Cigarettes*, N.Y. TIMES, Oct. 8, 2013 (describing European Parliament's decision to forgo proposals by health officials that e-cigarettes be tightly regulated as medical devices, yet still imposing tight restrictions on advertising and sponsorship and prohibiting sales to young people), available at <http://www.nytimes.com/2013/10/09/business/international/european-lawmakers-reject-tight-restrictions-on-e-cigarettes.html?pagewanted=all&r=0&pagewanted=print>. Also, 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.”

⁴⁷ U.S. Food & Drug Admin., *Summary of Results: Laboratory Analysis of Electronic Cigarettes Conducted by FDA* (July 22, 2009), <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm173146.htm>.