HOUSE BILL NO. 525

INTRODUCED BY A. REGIER

A BILL FOR AN ACT ENTITLED: "AN ACT GENERALLY REVISING LAWS RELATING TO NICOTINE AND VAPOR PRODUCTS; PROHIBITING DISTRIBUTING, SELLING, OR THE ATTEMPT TO SELL VAPOR PRODUCTS CONTAINING NICOTINE UNLESS INCLUDED IN A DIRECTORY MAINTAINED AND ENFORCED BY THE ATTORNEY GENERAL; PROHIBITING THE SALE OF DISPOSABLE VAPOR PRODUCTS; REQUIRING MANUFACTURERS OF VAPOR PRODUCTS CONTAINING NICOTINE TO CERTIFY THAT THEIR VAPOR PRODUCTS ARE IN COMPLIANCE WITH FEDERAL MARKETING AUTHORIZATION REQUIREMENTS; APPLYING THE TAX ON TOBACCO PRODUCTS TO VAPOR PRODUCTS THAT CONTAIN NICOTINE; PROVIDING A STATUTORY APPROPRIATION; PROVIDING DEFINITIONS; ESTABLISHING REPORTING REQUIREMENTS; PROVIDING AN APPROPRIATION; PROVIDING RULEMAKING AUTHORITY; AMENDING SECTIONS 16-11-102, 16-11-118, 16-11-119, 16-11-120, 16-11-128, 16-11-132, 16-11-141, 16-11-159, AND 17-7-502, MCA; AND PROVIDING AN EFFECTIVE DATE, AN APPLICABILITY DATE, AND A TERMINATION DATE."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

NEW SECTION. **Section 1. Definitions.** As used in this chapter, the following definitions apply:

(1) "Disposable vapor product" has the same meaning as "vapor product" as defined in this section except that a disposable vapor product is a prefilled, self-contained product designed for one-time use.

~~(1)~~(2) "FDA" means the United States food and drug administration.

~~(2)~~(3) "Importer" means a person or entity in a state or territory of the United States to whom vapor products that are manufactured outside the United States are shipped, delivered, or consigned for resale.

~~(3)~~(4) "Retailer" means a person, other than a wholesaler, who is licensed by the department of revenue and who is engaged in the business of selling vapor products to the ultimate consumer.

~~(4)~~(5) "Timely filed premarket tobacco product application" means an application pursuant to 21 U.S.C. 387j for a vapor product containing nicotine derived from tobacco marketed in the United States as of

August 8, 2016, that was submitted to the United States food and drug administration on or before September 9, 2020, and accepted for filing.

~~(5)~~(6) "Units sold" means the number of individual vapor products containing nicotine sold in the state by the applicable vapor product manufacturer, whether directly or through a wholesaler, retailer, or similar intermediary or intermediaries, during a given year or quarter.

~~(6)~~(7) (a) "Vapor product" has the same meaning as provided in 16-11-102, except that for the purposes of [sections 1 through 15], the vapor product must contain nicotine.

(b) The term does not include a product regulated as a drug or device by the FDA under Chapter V of the Federal Food, Drug, and Cosmetic Act.

~~(7)~~(8) "Vapor product manufacturer" means a person or entity that manufactures of fabricates vapor products for the purpose of sale or resale.

~~(8)~~(9) "Wholesaler" means a person or entity that:

(a) purchases vapor products from a vapor product manufacturer for the purpose of selling vapor products to retailers; or

(b) purchases vapor products from another wholesaler or any other person or entity for the purpose of selling vapor products to wholesalers or retailers.

NEW SECTION. **Section 2. Vapor product directory.** (1) By October 1, 2025, and annually afterward, a vapor product manufacturer whose vapor products containing nicotine are sold for retail sale in this state or to a consumer in this state, whether directly or through a retailer, wholesaler, importer, or similar intermediary or intermediaries, shall execute and deliver, on a form prescribed by the attorney general, a certification to the attorney general, under penalty of perjury, that as of the date of the certification the vapor product manufacturer is compliant with this chapter and that, for each vapor product containing nicotine sold for retail sale in this state or to a consumer in this state:

(a) the vapor product manufacturer has received a marketing granted order for the vapor product containing nicotine from the FDA pursuant to 21 U.S.C. 387j;

(b) the vapor product manufacturer submitted a timely filed premarket tobacco product application for the vapor product containing nicotine to the FDA pursuant to 21 U.S.C. 387j, and the application either

remains under review by the FDA or has received a denial order that has been and remains stayed by the FDA or court order, rescinded by the FDA, or vacated by a court; ~~or~~

(c) the vapor product manufacturer can demonstrate that the FDA has issued a rule, guidance, or other formal statement that temporarily exempts the vapor product containing nicotine from federal premarket tobacco application requirements; or

(d) the vapor product is not a disposable vapor product as defined in [section 1]. Disposable vapor products may not be offered to the public for sale in this state.

(2) The certification form must:

(a) separately list each brand name, product name, category, including but not limited to ~~disposable vapor product,~~ power unit, device, e-liquid cartridge, and e-liquid pod, and flavor for each vapor product containing nicotine that is sold in this state;

(b) identify the number of units sold in the state during the preceding calendar year for each brand family and product name;

(c) indicate by an asterisk a brand family or product name of a vapor product containing nicotine sold in the state during the preceding calendar year that is no longer being sold in the state as of the date of the certification;

(d) identify by name and address a vapor product manufacturer of vapor products containing nicotine; ~~and~~

(e) certify that the vapor product manufacturer has appointed an agent for service of process and has provided notice as required by [section 9]; and

(f) certify that the vapor product is not a disposable vapor product.

(3) An annual certification form must be accompanied by:

(a) a copy of:

(i) the marketing granted order issued by the FDA pursuant to 21 U.S.C. 387j;

(ii) the acceptance letter issued by the FDA pursuant to 21 U.S.C. 387j for a timely filed premarket tobacco product application;

(iii) a document issued by the FDA or by a court confirming that the premarket tobacco product application has received a denial order that has been and remains stayed by the FDA or court order, rescinded

by the FDA, or vacated by a court; or

(iv) a document issued by the FDA demonstrating that the vapor product containing nicotine is temporarily exempt from the premarket tobacco product application requirements; and

(b) a nonrefundable payment of $2,500 for each vapor product containing nicotine the first time a vapor product manufacturer submits a certification form for that product, and $1,000 for each vapor product containing nicotine each time a vapor product manufacturer submits an annual certification form for that product afterward.

(4) A vapor product manufacturer must notify the attorney general at least 30 days prior to making changes to the name, brand style, or packaging of a vapor product that was previously included in a certification under subsections (1) and (2) but is not required to submit an additional marketing granted order or premarket tobacco product application for this type of product change.

NEW SECTION. **Section 3. Confidentiality.** The information submitted by the vapor product manufacturer pursuant to [sections 2(3)(a) and 6(2)] constitutes a trade secret as defined in 30-14-402, is confidential information as defined in 2-6-1002, and is protected from disclosure.

NEW SECTION. **Section 4. Notice of changes.** A vapor product manufacturer required to submit a certification form pursuant to [section 2] shall notify the attorney general within 30 days of any material change to the certification form, including the issuance or denial of a marketing authorization or other order by the FDA pursuant to 21 U.S.C. 387j, or any other order or action by the FDA or any court that affects the ability of the vapor product containing nicotine to be introduced or delivered into interstate commerce for commercial distribution in the United States.

NEW SECTION. **Section 5. Directory -- publication -- updates.** (1) Starting January 1, 2026, the attorney general shall maintain and make publicly available on the attorney general's official website a directory that lists all vapor product manufacturers and all vapor products containing nicotine, such as brand names, product names, categories, including but not limited to ~~a disposable vapor product,~~ e-liquid, e-liquid cartridge, e-liquid pod, and power unit, and flavors, for which certification forms have been submitted and approved by the

attorney general.

(2) The attorney general shall update the directory as necessary in order to correct mistakes and to add or remove a vapor product manufacturer or vapor product containing nicotine to keep the directory in conformity with the requirements of this chapter. The attorney general shall establish a process to provide licensed retailers, wholesalers, importers, and other relevant parties notice of the initial publication of the directory and changes made to the directory in the prior month.

(3) A vapor product manufacturer or the vapor product manufacturer's vapor products containing nicotine may not be included or retained in the directory if the attorney general determines that any of the following apply:

(a) the vapor product manufacturer failed to provide a complete and accurate certification as required by [section 2];

(b) the vapor product manufacturer submitted a certification that does not comply with the requirements of [sections 2(2) and (3)(a)];

(c) the vapor product manufacturer failed to include with its certification the payment required by [section 2(3)(b)];

(d) the vapor product manufacturer sold vapor products containing nicotine in this state required to be certified under this chapter during a period when either the vapor product manufacturer or the vapor product containing nicotine had not been certified and listed on the directory;

(e) the information provided by the vapor product manufacturer in its certification is determined by the attorney general to contain false information or contains material misrepresentations or omissions;

(f) the vapor product manufacturer failed to submit a change notice to the attorney general as required by [section 4]; or

(g) the vapor product manufacturer failed to submit any reports required under 16-11-128.

NEW SECTION. **Section 6. Directory -- notice and inventory.** The attorney general shall provide vapor product manufacturers notice and an opportunity to cure deficiencies before removing vapor product manufacturers or vapor products containing nicotine from the directory.

(1) The attorney general may not remove the vapor product manufacturer or the vapor product