REQUIRES TWO-THIRDS MAJORITY VOTE EXEMPT
(§§ 6, 6.5)

(Reprinted with amendments adopted on June 2, 2023)

SECOND REPRINT **A.B. 322**

ASSEMBLY BILL NO. 322–ASSEMBLYMEN NGUYEN, YEAGER, GONZÁLEZ; BROWN-MAY, DICKMAN, D'SILVA AND GALLANT

MARCH 16, 2023

JOINT SPONSORS: SENATORS HANSEN; AND NGUYEN

Referred to Committee on Commerce and Labor

SUMMARY—Revises provisions relating to kratom products. (BDR 52-763)

FISCAL NOTE: Effect on Local Government: Increases or Newly Provides for Term of Imprisonment in County or City Jail or Detention Facility.
Effect on the State: Yes.

~

EXPLANATION – Matter in ***bolded italics*** is new; matter between brackets [~~omitted material~~] is material to be omitted.

AN ACT relating to public health; prohibiting a person from selling or offering to sell a kratom product to an end user unless the kratom product has been registered with the Division of Public and Behavioral Health of the Department of Health and Human Services; setting forth requirements for the registration of a kratom product with the Division; requiring a person who registers a kratom product to pay certain expenses and report certain information relating to the kratom product to the Division; authorizing the Division to adopt certain regulations governing kratom products; revising provisions establishing certain prohibited acts relating to kratom products; exempting a person who engages in certain acts relating to kratom products from certain criminal or legal penalties if certain substances in those products are designated as controlled substances; prohibiting the State Board of Pharmacy from including certain substances on a schedule of controlled substances; providing penalties; making an appropriation; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law defines "kratom product" to mean, in general, any product or ingredient containing any part of the leaf of the *Mitragyna Speciosa* plant if the plant contains the alkaloid mitragynine or 7-hydroxymitragynine, or any synthetic material that contains the alkaloid mitragynine or 7-hydroxymitragynine. Existing law prohibits a person from: (1) selling or offering to sell any material, compound, mixture or preparation containing a kratom product to a child under the age of 18 years; (2) preparing, distributing, advertising, selling or offering to sell a kratom product that is adulterated with certain substances; and (3) selling a kratom product that does not have a label that meets certain requirements. Existing law provides for the imposition of a civil penalty of not more than $1,000 against a person who violates those prohibitions. (NRS 597.998)

Section 5 of this bill revises the definition of kratom product to mean food containing any part of the leaf of the *Mitragyna Speciosa* plant. **Section 9** of this bill revises the prohibited acts relating to kratom products set forth under existing law to revise: (1) requirements relating to the type of kratom products that a person is prohibited from preparing, distributing, advertising, selling or offering to sell; and (2) the information that must be included on a label for a kratom product. **Section 9** eliminates the civil penalty imposed for engaging in such prohibited acts and **section 8.7** of this bill instead provides for the imposition of administrative fines by the Division of Public and Behavioral Health of the Department of Health and Human Services for certain violations relating to kratom products.

Section 6 of this bill prohibits a person from selling or offering to sell a kratom product to an end user unless the kratom product has been registered with the Division. **Section 6** sets forth certain requirements for a person to register a kratom product with the Division.

Sections 6.5 and 8 of this bill set forth circumstances under which the Division may require a person who registers a kratom product to submit the kratom product to a laboratory for certain additional testing. **Section 7.5** of this bill requires a person who registers a kratom product to submit to the Division a copy of certain reports concerning the kratom product that are required to be submitted to the United States Food and Drug Administration.

Section 7 of this bill authorizes the Division to adopt certain regulations to carry out the provisions of this bill. **Section 9.8** of this bill makes an appropriation from the State General Fund to the Division for personnel, travel, operating, equipment and information services expenses to carry out the provisions of this bill.

Existing law authorizes the State Board of Pharmacy to adopt regulations to add, delete or reschedule substances as controlled substances in schedules I, II, III, IV or V pursuant to the Uniform Controlled Substances Act. (NRS 453.146) Existing law prohibits certain substances from being included on such a schedule. (NRS 453.2186) **Section 9.5** of this bill prohibits the Board from including mitragynine or any of its constituent alkaloids on any schedule unless the substance is designated as a controlled substance pursuant to federal law. **Section 8.3** of this bill provides that if mitragynine or any of its constituent alkaloids is added to a schedule of controlled substances, a person who engages in the possession, delivery, production, sale or use of a kratom product that meets the requirements of this bill and who confines his or her activities to those authorized by this bill does not commit a violation of any law, ordinance, rule or regulation of this State or any political subdivision of this State and any such conduct must not constitute the basis for any investigation, detention, search, seizure, arrest, prosecution or other legal penalty against the person.

Sections 2.5-4.5 of this bill define certain other words and terms for the purposes of this bill.

THE PEOPLE OF THE STATE OF NEVADA, REPRESENTED IN SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:

Section 1. Chapter 597 of NRS is hereby amended by adding thereto the provisions set forth as sections 2 to 8.7, inclusive, of this act.

Sec. 2. *As used in NRS 597.998 and sections 2 to 8.7, inclusive, of this act, unless the context otherwise requires, the words and terms defined in sections 2.5 to 5, inclusive, of this act have the meanings ascribed to them in those sections.*

Sec. 2.5. *"Certificate of analysis" means a document produced by a laboratory describing the results of the laboratory's testing of a kratom product.*

Sec. 3. *"Division" means the Division of Public and Behavioral Health of the Department of Health and Human Services.*

Sec. 4. *"Food" means any food, food product, food ingredient, dietary ingredient, dietary supplement or beverage intended for ultimate human consumption.*

Sec. 4.5. *"Kratom extract" means a kratom product containing any part of the leaf of the Mitragyna Speciosa plant that has been extracted and concentrated to provide a dosage that is more standardized.*

Sec. 5. *"Kratom product" means food containing any part of the leaf of the Mitragyna Speciosa plant, or an extract thereof, which is manufactured as a powder, capsule, pill or other edible form.*

Sec. 6. *1. A person shall not sell or offer to sell a kratom product to an end user unless the kratom product has been registered with the Division pursuant to this section.*

2. A person who wishes to register a kratom product must submit to the Division:

(a) An application on a form prescribed by the Division.

(b) A fee in an amount established by the Division by regulation.

(c) A certificate of analysis for the kratom product which:

(1) Is produced by an independent laboratory that meets any requirements set forth in regulations adopted by the Division pursuant to section 7 of this act. Such requirements may include, without limitation, a requirement that the independent laboratory meet any accreditation standards required by the Division relating to the testing of food.

(2) Provides sufficient information about the kratom product to enable the Division to determine whether the kratom

product complies with the provisions of NRS 597.998 and sections 2 to 8.7, inclusive, of this act.

(d) Any other information and documentation that the Division deems necessary to ensure that the kratom product meets the requirements of NRS 597.998 and sections 2 to 8.7, inclusive, of this act and the regulations adopted pursuant thereto.

3. A registration issued pursuant to this section expires 1 year after issuance and may be renewed by submitting to the Division an application for renewal and the same fees and materials required by paragraphs (b), (c) and (d) of subsection 2 for an initial registration.

Sec. 6.5. *1. If the Division has reasonable cause to believe that the information contained on the label of, or the certificate of analysis for, a kratom product is inaccurate, the Division may require the person who registered the kratom product to send the kratom product to a laboratory selected by the Division to conduct testing on the kratom product.*

2. After the testing conducted pursuant to subsection 1 is completed, the Division shall send the person who registered the kratom product a bill for the costs of the testing. If the person fails to pay those costs within a period of time after the receipt of the bill established by the Division by regulation, the Division shall revoke the registration of the kratom product.

Sec. 7. *The Division may adopt regulations as it determines to be necessary or advisable to carry out the provisions of NRS 597.998 and sections 2 to 8.7, inclusive of this act.*

Sec. 7.5. *1. If a person submits to the United States Food and Drug Administration a report pursuant to 21 U.S.C. § 379aa-1 concerning a serious adverse event involving a kratom product that the person has registered pursuant to section 6 of this act, the person shall send a copy of that report to the Division by certified mail within a period of time established by the Division by regulation.*

2. Failure to send to the Division a copy of the report described in subsection 1 within the time required by subsection 1, constitutes grounds for the revocation of the registration of the kratom product about which the report relates.

Sec. 8. *1. Any person may report to the Division on a form prescribed by the Division a suspected violation of NRS 597.998 or sections 2 to 8.7, inclusive, of this act.*

2. If the Division determines that the allegations in a complaint are credible and relate to the content or labeling of, or a certificate of analysis for, a kratom product, the Division shall require the person who committed the alleged violation to obtain and provide to the Division, within a period of time prescribed by

the Division by regulation, a new certificate of analysis which complies with paragraph (c) of subsection 2 of section 6 of this act for the kratom product.

3. If a person fails to provide the Division with a certificate of analysis pursuant to subsection 2, the Division shall revoke the registration for the kratom product.

Sec. 8.3. ***Notwithstanding any other provision of law, if mitragynine or any of its constituent alkaloids are added to schedule I, II, III, IV or V by the State Board of Pharmacy by regulation pursuant to NRS 453.146, a person who engages in the possession, delivery, production, sale or use of a kratom product that meets the requirements of NRS 597.998 and sections 2 to 8.7, inclusive, of this act and who confines his or her activities to those authorized by NRS 597.998 and sections 2 to 8.7, inclusive, of this act does not violate any law, ordinance, rule or regulation of this State or any political subdivision of this State and such conduct may not constitute the basis for any investigation, detention, search, seizure, arrest, prosecution or other legal penalty against the person.***

Sec. 8.7. ***1. A person who violates any provision of NRS 597.998 and sections 2 to 8.7, inclusive, of this act is subject to an administrative fine in an amount not to exceed $500 for a first offense and $1,000 for a second or subsequent offense.***

2. Upon the request of a person to whom an administrative fine is issued, the Division shall provide notice of and conduct a hearing in accordance with the provisions of chapter 233B of NRS.

Sec. 9. NRS 597.998 is hereby amended to read as follows:

597.998 1. A person shall not knowingly ***distribute,*** sell or offer to sell any material, compound, mixture or preparation containing a kratom product to a child under the age of 18 years.

2. A person shall not knowingly prepare, distribute, advertise, sell or offer to sell a kratom product that ~~[is]~~ ***:***

(a) Is adulterated ***, as defined in 21 U.S.C. § 342, or combined or packaged*** with ~~[a]~~ ***:***

(1) A controlled substance or a dangerous drug, as defined in chapter 454 of NRS, or any poisonous or deleterious substance; or

(2) Any substance that affects the quality or strength of the kratom product to such a degree as to render the kratom product injurious to a consumer ~~[. A person has not violated the provisions of this subsection if he or she can show by a preponderance of evidence that he or she relied in good faith upon the representations of a manufacturer, processor, packer or distributor of the kratom product.~~

~~3. A person shall not sell a kratom product that does not have a label that clearly sets forth the ingredients and directions for the safe and effective use of the kratom product.~~

~~4. A person who violates any provision of this section is subject to a civil penalty of not more than $1,000 for each violation.~~

~~5. As used in this section, "kratom product" means any product or ingredient containing:~~

~~(a) Any part of the leaf of the Mitragyna Speciosa plant if the plant contains the alkaloid mitragynine or 7-hydroxymitragynine; or~~

~~(b) A synthetic material that contains the alkaloid mitragynine or 7-hydroxymitragynine,~~

~~➥ regardless of whether the product or ingredient is labeled or sold for human consumption.~~ ***;***

(b) Contains a level of 7-hydroxymitragynine in the alkaloid fraction that is greater than 1 percent of the alkaloid composition of the kratom product;

(c) Contains a synthetic alkaloid, including, without limitation, synthetic mitragynine, synthetic 7-hydroxymitragynine or any synthetically derived compound of the Mitragyna Speciosa plant;

(d) Does not include a label that complies with any requirements for the labeling of food established by the State Board of Health by regulations adopted pursuant to NRS 439.200 or 446.940 and that clearly sets forth:

(1) The recommended size of an individual serving;

(2) The maximum limits for individual servings per day;

(3) The number of servings equal to the size of one recommended individual serving that are contained in the package; and

(4) Directions for the safe and effective use of the kratom product.

(e) A kratom extract which contains levels of residual solvents that exceed the levels authorized by chapter 467 of the United States Pharmacopeia-National Formulary, published by the United States Pharmacopeial Convention.

Sec. 9.5. NRS 453.2186 is hereby amended to read as follows:

453.2186 1. Authority to control pursuant to NRS 453.146, 453.218, 453.2182 and 453.2184 does not extend to distilled spirits, wine, malt beverages or tobacco.

2. ***The Board shall not include mitragynine or any of its constituent alkaloids on any schedule unless the substance is designated as a controlled substance pursuant to federal law.***

3. The Board shall not include any nonnarcotic substance on any schedule if that substance is in a form suitable for final dosage and has been approved by the Food and Drug Administration for

sale over the counter without a prescription, unless the Board affirmatively finds that:

(a) The substance itself or one or more of its active ingredients is an immediate precursor of a controlled substance; and

(b) The substance is materially misbranded or mislabeled, or the public interest requires the scheduling of the substance as a controlled substance in schedule I, II, III or IV.

~~[3.]~~ ***4.*** In determining whether the public interest requires the scheduling of the substance, the Board shall consider:

(a) Whether the customary methods of marketing and distributing the substance are likely to lead to its unlawful distribution or use, including any relevant information with regard to a manufacturer or distributor of the substance concerning:

(1) His or her record of compliance with applicable federal, state and local statutes, ordinances and regulations;

(2) His or her past experience in the manufacture and distribution of controlled substances, and the existence in his or her establishment of effective controls against the unlawful distribution or use of the substance;

(3) Whether he or she has ever been convicted under any federal or state law relating to a controlled substance; and

(4) Whether he or she has ever furnished materially falsified or fraudulent material in any application filed pursuant to NRS 453.011 to 453.552, inclusive;

(b) Whether the substance is controlled under the federal Controlled Substances Act;

(c) The status of any pending proceeding to determine whether the substance should be controlled or exempted from control;

(d) Any history of abuse or misuse of the substance in this State; and

(e) Any other factors which are relevant to the public health and safety.

~~[4.]~~ ***5.*** In determining whether a substance is misbranded or mislabeled, the Board shall consider the requirements of the federal Food, Drug, and Cosmetic Act and the Code of Federal Regulations concerning indications for its use and any advertising for a use not so indicated.

Sec. 9.8. 1. There is hereby appropriated from the State General Fund to the Division of Public and Behavioral Health of the Department of Health and Human Services for personnel, travel, operating, equipment and information services expenses to carry out the provisions of this act the following sums:

For the Fiscal Year 2023-2024 ..... $121,162

For the Fiscal Year 2024-2025 ..... $140,010

2. Any balance of the sums appropriated by subsection 1 remaining at the end of the respective fiscal years must not be committed for expenditure after June 30 of the respective fiscal years by the entity to which the appropriation is made or any entity to which money from the appropriation is granted or otherwise transferred in any manner, and any portion of the appropriated money remaining must not be spent for any purpose after September 20, 2024, and September 19, 2025, respectively, by either the entity to which the money was appropriated or the entity to which the money was subsequently granted or transferred, and must be reverted to the State General Fund on or before September 20, 2024, and September 19, 2025, respectively.

Sec. 10. 1. This section becomes effective upon passage and approval.

2. Section 9.8 of this act becomes effective on July 1, 2023.

3. Sections 1 to 9.5, inclusive, of this act become effective:

(a) Upon passage and approval for the purpose of adopting any regulations and performing any other preparatory administrative tasks that are necessary to carry out the provisions of this act; and

(b) On January 1, 2024, for all other purposes.

㉚