Department of Legislative Services

Maryland General Assembly
2025 Session

FISCAL AND POLICY NOTE
First Reader

House Bill 996 (Delegate Bhandari)
Health and Government Operations

Public Health - Phenibut Consumer Protection Act

This bill generally requires a "retailer" that prepares, distributes, sells, or exposes for sale a "phenibut product" to disclose on the product label the factual basis on which the representation is made. A violator is subject to a civil penalty. A retailer is prohibited from (1) preparing, distributing, selling, or exposing for sale a phenibut product that does not comply with the specified disclosure, has not been recognized by the U.S. Food and Drug Administration (FDA) as a dietary ingredient or approved drug, or that is adulterated with, contaminated with, or contains other substances, as specified, and (2) distributing, selling, or exposing for sale a phenibut product to an individual younger than age 21. A violator is guilty of a misdemeanor and subject to a criminal penalty. A retailer may not advertise or market a phenibut product to minors, directly or indirectly, as specified and may not advertise a therapeutic benefit of phenibut, directly or indirectly. The Maryland Department of Health (MDH) must adopt regulations to implement the bill and collaborate with the Maryland Hospital Association (MHA) to report to the General Assembly by December 31, 2026, on the number of adverse health events observed in individuals after the use of phenibut.

Fiscal Summary

State Effect: Based on an analysis of similar legislation, the bill is not anticipated to materially affect State finances and operations. MDH can adopt regulations and collaborate with MHA to issue the report with existing budgeted resources. The civil and criminal penalty provisions of the bill are not anticipated to have a material impact on State finances or operations.

Local Effect: The bill is not anticipated to materially affect local finances and operations. Local health departments can handle enforcement with existing budgeted resources. The civil and criminal penalty provisions of the bill are not anticipated to have a material impact on local finances or operations.

Small Business Effect: Potential meaningful.

Analysis

Bill Summary: "Phenibut product" means a product marketed for human consumption containing any beta-phenyl-gamma-aminobutyric acid HCL.

"Retailer" means a person that (1) sells, prepares, or maintains phenibut products or (2) advertises, represents, or holds itself out as selling, preparing, or maintaining phenibut products. This includes a manufacturer, wholesaler, store, restaurant, hotel, catering facility, camp, bakery, delicatessen, supermarket, grocery store, convenience store, gas station, or food or drink company.

Labeling Requirement

A retailer that prepares, distributes, sells, or exposes for sale a phenibut product must disclose on the product label the factual basis on which any representations regarding the phenibut product are made. A violator is subject to a maximum civil penalty of $1,000 for a first violation and $2,000 for each subsequent offense.

Prohibitions

A retailer may not prepare, distribute, sell, or expose for sale a phenibut product that (1) does not comply with the specified disclosure requirement or (2) has not been recognized by the FDA as a dietary ingredient or approved drug. A violator is guilty of a misdemeanor and on conviction is subject to a fine of up to $5,000 and/or imprisonment for up to 90 days.

A retailer is also prohibited from preparing, distributing, selling, or exposing for sale:

- a phenibut product that is adulterated or contaminated with a dangerous substance other than phenibut (including a phenibut product that is mixed or packed with another substance that affects the quality or strength of the phenibut product to a degree as to render the phenibut product injurious to a consumer);
- a phenibut product that is contaminated with a dangerous substance – meaning a poisonous or otherwise deleterious ingredient, including a controlled dangerous substance; or
- a product containing phenibut that does not include on its package or label the amount of beta-phenyl-gamma-aminobutyric acid HCL.

A violator is guilty of a misdemeanor and on conviction is subject to a fine of up to $5,000 and/or imprisonment for up to 90 days.

A retailer may not distribute or sell a phenibut product to an individual younger than age 21. A violator is guilty of a misdemeanor and on conviction is subject to a fine of up to $5,000 and/or imprisonment for up to 90 days.

In addition to any penalty under the bill, a retailer is also liable for any civil damages sustained by an individual resulting from the violation. In a prosecution for a violation under the bill, it is a defense that the retailer relied in good faith on the representations of a manufacturer, processor, packer, or distributor of a phenibut product.

Advertising

A retailer may not advertise (directly or indirectly) a therapeutic benefit of phenibut.

A retailer may not advertise or market (directly or indirectly) phenibut products to minors. It is a violation of this prohibition for a retailer to use specified imagery or references in the advertising, promotion, packaging, or labeling of a phenibut product, including (1) a cartoon; (2) a superhero; (3) a video game reference; (4) an image of a food product primarily intended for minors; (5) a trademark that imitates or mimics the trademark of a product that has been advertised or marketed primarily to minors; (6) a symbol or celebrity that is primarily associated with minors or media primarily directed to minors; and (7) an image of an individual who appears to be younger than age 27.

It is also a violation of this prohibition for a retailer to advertise or promote a phenibut product on an outdoor billboard or signboard that is within 500 feet of a school or at specified locations or in certain media if individuals younger than age 21 constitute 15% or more of the total audience as measured by competent and reliable survey evidence, including (1) a newspaper, magazine, periodical, or other publication or (2) a concert, stadium, sporting event, or other public event.

Current Law: The State does not currently regulate phenibut. However, Chapters 249 and 748 of 2024 impose similar requirements and prohibitions on the labeling, advertising, and selling of tianeptine and kratom.

Phenibut is a controlled substance in several European countries and Australia but is legal to possess and sell in the United States. However, it is not approved by FDA for clinical use, and its marketing is regulated by FDA. Phenibut does not meet the definition of a dietary ingredient under the federal Food, Drug, and Cosmetic Act, but some companies have marketed phenibut products as dietary supplements or sleep aids. A dietary ingredient must fit into one of the following five categories, which phenibut does not fall into – amino

acid, vitamin, herb, mineral, or dietary supplement that increases dietary intake. Thus, in April 2019, FDA issued three warning letters to companies whose phenibut products were improperly marketed as dietary supplements. So long as it is not branded as a dietary enhancement or supplement, it is not illegal to buy, possess, or sell phenibut.

Small Business Effect: Small business retailers that prepare, distribute, sell, or expose for sale a phenibut product must comply with the bill's requirements. Violators are subject to civil and criminal penalty provisions.

Additional Comments: Phenibut is an anti-anxiety drug developed in Russia. It is considered a psychoactive substance, and often marketed as a supplement for relaxation, anxiety, and sleep, as well as to help with depression and post-traumatic stress disorder. In November 2021, Alabama made phenibut a Schedule II controlled substance.

Additional Information

Recent Prior Introductions: Similar legislation has not been introduced within the last three years.

Designated Cross File: None.

Information Source(s): Office of the Attorney General (Consumer Protection Division); Judiciary (Administrative Office of the Courts); American Addiction Centers; U.S. Food and Drug Administration; Department of Legislative Services

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