

Testimony
House Bill No. 1566
House Human Services Committee
Representative Matt Ruby, Chairman
January 28, 2025

Chairman Ruby, and members of the House Human Services Committee, I am Jason Wahl with the Department of Health and Human Services (Department). Due to language included in the bill and the significant changes identified by the Department, I appear before you in opposition to House Bill No. 1566 as it is currently written.

The Department acknowledges the House of Representatives did not want kratom added to the state's Controlled Substances Act as a Schedule I drug. While the Department agrees changes are necessary to protect the health and safety of the citizens of North Dakota, House Bill No. 1566 would require significant modifications in order to accomplish this task.

There are three areas regarding kratom that must first be addressed:

1. There are no drug products containing kratom or its two main chemical components (mitragynine and 7-hydroxymitragynine) that are legally on the market in the United States. The Food and Drug Administration (FDA) has not approved any prescription or over-the-counter drug products containing kratom or its two main chemical components.
2. Kratom is not appropriate for use as a dietary supplement. FDA concludes dietary supplements that are or contain kratom are adulterated.

3. FDA has determined that kratom, when added to food, is an unsafe food additive. FDA concludes that food containing an unsafe food additive, such as kratom, is adulterated.

Thus, kratom is not lawfully marketed in the United States as a drug product, a dietary supplement, or a food additive in conventional food. Therefore, the Department could not implement a regulatory framework for kratom products if they are to be called a drug, dietary supplement, or food. In addition, the manufacturing of a food product, including a beverage, with kratom or chemical components of kratom in North Dakota is prohibited by current laws. If the legislature's intent is to have a regulatory framework for kratom, laws must be written in a manner that does not refer to kratom or products containing kratom as a drug, dietary supplement, or food.

Each of the new sections that would be added to state law under the bill are further addressed below as well as other considerations and a brief discussion of the fiscal note.

Definitions

References to food, dietary supplement, and beverage should be removed. In order for a regulatory framework to exist, terminology will be a vital aspect. The Department would request the terms "kratom extract," kratom product," and "retailer" be modified. The term retailer includes a person who prepares and manufactures kratom products. The terms 'prepare' and 'manufacture' are not typically synonymous with someone simply selling products. If preparers and manufacturers are going to be included in the language with the intent such processes occur in North Dakota, significant modifications of the bill are necessary.

The Department would request the term minor be defined. While a penalty is included for selling a kratom product to an individual under 18 years of age, minor should be clearly identified in the definition section. The Department would request legislators consider having the minimum age requirement be 21 years of age. This is the age limit set for sales in eight other states including South Dakota. From a public health perspective, the Department is concerned with 18-year-old individuals being able to obtain kratom products and the effects it may have as well as possible diversion to others (i.e. high school age individuals being able to make purchases). With the minimum age for tobacco products now being 21 years of age, having the minimum age for kratom purchases be 21 years of age should be considered.

One other term that could be modified is "independent testing laboratory." While the definition makes reference to accrediting bodies, the Department would request a standard to be used be codified into law. For example, reference to ISO/IEC 17025 could be used. Such an addition will eliminate uncertainty.

Kratom product requirements – Administration

The bill states a retailer may not prepare a kratom product that meets certain conditions. The Department would request 'prepare' be removed as this would appear to allow a processor or manufacturer of kratom products to exist in the state. The bill provides limited, to no, information regarding requirements for processors or manufacturers.

While the bill requires the Department to adopt rules necessary to administer the chapter, the bill includes no specific language regarding the Department's authority for monitoring, inspections, and ensuring compliance of retailers. To ensure there is compliance with the law,

monitoring of retailers would need to take place. While certain requirements could be included in administrative code, the law should include language regarding this area. In addition, the law should clearly identify what, if any, authority the Department has if kratom products are found at retailers that are noncompliant products.

The bill includes language related to a kratom product produced or manufactured. Again, the Department would request removal of 'produced' and 'manufactured' unless additional language is included regarding kratom product processing, production, and manufacturing of kratom products in the state.

The Department appears to have the authority to adopt rules related to labeling. The Department could include a minimum font or include additional information (such as size/weight of the product in the container) to enhance labeling for users of kratom products. One additional labeling requirement the Legislature may want to consider is adding a statement that the product is not intended to diagnose, treat, cure, or prevent any disease.

Licensure – Registration

The bill requires a retailer to pay a fee. The Department would anticipate establishing fee amounts in administrative code. Similar to an alcohol license, the Department could establish different fee amounts for a retailer in a city with a population of 500 or more and for a retailer in a city with a population of 500 or less.

The Department would be required to maintain a website listing all registered kratom products for sale by licensed retailers. To ensure the list is accurate and that retailers comply with the requirement to register

products for sale, the Department will need to monitor/inspect retailers in the state.

The bill requires products containing kratom are to be manufactured, processed, and held in a facility that meets a specific federal citation (21 C.F.R. 111). The federal regulation relates to current good manufacturing practice for dietary supplements. The federal regulation does not apply to kratom product manufacturing. Assuming the kratom products are manufactured in another state, retailers may have a difficult time obtaining such certification.

Penalties

In addition to requested changes for the age limit and terms such as prepares and manufactures, the Department would request a fine amount be included in the penalties section. For example, a fine could be assessed when a retailer does not have a label on a product containing the required information by law. With the large workload of State's Attorneys, a misdemeanor case will more than likely not be pursued. The Department would also request the ability to be able to suspend and/or revoke a retailer license for noncompliance issues identified.

Other Considerations

With the establishment of new requirements regarding the sale of products already available for purchasing, legislators should consider including an implementation date for when retailers must comply with requirements/first date of sales. In addition, legislators may want to consider establishing authority for the Department to collect a fee related to the number of products registered (would be in addition to the annual license fee). With this authority, the Department could establish fees based on number of products registered by a retailer. For example, the

Department could assess no fee for up to five products being registered, establish a fee amount for 6 to 10 products registered, a different fee amount for 11 to 20 products registered, etc.

Fiscal Note

The Department estimated potential revenue and costs associated with the program. Using a potential annual fee of \$500 for a retailer in a city with a population of 500 and over and an annual fee of \$250 for a retailer in a city with a population of under 500, it is estimated the revenue collected would be \$171,000 in the 2025-2027 Biennium.

Expenses for implementing the regulatory framework included in the bill were estimated to be \$1.7 million in the 2025-2027 Biennium. The amount includes eight full-time equivalents (FTE) and related costs, information technology costs, and other costs. Additional details are included in the fiscal note submitted by the Department.

Conclusion

With the changes the Department has identified that are needed with the current version of House Bill No. 1566 to properly regulate kratom products, the Department opposes the bill. If legislators want to ensure an adequate regulatory framework is established for kratom products to protect the health and safety of citizens, changes are necessary. The Department would be happy to assist in proposing amendments to the bill for the committee's consideration.

This concludes my testimony. I am happy to answer questions you may have.