

Department of Legislative Services
 Maryland General Assembly
 2023 Session

FISCAL AND POLICY NOTE
 First Reader

House Bill 634 (Delegate Vogel, *et al.*)
 Economic Matters and Health and
 Government Operations

Public Health - Sale of Diet Pills to Minors - Prohibition (Protecting Teenagers
 From Unregulated Diet Pills)

This bill prohibits a person from selling, transferring, or otherwise furnishing “diet pills” to an individual younger than age 18 without a prescription. A “retail establishment” must limit access to diet pills in an area that is directly accessible only by employees and request valid identification from an individual attempting to purchase diet pills if the individual reasonably appears to be younger than 18. A “delivery seller” may neither sell, deliver, or cause to be delivered any diet pills to an individual younger than 18 nor accept a “delivery sale” order from an individual without obtaining and verifying specified information. A delivery seller must ship diet pills through a method of shipping that meets specified requirements. The Maryland Department of Health (MDH) (1) may adopt regulations establishing limitations on which diet pills are subject to the bill’s provisions and (2) must develop a specified notice about diet pills. Each retailer that sells diet pills must prominently display the notice. Violators of the bill are subject to a civil penalty of up to \$1,000.

Fiscal Summary

State Effect: MDH general fund expenditures increase by \$191,200 in FY 2024 for personnel. Future years reflect annualization, elimination of one-time costs, and ongoing operating costs. Potential minimal increase in general fund revenues due to the bill’s penalty provision.

(in dollars)	FY 2024	FY 2025	FY 2026	FY 2027	FY 2028
Revenues	\$0	\$0	\$0	\$0	\$0
GF Expenditure	191,200	227,700	237,600	247,900	260,600
Net Effect	(\$191,200)	(\$227,700)	(\$237,600)	(\$247,900)	(\$260,600)

Note:() = decrease; GF = general funds; FF = federal funds; SF = special funds; - = indeterminate increase; (-) = indeterminate decrease

Local Effect: None.

Small Business Effect: Potential meaningful.

Analysis

Bill Summary: The bill establishes several definitions. “Diet pills” means one of the following products that is labeled, marketed, or otherwise represented for the purpose of achieving weight loss or building muscle: (1) a dietary supplement as defined in federal law; or (2) a drug, as defined in federal law, that does not require a prescription under the federal Food, Drug, and Cosmetic Act. “Diet pills” does not include dietary fiber products. “Retail establishment” means any vendor that, in the course of regular business, sells diet pills at retail directly to the public. “Delivery sale” means a sale of diet pills to a consumer in which (1) the consumer submits the order by telephone or other method of voice transmission, the mail, or the Internet or the seller is otherwise not in the physical presence of the buyer when the purchase request is made or (2) the diet pills are delivered to the buyer by common carrier, private delivery service, or another method of remote delivery or the seller is otherwise not in the physical presence of the buyer when the buyer obtains possession of the diet pills. “Delivery seller” means a person, including an online retailer, who makes delivery sales of over-the-counter diet pills.

Responsibilities of Delivery Sellers

A delivery seller may not accept a delivery sale order from an individual unless the delivery seller obtains and verifies the individual’s full name, birth date, and residential address. A delivery seller must verify the information with a commercially acceptable database, consisting primarily of data from government sources, that are regularly used by government and businesses for age and identity verification purposes. The database may not be in the possession of, under the control of, or subject to any changes or supplementation by the delivery seller.

A delivery seller must ship diet pills using a shipping method that requires (1) the consumer placing the delivery sale order, or an adult who is at least age 18, to sign for delivery and (2) the individual who signs for delivery to provide a valid, government-issued photo identification proving that the individual is at least age 18.

Required Notice Regarding Potential Health Effects of Specified Diet Pills

MDH must develop a notice stating that specified diet pills may contribute to gastrointestinal impairment, tachycardia, hypertension, myocardial infarction, stroke, organ failure, severe liver injury sometimes requiring a transplant or leading to death, or

other serious injuries or death. Each retailer that sells diet pills must prominently display the notice in a location visible to customers.

Regulations Establishing Limitation on Diet Pills Subject to the Bill

MDH, in consultation with the U.S. Food and Drug Administration (FDA) and other interested stakeholders, may adopt regulations establishing limitations on diet pills subject to the bill's provisions. In developing regulations, MDH must consider whether (1) the diet pills contain an FDA-approved ingredient for weight loss, a steroid, creatinine, green tea extract, raspberry ketone, garcinia cambogia, or green coffee bean extract; (2) the labeling or marketing of the diet pills includes statements or images that state or imply that the diet pills will help modify, maintain, or reduce body fat, appetite, overall metabolism, or the process by which nutrients are metabolized; and (3) the diet pills or their ingredients are otherwise represented for the purpose of weight loss.

Current Law: Federal law defines “dietary supplement” as a product intended to supplement the diet that contains one or more dietary ingredients (vitamins or minerals, herbs or other botanicals, amino acids, dietary substances used to supplement the diet by increasing the total dietary intake, or concentrates, metabolites, constituents, extracts, or combinations of any other dietary ingredient). To be a dietary supplement, a product must be labeled as a dietary supplement or equivalent.

FDA regulates dietary supplements as foods unless the product meets the definition of a drug. FDA does not have the authority to approve dietary supplements before they are marketed. FDA regulations require those who manufacture, package, or hold dietary supplements to follow current good manufacturing practices that help ensure the identity, purity, quality, strength, and composition of dietary supplements. FDA generally does not approve dietary supplement claims or other labeling before use. FDA is responsible for enforcing the laws and regulations governing dietary supplements. To identify violations, the agency conducts inspections, monitors the marketplace, examines dietary supplements and dietary ingredients offered for import, and reviews new dietary ingredient notifications and other regulatory submissions for dietary supplements.

State Fiscal Effect: Currently, there is no expertise within MDH regarding diet pills as defined by the bill. Thus, additional resources are required to develop the standardized notice and promulgate regulations defining which diet pills are subject to the bill's provisions.

Accordingly, MDH general fund expenditures increase by \$191,198 in fiscal 2024, which accounts for the bill's October 1, 2023 effective date. This estimate reflects the cost to hire a minimum of two personnel (one clinical pharmacist and one program administrator) to develop standardized notices to be displayed in all retail establishments that sell diet pills,

review products that meet the bill’s definition of diet pills, and determine which diet pills are subject to the bill’s provisions. It includes salaries, fringe benefits, one-time start-up costs, and ongoing operating expenses.

Positions	2.0
Salaries and Fringe Benefits	\$168,325
Operating Expenses	<u>22,873</u>
Total FY 2024 State Expenditures	\$191,198

Future year expenditures reflect full salaries with annual increases and employee turnover as well as annual increases in ongoing operating expenses. This analysis reflects the constant need to monitor new products and determine whether they are subject to the bill’s provisions; it does not reflect the cost of any enforcement activities.

General fund revenues increase by a minimal amount beginning in fiscal 2024 – to the extent the bill’s civil penalty provision is applied.

Small Business Effect: Small business retail establishments must limit access to diet pills in their establishments, post a specified notice, and verify the age of an individual attempting to purchase diet pills if the individual reasonably appears to be younger than age 18. A small business delivery seller must verify the individual’s identity using a specified database and use specified shipping methods. Violators of the bill are subject to a civil penalty of up to \$1,000.

Additional Information

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

Designated Cross File: SB 602 (Senator Benson, *et al.*) - Finance.

Information Source(s): U.S. Food and Drug Administration; Office of the Attorney General (Consumer Protection Division); Maryland Department of Health; Department of Legislative Services

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