

**ANTHONY G. BROWN**  
*Attorney General*



**CANDACE MCLAREN LANHAM**  
*Chief of Staff*

**CAROLYN A. QUATTROCKI**  
*Deputy Attorney General*

**STATE OF MARYLAND**  
**OFFICE OF THE ATTORNEY GENERAL**

EMAIL  
amaccormack@oag.state.md.us

WRITER'S DIRECT DIAL NO.  
(410) 576-7052

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**TO:** The Honorable C.T. Wilson  
Chair, Economic Matters Committee

**FROM:** Anna MacCormack  
Assistant Attorney General, Office of the Attorney General

**RE:** House Bill 1033 – Business Regulation – Electronic Smoking Devices  
Manufacturers – Certifications

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The Office of Attorney General urges this Committee to report favorably on House Bill 1033 – Business Regulation – Electronic Smoking Devices Manufactures – Certifications.

House Bill 1033 brings much-needed improvements to Maryland's electronic smoking devices ("ESDs") law, Business Regulation Title 16.7. There have been many changes since Title 16.7 was enacted in 2017, including significant growth in the market and a changed federal landscape. House Bill 1033 incorporates improvements recommended by the Comptroller's 2020 Task Force on Electronic Smoking Devices to Maryland's ESD market and strengthens the licensing and regulatory systems for ESDs in the State.

ESD use has grown, including youth ESD use, and products have flooded the market. From January 2020 to December 2022, total U.S. e-cigarette unit sales increased by 46.6%, from 15.5 million to 22.7 million units.<sup>1</sup> ESDs are the second largest nicotine product category after traditional combustible cigarettes for adult users, but for youth, ESD use is higher than cigarettes: the 2021 Maryland High School Survey reports that while 3.6% of high school students smoked

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<sup>1</sup> CDC, F.R. Ali et al. "E-cigarette Unit Sales by Product and Flavor Type, and Top-Selling Brands, United States, 2020–2022," *Morbidity & Mortality Weekly Report*, vol. 72 no. 25, 672–77 (June 23, 2023), <https://www.cdc.gov/mmwr/volumes/72/wr/pdfs/mm7225a1-H.pdf>.

This bill letter is a statement of the Office of Attorney General's policy position on the referenced pending legislation. For a legal or constitutional analysis of the bill, Members of the House and Senate should consult with the Counsel to the General Assembly, Sandy Brantley. She can be reached at 410-946-5600 or [sbrantley@oag.state.md.us](mailto:sbrantley@oag.state.md.us).

cigarettes, 14.7% of high school students currently used ESDs—the equivalent of more than 4 students in a class of 30.<sup>2</sup> A 2022 national survey of students found that of the 2.55 million U.S. middle and high school students currently using e-cigarettes, most reported using flavored products, and, among those students, approximately 7 of 10 used fruit flavors.<sup>3</sup> Nicotine is highly addictive and can harm developing brains. Early nicotine exposure can prime the brain for addiction to other drugs, and nearly 90% of adults who smoke daily started smoking by age 18, and 98% by age 25.

As sales and use have risen, changes have also come to the legal landscape. In 2016, pursuant to the Family Smoking Prevention and Tobacco Control Act, 21 U.S.C. § 387 *et seq.* (“Tobacco Control Act”), the FDA adopted the “Deeming Rule,” which provided that ESDs would be treated as “tobacco products.” This meant that ESDs were subject to the Tobacco Control Act and regulated by FDA. Products that were on the market as of August 8, 2016, could remain on the market provided the manufacturer submitted a premarket tobacco product application to the FDA by September 9, 2020. In other words, to legally market a new tobacco product—which includes ESDs—a company must apply for and receive a written marketing order from FDA.

The window for ESD manufacturers to apply for a marketing order has now closed and the FDA has taken action on most of the approximately 26 million premarket tobacco product applications it received. Millions of products either received denials or received refuse to accept or refuse to file letters from the FDA. For non-tobacco nicotine products, the FDA reviewed more than 9,000 applications but has not issued any marketing orders for these. An unknown number of ESDs still have pending premarket applications, and the FDA has now issued marketing orders for 23 tobacco-flavored e-cigarette and vapor products. This process has finally given such much-needed clarity regarding what ESDs are authorized for sale by federal law.

House Bill 1033 would improve Maryland’s ESD industry in two main ways. First, House Bill 1033 would bring the ESDs sold in Maryland into compliance with federal and state law. It does this by establishing an ESD directory, similar to the cigarette directory that Maryland has had for twenty years. To comply with federal and existing state law, House Bill 1033’s directory would only include ESDs that are legal for sale because they have received FDA marketing orders. This would protect Maryland teens and other consumers from ESDs made by unknown manufacturers with unregulated and potentially dangerous product components. In addition, by establishing a directory of legal products, House Bill 1033 will enable law-abiding State licensees to avoid selling illegal and dangerous products unknowingly. House Bill 1033 empowers the Office of the Attorney General, which would administer the ESD directory, as it does for the existing cigarette

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<sup>2</sup> Maryland Dep’t of Health, *Youth Risk Behavior Survey/Youth Tobacco Survey (YRBS/YTS) 2021-2022*, <https://health.maryland.gov/phpa/ccdpc/Reports/Pages/State-Level-Data,-2021-2022.aspx>.

<sup>3</sup> CDC, M. Cooper et al., “Notes from the Field: E-cigarette Use Among Middle and High School Students—United States, 2022,” *Morbidity & Mortality Weekly Report*, vol. 71 no. 40, 1283–85 (Oct. 7, 2022), <https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7140a3-H.pdf>.

directory, to obtain information about the companies and their products before allowing ESDs to enter Maryland. Furthermore, applicants to the directory must either register to do business in the State or appoint an agent for service of process, enabling the State to find these manufacturers if there are any violations of the law.

An ESD directory is a commonsense solution to a market that has been flooded with noncompliant products, including disposable products and synthetic nicotine products. The Associated Press reports that according to sales data, since 2020 the number of different ESDs sold in the United States has tripled to more than 9,000, “driven almost entirely by a wave of unauthorized disposable vapes from China.”<sup>4</sup> With so many products entering and exiting the market, it is difficult for wholesalers, retailers, and vape shop vendors to know what ESDs are legal for sale, resulting in many illicit products remaining available to consumers.

Additionally, House Bill 1033 grants the Alcohol, Tobacco, and Cannabis Commission (“ATCC”) authority to conduct unannounced inspections of retailers and vape shop vendors to ensure compliance with the Title and the requirement that ESDs may only be sold to individuals age 21 and older. The ATCC already conducts retail checks for cigarettes and Other Tobacco Products (“OTP”), including directory checks for those products. Giving the Commission similar authority to check ESD compliance is another way in which House Bill 1033 seeks to treat ESDs similarly to traditional tobacco products.

The second way in which House Bill 1033 improves Maryland’s ESD industry is by making important modifications to Maryland’s ESD licensure system. Right now, many entities selling ESDs do not have ESD licenses because they already have cigarette or OTP licenses, and the law exempts them from getting a separate ESD license. House Bill 1033 requires that all businesses obtain a separate ESD license, enabling the State to know what businesses are buying and selling ESDs in Maryland. House Bill 1033 also requires all sales be made by and to businesses with Maryland ESD licenses, as is required for traditional tobacco products.

House Bill 1033 would also close a significant loophole in the current law that allows ESD manufacturers to sell their products over the internet or by mail directly to consumers. Online sales are not allowed for cigarettes or OTP, and House Bill 1033 removes this exception for ESDs so that ESDs are treated the same as cigarettes and OTP. House Bill 1033 requires that all purchases by consumers be face-to-face sales, which are better able to prevent illegal, underage sales.

The provisions in House Bill 1033 come from the State’s long experience with traditional tobacco products, as well as the recommendations of the Comptroller’s Task Force on Electronic Smoking

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<sup>4</sup> M. Perrone, “Thousands of unauthorized vapes are pouring into the US despite the FDA crackdown on fruity flavors,” *Associated Press* (June 26, 2023), <https://apnews.com/article/fda-vapes-vaping-elf-bar-juul-80b2680a874d89b8d651c5e909e39e8f>.

Devices.<sup>5</sup> The Task Force, which was established in 2019, was made up of 40 appointed members from every region of the State, comprised of educators, ESD retailers, public health experts, concerned parents, and local and state elected officials. After holding four public meetings and soliciting feedback from both industry and the public, the Task Force’s 2020 Report made two recommendations found in House Bill 1033: banning all direct-to-consumer internet and mail order sales of ESDs, and requiring separate ESD licenses with higher fees. The Report also recommended obtaining more information from manufacturers to better “know precisely what e-liquids and ESD devices contain before these products ever reach consumers.” House Bill 1033 improves on that by requiring that ESDs sold in the State have marketing orders issued by the FDA.

Finally, the anticipated proposed amendments would make additional improvements to Maryland’s ESD laws. These amendments would expand the ESDs permitted for sale by allowing both ESDs with marketing orders, but also those that have timely applied for FDA authorization and are awaiting a ruling or that have a court order staying a final decision on the directory. Only licensed vape shops would be permitted to sell the larger class of ESDs with pending applications, keeping them out of convenience stores and restricting them to stores that cater to individuals over the age of 21. The amendments would also establish a two-tiered fee system for Maryland’s ESD directory: manufacturers applying for ESDs with marketing orders will have a fee of \$1,000 per product, while ESDs with pending FDA applications will have a fee of \$5,000 per product, paid to the Attorney General to be used for administration and enforcement of this law. Similarly, a new subsection is included requiring that manufacturers post security, the amount of which depends on what products they are certifying. These funds would be available to the ATCC for the costs of collection and disposing of any ESDs taken off the directory or which violate federal, state, or local law.

The amendments would also revise the penalties section, providing the State with tools to effectively enforce the Directory. Sales of off-directory products would also be deemed an unfair and deceptive trade practice in violation of the Consumer Protection Act. Lastly, the amendments would provide additional process when a product is removed from the directory.

For the foregoing reasons, the Office of the Attorney General urges a favorable report on House 1033.

cc: Committee Members

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<sup>5</sup> Comptroller’s Task Force on Electronic Smoking Devices, *Electronic Smoking Devices in Maryland: A Safer Path Forward* (2020), <https://mdlaw.ptfs.com/awweb/pdfopener?md=1&did=31028>.