

## KRATOM CONSUMER PROTECTION AND REGULATORY ACT

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**House Bill 5477 (proposed substitute H-1)**

**Sponsor: Rep. Lori M. Stone**

**Committee: Regulatory Reform**

**Complete to 3-8-22**

Analysis available at  
<http://www.legislature.mi.gov>

### SUMMARY:

House Bill 5477 would create a new act, the Kratom Consumer Protection and Regulatory Act, to do, among other things, all of the following:

- Require a license to distribute, sell, or manufacture a kratom product, establish a license fee, and establish administrative penalties and remedies for a licensee violating the act.
- Prohibit sales of kratom products to minors.
- Establish requirements for labeling kratom products, including certain health and safety warnings.
- Require certain information to be provided to the Department of Licensing and Regulatory Affairs (LARA) before a kratom product can be manufactured, distributed, or sold in Michigan.
- Require testing of raw materials used in the manufacture of kratom products to be sold or distributed in Michigan.
- Prohibit the sale or distribution of kratom products that contain certain substances or do not comply with certain labeling requirements.
- Allow LARA to seek declaratory relief or an injunction, or both, against a person engaging in conduct that violates the act.
- Require LARA to promulgate rules regarding requirements for licensure, the initial and renewal license application process, and the testing of kratom products.

### Licensure requirements

Under the bill, beginning January 1, 2023, a person could not distribute, sell, or manufacture a *kratom product* in Michigan unless licensed to do so.

*Kratom product* would mean a food that contains any part of the leaf of the plant *Mitragyna speciosa*.

A license would be required for each location in which a person distributes, sells, or manufactures a kratom product in Michigan. A license also would be required to distribute, sell, or offer to distribute or sell a kratom product online.

An application would have to be made on a form and in a manner prescribed by LARA and submitted with a license fee of \$150. The applicant would have to certify the accuracy of the information supplied in the application. LARA would have to issue a certificate of licensure (a document issued as evidence of authorization to distribute, sell, or manufacture a kratom product) to a person granted a license. A license would not be transferable and would be valid for three years. The bill would require LARA to promulgate rules regarding the application process, including the process for a license renewal. [The bill is silent as to the fee for a license renewal, whether the \$150 license fee is for a single year of the three-year license cycle or for the entire three-year cycle, and any restrictions on use of the fee revenue (for example, implementation and enforcement of the act).]

Before distributing, selling, manufacturing, or offering for distribution or sale a kratom product, a licensee would have to do both of the following:

- Provide LARA with a list of each kratom product intended to be distributed, sold, or manufactured in Michigan by the licensee.
- Have a sample of the raw materials used to produce each kratom product tested by a qualified laboratory (a laboratory approved by LARA by rule) to certify that the product does not contain any of the prohibited substances listed below. If there were no prohibited substances, the qualified laboratory would have to provide the licensee with a certificate of analysis stating that the raw materials meet the bill's requirements. The licensee would have to provide a copy of the analysis to LARA upon request. In addition, LARA could request that a licensee have a sample of raw materials retested by a qualified laboratory and provide an updated certificate of analysis.

### **Labeling requirements**

A kratom product would have to be labeled with the following information:

- A statement, as specified in the bill, that *Mitragyna speciosa* is an unapproved dietary ingredient and that ingesting it may be dangerous, that a person should consult their physician as to its suitability, use, safety, and possible complications, among other things, and inform the physician of the product's alkaloid content as listed on the label.
- A statement, as specified in the bill, warning to keep the product out of reach of children and to avoid using it if pregnant, planning to become pregnant, or while breastfeeding, as well as a statement that the product is not for sale to minors.
- The product's alkaloid content.
- The amount of mitragynine and 7-hydroxymitragynine in the product.

### **Prohibitions**

A licensee, whether in person or through an online website, could not distribute, sell, or offer for distribution or sale a kratom product to an individual under 21 years of age.

A person, whether in person or through an online website, could not sell, distribute, manufacture, or offer for distribution or sale any of the following:

- A kratom product adulterated with a dangerous nonkratom substance. (This would be a kratom product that is mixed or packed with a substance affecting the quality or strength of the kratom product to such a degree as to render it injurious to a consumer.)
- A kratom product contaminated with a dangerous nonkratom substance. (This would be a kratom product that contains a poisonous or otherwise deleterious non-kratom ingredient, including, but not limited to, any Schedule 1 substances.)
- A kratom product containing a level of 7-hydroxymitragynine in the alkaloid fraction that is greater than 2% of the alkaloid composition of the product.
- A kratom product that contains a synthetic alkaloid, including, but not limited to, synthetic mitragynine, synthetic 7-hydroxymitragynine, or any other synthetically derived compound of the plant *Mitragyna speciosa*.
- A kratom product that does not include on its package or label the amount of mitragynine and 7-hydroxymitragynine contained in the kratom product.

In addition, a person could not purchase a kratom product over the internet in Michigan if the product did not comply with the above.

### **Penalties**

A licensee violating section 7 (labeling requirements), section 9 (adulterated or contaminated products, levels of or products containing certain alkaloids, and failing to include certain product ingredients), or section 11 (distribution or sale to minor or internet purchase of a product that does not comply with section 9 requirements) would be subject to an administrative fine of up to \$500 for a first offense and up to \$1,000 for a second or subsequent offense. LARA would have to conduct a hearing under the Administrative Procedures Act upon request by the person issued the fine. [Note: The bill does not specify a penalty for a person who is not a licensee and who violates the prohibition against purchasing a kratom product online that does not comply with section 9.]

The director of LARA could, after notice and an opportunity for an evidentiary hearing, deny, limit, suspend, or revoke the license of, or impose an administrative fine on, a licensee that violated the bill or a rule promulgated under it. In addition to any other action authorized by the bill, the director could bring an action to obtain a declaratory judgment that a method, act, or practice is in violation of the bill or to obtain an injunction against a person who is engaging, or about to engage, in a method, act, or practice that violates the bill, or to obtain both.

### **Rules**

By January 1, 2023, LARA would have to promulgate rules to implement the act, including at least rules governing all of the following:

- Initial application and other requirements for licensure.
- License renewal process.
- Testing of kratom products.

### **FISCAL IMPACT:**

House Bill 5477 would have an indeterminate fiscal impact on LARA. The department would experience cost increases resulting from new responsibilities related to kratom licensure. These responsibilities would include intaking and processing licensure applications and enforcement activity. The magnitude of the costs would depend on the volume of licenses and the degree to which existing department personnel and infrastructure could accommodate the new regulatory activity. The bill would establish a licensing fee of \$150. It is unclear whether this fee revenue would be sufficient to offset LARA's regulatory costs. The bill would establish administrative fines of up to \$500 for a first offense and up to \$1,000 for a second or subsequent offense, although the bill is silent as to where these revenues would be deposited or how they could be used (presumably any revenue would be deposited to the state's general fund).

In addition, there could be a fiscal impact on local court units under provisions of the bill that authorize the director to bring an action to obtain either a declaratory judgment or an injunction against a practice or person found to be in violation. The fiscal impact would be directly related to how provisions of the bill affected court caseloads and related administrative costs.

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■ This analysis was prepared by nonpartisan House Fiscal Agency staff for use by House members in their deliberations and does not constitute an official statement of legislative intent.