HB5482

LRB10120458CPF70023b

101ST GENERAL ASSEMBLY

State of Illinois

2019 and 2020

HB5482

by Rep. Robert Rita

SYNOPSIS AS INTRODUCED:

New Act

Creates the New Tobacco Product Certification Act. Provides that by a specified date every new tobacco product manufacturer whose new tobacco products are sold in the State shall execute and deliver a certification to the Department of Revenue with specified information. Requires new tobacco product manufacturers to notify the Department within 30 days of receiving an order issued by the U.S. Food and Drug Administration with regard to a new tobacco product or of any notice of action taken by the U.S. Food and Drug Administration affecting the ability of the new tobacco product to be introduced or delivered into interstate commerce for commercial distribution. Requires new tobacco product manufacturers to pay a fee to the Department not to exceed $500. Provides that a violation of the Act shall result in a $500 civil penalty. Allows the Department to adopt rules that are necessary and proper to implement and enforce the Act. Contains other provisions.

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FISCAL NOTE ACT
MAY APPLY

A BILL FOR

AN ACT concerning health.

Be it enacted by the People of the State of Illinois, represented in the General Assembly:

Section 1. Short title. This Act may be cited as the New Tobacco Product Certification Act.

Section 5. Definitions. In this Act:

"Alternative nicotine product" means any noncombustible product containing nicotine without the presence of tobacco leaf that is intended for human consumption, whether chewed, absorbed, dissolved, or ingested by any other means. "Alternative nicotine product" does not include: any tobacco product or vapor product; any product regulated as a drug or device by the U.S. Food and Drug Administration under Subchapter V of the federal Food, Drug, and Cosmetic Act; or any nontobacco food product in which nicotine is a naturally occurring compound.

"Cigar" means any roll for smoking, except cigarettes, made chiefly of tobacco or any substitute for tobacco. "Cigar" includes any tobacco product manufactured or packaged as a wrap or as a hollow tube made, wholly or in part, from tobacco that is designed or intended to be filled by the consumer with loose tobacco or other fillers.

"Department" means the Department of Revenue.

"Finished new tobacco product" means any new tobacco product that will not be subject to any additional processing before sale to a consumer.

"New tobacco product" means any alternative nicotine product, cigar, or vapor product that:

(1) was not commercially distributed or sold, including, but not limited to, products distributed or sold in test markets, in the United States on or before February 15, 2007; or

(2) was modified in design, contains a component or part that was modified, changed in the content or amount of any additive or ingredient at any time after February 15, 2007, and for which the U.S. Food and Drug Administration has issued a regulation or other formal guidance determining that the modification or change alters the product to such an extent that it is no longer substantially equivalent to a product commercially distributed or sold on or before February 15, 2007.

"New tobacco product manufacturer" means any person who manufactures, fabricates, assembles, processes, mixes, prepares, labels, repacks, or relabels a finished new tobacco product. "New tobacco product manufacturer" includes, but is not limited to, an owner of a brand or formula for a new tobacco product who contracts with another person to complete the fabrication and assembly of the product to the brand or formula owner's standard.

"Vapor product" means any noncombustible product that employs a heating element, power source, electronic circuit, or other electronic, chemical, or mechanical means, regardless of shape or size, that is intended to aerosolize a liquid or other substance containing nicotine. "Vapor product" includes any electronic cigarette, electronic cigar, electronic cigarillo, electronic pipe, electronic hookah, vape pen, vaporizer, or similar product or device, any component or part of such product or device, and any container or cartridge containing a liquid or other substance containing nicotine that has been manufactured to be used with or in a vapor product. "Vapor product" does not include any product regulated as a drug or device by the U.S. Food and Drug Administration under Chapter V of the federal Food, Drug, and Cosmetic Act.

Section 10. Manufacturer certification.

(a) Beginning June 1, 2020 or 30 days after a premarket tobacco application submission deadline is issued by the U.S. Food and Drug Administration, whichever is later, a new tobacco product manufacturer whose new tobacco product is sold in this State, whether directly or through a distributor, retailer, or similar intermediary, shall execute and deliver on a form prescribed by the Department a certification to the Department certifying, under penalty of perjury, the following:

(1) a premarket tobacco application has been submitted to the U.S. Food and Drug Administration with respect to

each new tobacco product that is sold in this State by the new tobacco product manufacturer; and

(2) the date the premarket tobacco application was submitted to the U.S. Food and Drug Administration.

A certification under this subsection shall include a copy of the cover page of the premarket tobacco application with evidence of receipt of the application by the U.S. Food and Drug Administration.

(b) The Department shall maintain a directory on its website and make available to the public a list of all new tobacco products that may lawfully be distributed or sold in this State. The Department shall add each new tobacco product that is compliant with subsection (a) to the new tobacco product directory within 30 days after receipt of proper certification under this Section.

(c) Notwithstanding subsections (a) and (b) of this Section, if a new tobacco product manufacturer can demonstrate to the Department that the U.S. Food and Drug Administration has issued a rule, guidance, or any other formal statement that temporarily exempts a new tobacco product from the federal premarket tobacco application requirements, the new tobacco product may be added to the new tobacco product directory under subsection (b) upon request by the new tobacco product manufacturer if the new tobacco product manufacturer provides sufficient evidence that the new tobacco product is compliant with federal enforcement discretion.

Section 15. Manufacturer notification. Any new tobacco product manufacturer who has made a certification as required under Section 10 shall notify the Department within 30 days of receiving:

(1) an order issued by the U.S. Food and Drug Administration with regard to a new tobacco product under 21 U.S.C. 387e or 21 U.S.C. 387j; or

(2) any notice of action taken by the U.S. Food and Drug Administration affecting the ability of the new tobacco product to be introduced or delivered into interstate commerce for commercial distribution.

Section 20. Fee. The Department shall designate a fee not to exceed $500 per new tobacco product to be paid by each new tobacco product manufacturer. The fee shall reasonably reflect the cost incurred by the Department for:

(1) processing the certification required under Section 10 and the notification required under Section 15; and

(2) operation of the directory required under subsection (b) of Section 10.

Section 25. Noncompliance; rebuttable presumption; civil penalty.

(a) Beginning July 1, 2020, it is unlawful for any

manufacturer, distributor, or retailer to distribute or sell any new tobacco product that has not sufficiently complied with the new tobacco product certification requirements under Section 10 or notification requirements under Section 15.

(b) There is a rebuttable presumption that an alternative nicotine product, cigar, or vapor product distributed or sold in this State that is not listed on the directory described under subsection (b) of Section 10 is being distributed or sold unlawfully in this State.

(c) A knowing violation of this Act shall result in a civil penalty of $500. Each distribution or sale in this State of a new tobacco product that is not listed on the directory described under subsection (b) of Section 10 shall constitute a separate violation.

Section 30. Rules. The Department may adopt rules that are necessary and proper to enforce and implement this Act.