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House Bill 5477 (Substitute H-3 as passed by the House)

Sponsor: Representative Lori Stone

House Committee: Regulatory Reform
Rules and Competitiveness

Senate Committee: Regulatory Reform

Date Completed: 9-20-22

CONTENT

The bill would enact the "Kratom Consumer Protection and Regulatory Act" to do the following:

- **Prohibit a person from distributing, selling, or manufacturing a kratom product in Michigan unless the person held a license.**
- **Require a person applying for a license to distribute, sell, or manufacture a kratom product to do so on a form and in a manner prescribed by the Department of Licensing and Regulatory Affairs (LARA), and prescribe the information that would have to be included in an application.**
- **Require LARA to issue a license if the applicant filed a completed application, paid a \$200 application fee, and met the Act's qualifications for licensure.**
- **Require a person who wished to distribute, sell, or manufacture a kratom product to have the raw materials used to produce each product tested by a qualified laboratory to certify that the product did not contain any substance in violation of the Act.**
- **Require a kratom product to be labeled as specified in the Act.**
- **Prohibit kratom products from including certain substances.**
- **Prohibit a person from selling a kratom product to an individual in Michigan who was under 21 years of age.**
- **Prescribe various penalties for violations of the Act.**
- **Require LARA, by January 1, 2023, to promulgate rules to implement the Act.**

Definitions

"Kratom product" would mean a food that contains any part of the leaf of the plant *Mitragyna speciosa*. "Food" would mean that term as defined in Section 1107 of the Food Law: articles used for food or drink for humans or other animals, chewing gum, and articles used for components of any such article.

"Certificate of licensure" would mean a document issued as evidence of authorization to distribute, sell, or manufacture a kratom product.

Licensure

Under the proposed Act, beginning January 1, 2023, a person could not distribute, sell, or manufacture a kratom product in Michigan unless the person held a license. A person would

have to obtain a license for each location in which the person distributed, sold, or manufactured a kratom product in Michigan. A person also would have to obtain a license if the person distributed, sold, or offered to distribute or sell a kratom product through a website to a person in Michigan.

A person applying for a license for these purposes would have to do so on a form and in a manner prescribed by LARA. The application would have to include all of the following information:

- The applicant's full name, date of birth, telephone number, and address; if the applicant were not an individual, the application would have to include the applicant's employer identification number.
- The address of each business or location where a kratom product would be distributed, sold, or manufactured or offered for distribution or sale.
- A list of the products that would be distributed, sold, or manufactured or offered for sale at each business or location.
- A copy of a certificate of analysis.
- A statement that the information supplied by the applicant, to the best of the applicant's knowledge, was true and was signed under penalty of perjury.

The Department would have to grant an applicant a license if the applicant submitted a completed application and an application fee of \$200 and met the qualifications for licensure under the Act. The Department would have to approve or deny an application within 30 business days after it was received and would have to deny the application if it were incomplete. If it denied application because it was incomplete, LARA would have to notify the applicant of the denial within 30 business days after the application was received, state the deficiency, and request additional information.

A license would not be transferable and would be valid for three years.

To renew a license, an applicant would have to submit a completed license application and submit a renewal fee of \$125. A licensee would have to display the certificate of licensure at each business or location where kratom products were distributed, sold, or manufactured or offered for distribution or sale.

Testing

Before applying for a license, a person who wished to distribute, sell, or manufacture or offer for distribution or sale a kratom product would have to have a sample of the raw materials used to produce each kratom product tested by a qualified laboratory to certify that the kratom product did not contain any substance in violation of the Act. If the tested materials did not contain a prohibited substance, the qualified laboratory would have to provide the person with a certificate of analysis that stated that the raw materials met the requirements prescribed under the Act. "Qualified laboratory" would mean a laboratory approved by the Department by rule.

A person would have to provide a copy of the certificate of analysis to LARA with an application for a license and upon request. The Department could request that a person have a sample of raw materials retested by a qualified laboratory and provide an updated certificate of analysis. If LARA requested that a person do so, the person would be responsible for the testing costs.

Labeling

The Act would require a kratom product to be labeled, and the product label would have to contain the alkaloid content in the product and the amount of mitragynine and 7-hydroxymitragynine contained in the product. Also, the product label would have to contain the following statements:

- "*Mitragyna speciosa* is an unapproved dietary ingredient. Ingesting *Mitragyna speciosa* may be dangerous. Consult your physician about whether this product is for you, how to use this product safely, potential interactions, precautionary measures before considering this product, and potential dependency, seizures, and other possible complications. Inform your physician of the alkaloid content labeled on this package."
- "Keep out of reach of children. DO NOT USE IF YOU ARE PREGNANT, PLAN TO BECOME PREGNANT, OR WHILE BREASTFEEDING. NOT FOR SALE TO MINORS."

Prohibitions

The Act would prohibit a person from distributing, selling, manufacturing, or offering for distribution or sale any of the following in person or through a website:

- A kratom product that was adulterated with a dangerous nonkratom substance; a kratom product would be adulterated with a dangerous nonkratom substance if the kratom product were mixed or packed with a nonkratom substance and that substance affected the quality or strength of the kratom product to such a degree as to render the kratom product injurious to a consumer.
- A kratom product that was contaminated with a dangerous nonkratom substance; a kratom product would be contaminated with a dangerous nonkratom substance if the kratom product contained a poisonous or otherwise deleterious nonkratom ingredient, including any of the substances listed in Schedule 1 controlled substances.
- A kratom product that contained a level of 7-hydroxymitragynine in the alkaloid fraction that was greater than 2.0% of the alkaloid composition of the product.
- A kratom product that contained a synthetic alkaloid, including any of the following: a) synthetic mitragynine, b) synthetic 7-hydroxymitragynine, or c) any other synthetically derived compound of the plant *Mitragyna speciosa*.
- A kratom product that did not include on its package or label the amount of mitragynine and 7-hydroxymitragynine contained in the product.
- A kratom product to an individual in Michigan who was under 21 years of age.

The Act also would prohibit a person from purchasing a kratom product over the internet in Michigan if the product did not comply with the above restrictions.

Penalties

For a violation of the provisions relating to labeling, prohibited substances, or sales to a person under 21 years of age, after notice and an opportunity for a hearing under the Administrative Procedures Act, a licensee could be subject to an administrative fine of at least \$500 for the first offense and up to \$1,000 for a second or subsequent offense. In addition to an administrative fine for the above violations or for any other violation of the Act or a rule promulgated under the Act, a licensee also would be subject to a denial, limitation, suspension, or revocation of a license.

A person who violated the requirement to obtain a license could be ordered to pay a civil fine of at least \$500 for the first offense and not more than \$1,000 for a second or subsequent offense.

In addition to any other action authorized by the Act, the Director could bring an action to do or more of the following:

- Obtain a declaratory judgment that a method, act, or practice was in violation of the Act.
- Obtain an injunction against a person that was engaging, or about to engage, in a method, act, or practice that violated the Act.

BACKGROUND

According to the Mayo Clinic, kratom is an herbal extract that comes from the leaves of a Southeast Asian evergreen tree (i.e., *Mitragyna speciosa*). Kratom leaves can be chewed, and dry kratom can be swallowed or brewed. At low doses, ingested kratom has stimulative effects; at higher doses, it acts like an opioid. Kratom is used recreationally and as an alternative medicine; however, according to the United States Food and Drug Administration (FDA), there is little scientific evidence that it is safe or effective for any medical use.¹

Legislative Analyst: Jeff Mann

FISCAL IMPACT

The bill could have an indeterminate negative fiscal on LARA for costs associated with the issuance of new licenses for kratom. The Department would be authorized to charge fees for the issuance of original kratom licenses and renewals; however, it is unknown if the additional revenue would be sufficient to cover the Department's anticipated costs to process license applications, promulgate new rules related to kratom licensure, and for enforcement activities. Those costs would depend on the number of license applications and the degree to which Department resources would be sufficient; thus, additional appropriations could be required to comply with the bill's requirements. Also, the bill would allow the Department to assess for administrative fines; however, the bill does not provide direction for the disposition or expenditure of fine revenue.

Fiscal Analyst: Joe Carrasco, Jr.

¹ "Statement from FDA Commissioner Scott Gottlieb, M.D. on FDA advisory about deadly risks associated with kratom", US Food and Drug Administration, 11-14-2017.

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