

PROPOSED AMENDMENTS TO

HOUSE BILL NO. 1566

Introduced by

Representatives D. Johnston, Christianson, Klemin, J. Olson, Schneider, VanWinkle

1 A BILL for an Act to create and enact a new chapter to title 19 of the North Dakota Century
2 Code, relating to the regulation of kratom; and to provide a penalty.

3 **BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:**

4 **SECTION 1.** A new chapter to title 19 of the North Dakota Century Code is created and
5 enacted as follows:

6 **Definitions.**

7 As used in this chapter:

- 8 1. "Independent testing laboratory" means a laboratory accredited by a third-party
9 accrediting body as a competent testing laboratory in accordance with the international
10 organization for standardization and international electrotechnical commission 17025
11 laboratory standards.
- 12 2. "Kratom" means any part of the mitragyna speciosa plant, including all components
13 present in the natural plant.
- 14 3. "Kratom extract" means a substance or compound obtained by the extraction of
15 kratom intended for ingestion containing more than trace amounts of kratom and other
16 alkaloids of the plant.
- 17 4. "Kratom product" means a ~~food, dietary supplement, or beverage, or a food or dietary~~
18 ~~ingredient intended for human consumption, that contains kratom and is manufactured~~
19 ~~or served in an edible form, including a pill, powder, capsule, beverage, or liquid, or~~
20 other edible product containing kratom or kratom extract.

1 5. "Retailer" means a person that advertises, sells, prepares, manufactures, distributes,
2 or maintains kratom products.

3 6. "Synthesized material" means an alkaloid or alkaloid derivative created by chemical
4 synthesis or biosynthetic means that alters the composition of a kratom alkaloid or
5 constituent.

6 **Kratom product requirements - Administration.**

7 1. A retailer may not prepare, sell, distribute, or expose for sale a kratom product:

8 a. Containing a level of 7-hydroxymitragynine in the alkaloid fraction that is greater
9 than two percent of the alkaloid composition of the kratom product;

10 b. Containing synthesized material;

11 c. Containing alkaloids or other plant constituents that are isolated or manipulated
12 to increase potency;

13 d. Containing a level of residual solvent higher than permitted by United States
14 pharmacopeia chapter 467; or

15 e. Using combustion, vaporization, or injection as a means of introduction into the
16 human body; ~~or~~

17 ~~f. Adulterated with a dangerous nonkratom substance including:~~

18 ~~(1) Controlled substances;~~

19 ~~(2) Psychoactive compounds;~~

20 ~~(3) Synthetic cannabinoids and cathinones; or~~

21 ~~(4) A cytochrome P450 enzyme inhibitor.~~

22 2. A kratom product may not be marketed or sold to a minor.

23 3. A kratom product produced, manufactured, distributed, or sold in this state must have
24 attached a label which includes:

25 a. A statement against use by an individual who is:

26 (1) Under ~~eighteen~~twenty-one years of age;

27 (2) Pregnant; or

28 (3) Breastfeeding.

29 b. A recommendation to consult a health care provider before use;

30 c. A statement that the product may be habit forming;

- 1 d. A disclosure that the product is not evaluated by the federal food and drug
2 administration;
- 3 e. A disclosure that the product is not intended to diagnose, treat, cure, or prevent
4 any disease;
- 5 f. A list of all ingredients, including the amount of ~~kratom alkaloids~~mitragynine and
6 7-hydroxymitragynine; and
- 7 f.g. A recommended amount of product per serving that is clearly defined for the
8 product format.
- 9 4. A kratom product produced, manufactured, distributed, or sold in this state must be
10 analyzed by an independent testing laboratory for:
- 11 a. Alkaloid content;
- 12 b. Residual solvents;
- 13 c. Biological contaminants;
- 14 d. Heavy ~~metals specified by the department~~metal contaminants; and
- 15 e.e. Any other contaminant identified by department rule.
- 16 5. The department shall adopt rules necessary to administer this chapter, including the:
- 17 a. Process for registering a kratom product;
- 18 b. Requirements for enforcing the age restriction of kratom product sales; and
- 19 c. Requirements for enforcing subsection 4.

20 **Licensure - Registration.**

- 21 1. A retailer in the state must be licensed by the department. To obtain licensure, a
22 retailer shall:
- 23 a. Pay a fee; and
- 24 b. Register each product containing kratom intended for sale by providing
25 certification that the product:
- 26 (1) Is manufactured, processed, and held in a facility that meets the
27 requirements under 21 C.F.R. 111;
- 28 (2) Adheres to the labeling requirements under this chapter;
- 29 (2) Is safe for consumption under the conditions set forth on the label; and
- 30 (3) Is certified by an independent testing laboratory to meet the requirements
31 under this chapter.

1 2. The department shall maintain a kratom registration page on the department's official
2 website listing all registered kratom products for sale by licensed retailers.

3 **Penalties.**

4 1. A retailer that sells a kratom product not registered with the department is guilty of a
5 class A misdemeanor.

6 2. A retailer that sells a kratom product to an individual under eighteen years of age is
7 guilty of a class A misdemeanor.

8 3. A retailer that advertises, sells, prepares, manufactures, distributes, or maintains a
9 kratom product that contains a controlled substance identified in chapter 19-03.1 or
10 19-03.2 must be charged under chapter 19-03.1 or 19-03.2.

11 4. A person that advertises, sells, prepares, manufactures, distributes, or maintains a
12 kratom product without a retailer license issued by the department is guilty of a class C
13 felony.