HB 1256

Department of Legislative Services

Maryland General Assembly
2021 Session

FISCAL AND POLICY NOTE
First Reader

House Bill 1256 (Delegate K. Young)
Health and Government Operations

Maryland Department of Health – Gene Synthesis Providers and Manufacturers of Gene Synthesis Equipment – Certification

This bill requires the Maryland Department of Health (MDH), by January 1, 2023, to develop specified gene sequence and customer screening guidelines for "gene synthesis providers" and manufacturers of "gene synthesis equipment." MDH must develop a process to certify that gene synthesis providers and manufacturers of gene synthesis equipment are in compliance with such guidelines, including a review of each entity's compliance at least once every two years. Beginning January 1, 2024, a gene synthesis provider or manufacturer of gene synthesis products must be certified by MDH in order to create gene synthesis products for delivery in the State, distribute such products in the State, or manufacture equipment needed to produce such products in the State. The bill establishes a civil penalty of $1,000 per day for failure to obtain or maintain certification and requires MDH to develop a related appeals process. Beginning January 1, 2024, specified entities that receive State resources may purchase gene synthesis products and equipment only from certified providers and manufacturers. Entities that fail to comply may have access to State resources revoked.

Fiscal Summary

State Effect: MDH general fund expenditures increase by an indeterminate, but likely significant, amount beginning in FY 2022 to implement the bill, as discussed below. General fund revenues may increase by an indeterminate amount from civil penalties beginning in FY 2024.

Local Effect: None.

Small Business Effect: Potential meaningful.

Analysis

Bill Summary: "Gene synthesis provider" means an entity that creates gene synthesis products for delivery to a customer or distributes gene synthesis products and includes (1) an entity that manufactures gene products for use by other parties, both inside and outside of the entity, or (2) a third-party entity that is not the end user of a gene synthesis product and does not make gene synthesis products but otherwise fills, complete, modifies, or purifies gene synthesis products.

"Gene synthesis equipment" means equipment needed to produce gene synthesis products that is not readily used for any other purpose, as specified by MDH.

"Dangerous pathogen" means a pathogen (1) on the select agents and toxins list maintained by the Federal Select Agent Program; (2) on the list of human and animal pathogens and toxins for export control maintained by the Australia Group; or (3) identified by MDH.

Guidelines

The gene sequence and customer screening guidelines for gene synthesis providers and manufacturers of gene synthesis equipment must increase gene synthesis security and improve biosecurity efforts to prevent, deter, detect, attribute, and mitigate the misuse of gene synthesis products in the State. The guidelines must include requirements that (1) a gene synthesis provider identify gene synthesis product orders that include dangerous pathogen sequences and other potentially dangerous sequences and (2) if a dangerous pathogen or other potentially dangerous sequence is identified by a gene synthesis provider, the gene synthesis order be reviewed by a human and subject to additional screening requirements.

Entities Receiving State Resources

Beginning January 1, 2024, an entity that receives State resources (as specified) may purchase gene synthesis products only from a certified gene synthesis provider and gene synthesis equipment from a certified manufacturer of gene synthesis equipment regardless of whether or not the gene synthesis provider or manufacturer of gene synthesis equipment is operating in the State. An entity that does not comply may have access to all State resources revoked for the duration of the noncompliance.

Current Law: Chapter 99 of 2005 established the biotechnology investment incentive tax credit program, which offers a refundable income tax credit for investments in qualified biotechnology companies. An investor who invests at least $25,000 in a qualified Maryland biotechnology company can claim a credit equal to 50% of the investment, not to exceed $250,000. If the qualified biotechnology company is located in Allegany, Dorchester,

Garrett, or Somerset counties, the value of the credit for investments made in these companies is equal to 75% of the investment, not to exceed $500,000. The Maryland Department of Commerce administers the tax credit application process, and the total amount awarded in each year is generally limited to the amount appropriated to the program. The Governor's proposed fiscal 2022 operating budget includes $12.0 million in funding for the program.

Pursuant to the federal Public Health Service Act, the U.S. Department of Health and Human Services published *Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA*. The stated primary goal of the guidance is to minimize the risk that unauthorized individuals or individuals with malicious intent will obtain toxins and agents of concern through the use of nucleic acid synthesis technologies and to simultaneously minimize any negative impacts on the conduct of research and business operations. The guidance outlines a screening framework that will assist providers in meeting this goal.

The Federal Select Agent Program, established pursuant to a U.S. Congressional mandate to regulate the possession, use, and transfer of biological select agents and toxins that have the potential to pose a severe threat to public, animal, or plant health or to animal or plant products, maintains the *Select Agents and Toxins List*. Entities that wish to possess, use, or transfer biological select agents and toxins must register with the Federal Select Agent Program.

State Expenditures: MDH advises that the bill requires the certification and oversight of two separate industries (gene synthesis providers and manufacturers of gene synthesis equipment) with different technical expertise requiring the development of two separate sets of guidelines and the implementation of two separate certification processes to regulate each industry. MDH further advises that there are an estimated 40 businesses creating gene synthesis products and an estimated 12 businesses manufacturing gene synthesis equipment located all around the world that sell products or equipment in the State. Thus, MDH advises that the bill requires a significant increase in (1) staff resources, beginning in fiscal 2022, including the creation of a new unit with six permanent staff positions and (2) beginning in fiscal 2023, travel expenditures to certify and review compliance of entities located all over the world. The Department of Legislative Services agrees that there is a need for potentially significant additional resources, but advises that, without actual experience under the bill, it is impossible to determine a reliable estimate as no other entities, including federal and state governments, currently regulate these industries.

To the extent that State resources are revoked for any recipient that fails to comply with the bill's provisions, State expenditures are reduced beginning in fiscal 2024. Assuming compliance under the bill, any impact is likely to be minimal.

Small Business Effect: Access to products and equipment from gene synthesis providers and manufacturers of gene synthesis equipment by small businesses in the State may be restricted to the extent that out-of-state providers or manufacturers choose not to become certified.

Additional Comments: The Australia Group maintains the *List of Human and Animal Pathogens and Toxins for Export Control*.

Similar legislation has been introduced in the California State Legislature during its two most recent legislative sessions.

Additional Information

Prior Introductions: None.

Designated Cross File: None.

Information Source(s): Maryland Department of Health; Department of Legislative Services

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