# **Department of Legislative Services**

Maryland General Assembly 2024 Session

# FISCAL AND POLICY NOTE First Reader

House Bill 1197

(Delegate Rogers)

**Economic Matters** 

# **Business Regulation - Electronic Smoking Devices Manufacturers - Certifications**

This bill alters regulation of electronic smoking devices (ESD) by, among other things, (1) establishing a certification requirement for ESD manufacturers; (2) requiring the Office of the Attorney General (OAG) to develop a directory of ESD manufacturers; (3) altering the distribution of ESD, including prohibiting direct shipment to consumers or retailers; (4) requiring licensees to obtain a separate ESD license; and (5) increasing application fees for ESD licenses. The bill prohibits the sale, possession, or importing for personal consumption of any ESD not included in the directory, with a specified exception. Violators are guilty of a misdemeanor and subject to a fine of up to \$5,000 and/or imprisonment for up to one year. In addition, a tobacco product manufacturer must submit, with its already required annual certification to OAG, a fee of \$1,000, which must be distributed to a special fund to be used for enforcement of the Tobacco Product Manufacturers Escrow Act (Escrow Act).

# **Fiscal Summary**

**State Effect:** General fund and special fund revenues increase by \$45,400 and \$16,000, respectively, annually beginning in FY 2025 from fees. General fund expenditures increase by \$265,000 in FY 2025 for one-time programming costs and by an indeterminate amount beginning in FY 2025 for enforcement (not quantified below). To the extent the bill reduces the amount of ESD sold, general fund revenues decrease beginning in FY 2025 (not quantified below). Potential minimal increase in general fund revenues and expenditures due to the bill's penalty provisions.

(in dollars)	FY 2025	FY 2026	FY 2027	FY 2028	FY 2029
GF Revenue	\$45,400	\$45,400	\$45,400	\$45,400	\$45,400
SF Revenue	\$16,000	\$16,000	\$16,000	\$16,000	\$16,000
GF Expenditure	\$265,000	\$0	\$0	\$0	\$0
Net Effect	(\$203,600)	\$61,400	\$61,400	\$61,400	\$61,400

Note:() = decrease; GF = general funds; FF = federal funds; SF = special funds; - = indeterminate increase; (-) = indeterminate decrease

**Local Effect:** Local government revenues increase from the \$5 fee increase for specified ESD licenses, as discussed below. Potential minimal increase in revenues and expenditures due to the bill's penalty provisions.

Small Business Effect: Meaningful.

# **Analysis**

### **Bill Summary/Current Law:**

### **Definitions**

The bill specifies that "tobacco product," "other tobacco products," and "ESD" do not include a drug, device, or combination product authorized for sale as a *nicotine replacement product* by the U.S. Food and Drug Administration (FDA). Further, "ESD" is redefined to include nicotine salts and any cartridge or tank of such a device. The definitions of "ESD manufacturer," "ESD retailer," and "ESD wholesaler distributor" are altered to reflect the bill's regulatory changes as discussed further in this analysis.

# Licensing and Regulation

Generally, the Business Regulation Article governs the licensing of cigarette, other tobacco products (OTP), and ESD manufacturers, wholesalers, retailers, storage warehouses, and vending machine operators. The Alcohol, Tobacco, and Cannabis Commission (ATCC) issues manufacturer, wholesaler, storage warehouse, and vending machine operator licenses. The clerks of the circuit courts issue retail licenses. Without an appropriate license (with limited exception), a person may not act, attempt to act, or offer to act as (1) a cigarette manufacturer, retailer, storage warehouse, subwholesaler, vending machine operator, or wholesaler; (2) an OTP manufacturer, retailer, storage warehouse, wholesaler, or tobacconist; or (3) an ESD manufacturer, retailer, wholesaler distributor, wholesaler importer, or vape shop vendor. Violators are guilty of a misdemeanor and are subject to a fine up to \$1,000 and/or imprisonment for up to 30 days. Each day that a violation continues is a separate offense.

Maryland Escrow Requirements for Nonparticipating Tobacco Product Manufacturers

In 1999, the State enacted the Escrow Act, under which a tobacco product manufacturer must either (1) become a participating manufacturer by joining the Master Settlement Agreement and generally comply with its financial obligations or (2) establish an escrow account as a nonparticipating manufacturer and pay into it as required under law.

A tobacco product manufacturer whose cigarettes are sold in this State, whether directly or through a distributor, retailer, or similar intermediary, must annually execute and deliver a certification to the Attorney General, as specified. The certification must indicate whether the manufacturer is a participating manufacturer; or is in full compliance with the Escrow Act. OAG must subsequently develop and make available for public inspection a directory listing all tobacco product manufacturers that have complied with the certification requirement and all associated brand families that are listed in the provided certifications.

Under the bill, a tobacco product manufacturer must pay a fee of \$1,000 to the Comptroller when submitting its annual certification. OAG must publish in its directory listing all tobacco product manufacturers that *OAG has determined are in compliance with all applicable federal, State, and local laws*, including all brand families that are listed in the certifications *that are compliant*. The revenues collected by the Comptroller from the certification fee must be distributed to a special fund to be used by OAG for the enforcement of the Escrow Act.

# ESD License Required for Cigarette and OTP Licensees

Under current law, any person with an applicable cigarette business license or OTP license (or the applicable affiliate) is also authorized to manufacture, distribute, or sell ESD, as appropriate.

The bill requires any person with a cigarette business license or OTP license that is also seeking to manufacture, distribute, or sell ESD to obtain a separate license to manufacture, distribute, or sell ESD. However, such persons may not be required to pay any additional application fee for an ESD license.

#### ESD License Fees

The bill increases the application fees for ESD licenses as follows: from \$25 to \$1,000 for an ESD manufacturer license; from \$150 to \$750 for an ESD wholesaler or ESD importer license; and from \$25 to \$30 for an ESD retailer or vape shop vendor license.

## ESD Manufacturer License

Under current law, an ESD manufacturer license authorizes the licensee to sell ESD to a licensed ESD wholesaler, an ESD wholesaler or retailer outside the State if the ESD may be lawfully sold in Maryland, a licensed vape shop vendor, and a consumer.

Under the bill, an ESD manufacturer may only sell ESD to a licensed ESD wholesaler *distributor* or a *licensed ESD wholesaler importer*. Direct sales to consumers are repealed. However, an ESD manufacturer licensee that also holds an ESD retailer or vape shop HB 1197/ Page 3

license may transfer ESD to inventory for sale under those licenses (as under current law); however, such a licensee may not distribute ESD to another licensed ESD retailer or vape shop vendor.

ESD Retailer, Wholesale Distributor, and Wholesaler Importer Licenses

The bill further alters the distribution chain of ESD so that an ESD retailer or vape shop vendor may no longer buy ESD from a wholesaler importer or from an ESD manufacturer. More specifically:

- An ESD wholesaler distributor must obtain ESD devices from a licensed ESD manufacturer, a licensed ESD wholesaler distributor, or a licensed ESD wholesaler importer. An ESD wholesaler distributor may hold ESD and may sell ESD to a licensed retailer or vape shop vendor as well as to another licensed ESD wholesaler distributor or licensed ESD wholesaler importer.
- An ESD wholesaler importer must obtain at least 70% of its ESD from a licensed ESD manufacturer located in a foreign country. An ESD wholesaler importer license authorizes the licensee to (1) sell ESD to a licensed ESD wholesaler distributor or a licensed ESD wholesaler importer; (2) buy ESD directly from a licensed ESD manufacturer, a licensed ESD wholesaler importer, or a licensed ESD wholesaler distributor; and (3) hold ESD.
- With the exception noted above for an ESD retailer that also holds an ESD manufacturer license, an ESD retailer must buy ESD from a *licensed* ESD wholesaler distributor and may not buy ESD from an ESD manufacturer or an ESD wholesaler importer. The bill also repeals language permitting an ESD retailer to distribute sample ESD to consumers.
- With the exception noted above for a vape shop vendor that also holds an ESD manufacturer license, a vape shop vendor must buy ESD from a licensed ESD wholesaler distributor and may not buy ESD from an ESD manufacturer or an ESD wholesaler importer.

# Certification Requirement for ESD Manufacturers

Similar to the process currently required for tobacco product manufacturers, the bill requires an ESD manufacturer whose products are sold in the State to execute and deliver a certification to OAG by June 30 each year, certifying that the ESD manufacturer has received authorization from FDA to sell its ESD devices in the United States. For each certification submitted, an ESD manufacturer must pay OAG a fee of \$1,000. In the certification, an ESD manufacturer must:

- identify all of its ESD brand families that are being sold in the United States as of the date of certification;
- identify any ESD brand family that the ESD manufacturer seeks to sell in the State in the upcoming fiscal year;
- indicate with an asterisk any brand family sold in the State during the preceding three calendar years that are no longer sold in the State as of the date of certification;
- identify by name and address any other manufacturer of such brand families in the preceding or current fiscal year;
- indicate whether the ESD brand family being certified includes an aerosolizing device or the juice, salt, or other consumable substance to be aerosolized or both;
- indicate by number the decision summary for the market order authorizing the ESD to be sold in the United States and include a copy of the FDA authorization; and
- identify any other information required by OAG to confirm that the ESD manufacturer and its brand families are compliant with all applicable federal, State, and local laws.

In addition, an ESD manufacturer must further certify that it is (1) registered to do business in the State or has appointed a resident agent for service of process and provided notice of the appointment; (2) is licensed by ATCC to operate as an ESD manufacturer; and (3) is in full compliance with all applicable local, State, and federal laws regarding the manufacture and sale of ESD.

Generally, if an ESD manufacturer has (1) not previously submitted a certification with the State or (2) is not listed in the directory, the manufacturer may submit an initial certification at any point during the year.

The bill prohibits an ESD manufacturer from including a brand family or brand style in its certification unless it affirms that (1) it is the entity that fabricates, manufactures, mixes, or otherwise produces the ESD included in the certification and (2) to the best of the ESD manufacturer's knowledge, no other ESD manufacturer is fabricating, manufacturing, mixing, or otherwise producing ESD for sale in the United States with the same brand name as a brand family included in the certification.

The State retains the right to refuse to include an ESD in the directory if OAG has reason to believe that a brand family or brand style included in a certification is an ESD produced by a different ESD manufacturer.

An ESD manufacturer listed in the directory must update its listing to reflect any addition, discontinuance, or modification to its listed ESD brand families by executing and delivering a supplemental certification no less than 30 calendar days prior to the change.

### Directory of ESD Manufacturers

OAG must develop and make available for public inspection a directory listing all ESD manufacturers that have provided current and accurate certifications and all approved ESD brand families and brand styles included in the certifications. OAG may not include or retain in the directory any brand families or brand styles of any ESD manufacturer that fails to provide the required certification, fee, or whose certification OAG determines is not in compliance with the bill, unless the violation has been cured. OAG must update the directory as necessary to correct mistakes and to add or remove an ESD manufacturer or any brand family or brand style of an ESD to keep the directory in conformity with the bill's requirements.

Each licensed ESD wholesaler distributor and ESD wholesaler importer must provide OAG, and update as necessary, current contact information for the purpose of receiving any notifications, including a point of contact person, a physical location, and an electronic mail address. Further, each licensed ESD manufacturer must maintain for a period of at least five years all invoices and documentation of sales, all approval letters and underlying applications and materials, and any other information relied on for its certification.

### Resident Agent and Service of Process

Any nonresident or foreign ESD manufacturer that has not registered to do business in the State as a foreign corporation or business entity must appoint, and continually engage, an agent in the State for the service of process on the nonresident or foreign ESD manufacturer, before its brand families or brand styles may be included or retained in the directory.

Any process, action, or proceeding against a nonresident or foreign ESD manufacturer concerning or arising out of the enforcement of the bill or the Business Regulation Article may be served in any manner authorized by law. The service of process on the designated agent constitutes legal and valid service of process on the ESD manufacturer. The ESD manufacturer must provide, to the satisfaction of ATCC and OAG, the name, address, telephone number, and proof of the appointment and availability of the agent.

An ESD manufacturer must provide (1) notice to ATCC and OAG no less than 30 calendar days prior to the termination of the authority of an agent and (2) proof of the appointment of a new agent no less than five calendar days prior to the termination of an existing agent.

If an agent terminates an agency appointment, the ESD manufacturer must notify ATCC and OAG of the termination within five calendar days and include proof of the appointment of a new agent.

### Enhanced ESD Enforcement and Penalties

The bill prohibits an *individual* from selling, offering for sale, possessing for sale in the State, or importing for personal consumption in the State, any ESD, brand family, or brand style not included in the directory or any ESD manufactured by an ESD manufacturer that is not included in the directory. An individual who does so, under separate provisions discussed below, is guilty of a misdemeanor. On conviction, a violator is subject to a fine of up to \$5,000 and/or imprisonment for up to one year.

A person that sells, distributes, acquires, holds, owns, possesses, transports, imports, or causes to be imported ESD for resale to a consumer that the person knows or should have known are intended for distribution or sale in the State but are not included in the directory or are manufactured by an ESD manufacturer that is not in the directory is guilty of a misdemeanor. On conviction, a violator is subject to a fine of up to \$5,000 and/or imprisonment for up to one year. However, a person that possesses less than \$100 worth of ESD solely for personal consumption and not for resale to a consumer is not subject to these penalty provisions.

In addition to any other civil or criminal remedy, on determination that a licensed ESD wholesaler has violated the bill's (1) prohibition against the sale or possession of any ESD not included in the directory or manufactured by an ESD not in the directory or (2) monthly reporting requirement regarding sales of ESD, ATCC may revoke or suspend the license, as specified.

ATCC may also impose a civil penalty in an amount not to exceed the greater of (1) 500% of the retail value of the ESD sold or offered for sale or (2) \$5,000 on a determination of a violation of the prohibition against the sale or possession of any ESD not included in the directory or manufactured by an ESD not in the directory. Each sale of and each offer to sell ESD in violation of the bill's provisions constitutes a separate violation.

Any ESD sold, offered for sale, or possessed for sale in the State, or imported for personal consumption in the State in violation of the bill's provisions must be deemed contraband and subject to seizure and forfeiture. Seized and forfeited ESD may not be resold and may be destroyed.

OAG, on behalf of ATCC, may seek an injunction to restrain a threatened or actual violation of the bill's (1) prohibition against the sale or possession of any ESD not included in the directory or manufactured by an ESD not in the directory or (2) monthly reporting requirement regarding sales of ESD, and compel a licensed ESD wholesaler distributor to comply.

The bill authorizes specific information sharing among ATCC, OAG, and the Comptroller's Office regarding compliance and enforcement of the bill's provisions.

If a court or other adjudicative body determines that a person has violated the bill's provisions, it must order any profits, gain, gross receipts, or other benefit from the violation to be paid to OAG. Unless otherwise expressly provided, the remedies or penalties provided under the bill are cumulative to each other, and to the remedies or penalties available under all other State laws.

# Review and Regulations

A determination by the Attorney General to omit or to delete from the directory a brand family, brand style, or ESD manufacturer is subject to review in accordance with applicable State law. OAG and ATCC may adopt regulations necessary to carry out the bill. In any action brought by the State under the bill, the State is entitled to recover the costs of investigation, expert witness fees, costs of the action, and reasonable attorney's fees.

ATCC or OAG may adopt regulations requiring a licensee to submit any additional information or documentation as necessary to determine the accuracy of any information submitted or otherwise promote compliance with the bill.

## ESD Wholesaler Distributor Reporting and Recordkeeping

No later than 21 days after the end of each calendar month, and more frequently if directed, each licensed ESD wholesaler distributor must submit true and accurate information to ATCC to facilitate compliance with the bill, including a list by brand family and brand style of the total quantity of ESD sold by the licensed ESD wholesaler to a licensed ESD retailer or licensed vape shop vendor during the previous calendar month.

A licensed ESD wholesaler distributor must maintain and make available to ATCC and OAG for a period of five years all invoices and documentation of sales of all ESD and any other information relied on in reporting to ATCC and OAG.

ATCC may disclose to OAG and the Comptroller's Office any applicable information received and requested by OAG or the Comptroller for the purposes of determining compliance with the bill.

### Monitoring and Enforcement

ATCC and OAG may require a licensed ESD manufacturer, wholesaler distributor, wholesaler importer, retailer, or vape shop vendor to submit any additional information, including invoices, receipts, correspondence, confirmations of approval, marketing, HB 1197/ Page 8

advertising materials, and samples of packaging or labeling of each brand family, as is necessary to enable OAG to determine whether a licensed ESD manufacturer is compliant with the bill and all other applicable federal, State, and local laws.

### **State Revenues:**

Office of the Attorney General

The bill requires that each tobacco product manufacturer pay to the Comptroller a fee of \$1,000 when submitting its annual certification to OAG. Revenues must be distributed to a special fund to be used by OAG to enforce the Escrow Act. It is assumed that the 16 tobacco product manufacturers listed in the current <u>directory</u> pay the new fee, special fund revenues increase by \$16,000 annually beginning in fiscal 2025.

The bill also requires each licensed ESD manufacturer to pay a fee of \$1,000, but directly to OAG, for each certification submitted. OAG estimates that each of the three ESD manufacturers that have received authorization from FDA are likely to submit a certification under the bill. Consequently, OAG general fund revenues increase by \$3,000 annually beginning in fiscal 2025. (As the bill does not specify that these revenues accrue to a special fund, they are assumed to accrue to the general fund.) To the extent that the number of licensed ESD manufacturers increases under the bill due to the requirement to hold a separate ESD-specific license, revenues increase accordingly. Conversely, if the distribution and certification provisions in the bill reduce the number of ESD manufacturers, revenues from certification decrease.

Alcohol, Tobacco, and Cannabis Commission

ESD Manufacturer License: Assuming that each of the three ESD manufacturers that have received authorization from FDA apply for a license to act as an ESD manufacturer and pay the \$1,000 application fee (compared with the \$25 fee paid under current law by 31 ESD manufacturers, 28 of which have not received FDA authorization), ATCC revenues increase by \$2,225 beginning in fiscal 2025. To the extent that additional entities apply for this license, revenues increase accordingly. The requirement to hold an ESD-specific license is assumed to have no effect on revenues as manufacturers of cigarettes and/or OTP that may currently manufacture ESD without a separate license are exempt from paying an application fee for an ESD manufacturer license.

Fee Increases for ESD Wholesaler Distributors and Importers: The bill increases the license fees for an ESD wholesaler distributor or ESD wholesaler importer from \$150 to \$750 (\$600 per license). Assuming that the 63 ESD wholesaler distributors and 4 ESD wholesaler importer license holders renew, ATCC revenues further increase by \$40,200 beginning in fiscal 2025. The requirement to hold an ESD-specific license is assumed to

have no effect on revenues as wholesaler distributors and importers of cigarettes and/or OTP that may currently distribute or import ESD without a separate license are exempt from paying an application fee for the comparable ESD license.

Related Revenues: ATCC notes that approximately 6,000 retail licensees sell cigarettes or OTP and may also carry ESD. ATCC anticipates that the bill's increased fees may increase ATCC licensing revenue. However, the requirement to obtain ESD-specific licenses is assumed to have no effect on revenues as a retail licensee is exempt from paying an application fee for the comparable ESD retail license. Further, any increase in revenues could be offset if a significant number of licensees exit the market because their products are not eligible to be in the directory and, thus, cannot be sold in Maryland.

### Penalty Provisions

General fund revenues may increase minimally as a result of the bill's monetary penalty provision from cases heard in the District Court. In addition, under the bill, ATCC may impose a civil penalty on the sale or possession of any ESD not included in the directory or manufactured by an ESD not in the directory. Each sale of and each offer to sell ESD in violation of the bill's provisions constitutes a separate violation. To the extent ATCC imposes such penalties, general fund revenues increase by an indeterminate amount.

#### Sales and Use Tax Revenues

A sales and use tax rate of 12% is imposed on the final retail price of ESD (60% in the case of vaping liquid sold in a container that contains at least 5 milliliters of vaping liquid). To the extent the bill reduces the amount of ESD sold in the State, general fund revenues decrease by an indeterminate amount beginning in fiscal 2025 due to foregone sales and use tax revenues.

## **State Expenditures:**

### Comptroller's Office

The Comptroller's Office advises that the need to share specific information with other agencies under the bill necessitates one-time programming changes. Thus, general fund expenditures for the Comptroller's Office increase by \$265,000 in fiscal 2025 only.

### Office of the Attorney General

OAG advises that, at least in the short term, it can use existing personnel to review certifications, investigate applicants, and oversee the maintenance of the new ESD directory.

HB 1197/ Page 10

### Alcohol, Tobacco, and Cannabis Commission

ATCC advises that the bill has a significant but indeterminate impact on its expenditures, as the bill increases the enforcement powers of ATCC and is expected to increase the volume of seizures, administrative actions, and records review tasks.

Under the bill, ATCC notes that the scope of ESD products that will be eligible for sale is expected to be much smaller than the current market as only a few manufacturers have received FDA approval for their products. Currently, seizure of ESD by ATCC is rare as ESD are not subject to forfeiture based on failure to pay an excise tax. Thus, it is difficult to determine the potential cost to confiscate, store, and safely dispose of any contraband ESD under the bill, though such costs will likely be greater than current costs for other products.

Accordingly, ATCC expenditures increase by an indeterminate amount beginning in fiscal 2025 for enforcement, administrative actions, records review, and seizure of contraband products. These expenditures are offset by additional revenues and may be offset by the imposition of civil penalties for licensees that sell ESDs in violation of the bill.

### Judiciary

The Judiciary advises that there may be additional cases for violations under the bill. Any increase in caseloads results in additional operational impact on the courts. However, the bill is not anticipated to materially affect the operations or finances of the Judiciary.

### Penalty Provisions

General fund expenditures may increase minimally as a result of the bill's incarceration penalty due to more people being committed to State correctional facilities for convictions in Baltimore City.

**Local Revenues:** Local government revenues increase as a result of the bill's changes to the fee schedule for ESD retailer and vape shop vendors. The bill increases these license fees from \$25 to \$30. Therefore, for each license issued, local government revenues increase by \$5.

As noted above, Montgomery County imposes a 30% tax on the wholesale value of vaping products. To the extent the bill reduces the amount of ESD sold, Montgomery County tax revenues decline beginning in fiscal 2025. The amount of the decline depends on the decrease in vaping products sold as a result of the bill.

Revenues may increase minimally as a result of the bill's monetary penalty provision from cases heard in the circuit courts.

**Local Expenditures:** Expenditures may increase minimally as a result of the bill's incarceration penalty. Counties pay the full cost of incarceration for people in their facilities for the first 12 months of the sentence. *Per diem* operating costs of local detention facilities have ranged from approximately \$90 to \$300 per incarcerated individual in recent years.

**Small Business Effect:** ESD manufacturers, some of which may be small businesses, are required to hold a specific ESD manufacturer license, submit an annual certification to OAG, and pay both an annual \$1,000 license fee to ATCC and \$1,000 certification fee to OAG. Direct sales of ESD to consumers are repealed. Businesses are prohibited from selling ESD that are not in the directory and must dispose of any inventory that can no longer be sold.

### **Additional Information**

**Recent Prior Introductions:** Similar legislation has not been introduced within the last three years.

**Designated Cross File:** None.

**Information Source(s):** Baltimore, Frederick, and Montgomery counties; Maryland Association of County Health Officers; Alcohol, Tobacco, and Cannabis Commission; Comptroller's Office; Judiciary (Administrative Office of the Courts); Maryland Department of Health; Office of the Attorney General; Department of Legislative Services

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