HOUSE BILL 1256

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By: **Delegate K. Young**
Introduced and read first time: February 8, 2021
Assigned to: Health and Government Operations

A BILL ENTITLED

AN ACT concerning

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

FOR the purpose of requiring the Maryland Department of Health to develop certain guidelines that include certain requirements for gene synthesis providers and manufacturers of gene synthesis equipment on or before a certain date; requiring the Department to develop a process to certify that gene synthesis providers and manufacturers of gene synthesis equipment are in compliance with certain guidelines; requiring the Department to certify certain gene synthesis providers and manufacturers of gene synthesis equipment on or after a certain date; requiring certain gene synthesis providers or manufacturers of gene synthesis equipment to be certified on or after a certain date before performing certain functions; providing that gene synthesis providers and manufacturers of gene synthesis equipment that are not certified or fail to maintain certification while performing certain functions are subject to a certain penalty; authorizing, on or after a certain date, certain recipients of certain State resources to purchase gene synthesis products only from gene synthesis providers and gene synthesis equipment from manufacturers of gene synthesis equipment that are certified; providing for the revocation of certain State resources under certain circumstances and for a certain period of time; requiring the Department to develop a certain appeals process; requiring that a certain appeals process ensure certain due process; defining certain terms; and generally relating to gene synthesis providers and manufacturers of gene synthesis equipment.

BY adding to
Article – Health – General
Section 17–801 through 17–806 to be under the new subtitle "Subtitle 8. Certification of Gene Synthesis Providers and Manufacturers of Gene Synthesis Equipment"
Annotated Code of Maryland
(2019 Replacement Volume and 2020 Supplement)

EXPLANATION: **CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.**
[Brackets**]** indicate matter deleted from existing law.

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article – Health – General

SUBTITLE 8. CERTIFICATION OF GENE SYNTHESIS PROVIDERS AND MANUFACTURERS OF GENE SYNTHESIS EQUIPMENT.

17–801.

(A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.

(B) "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 THE DEPARTMENT.

(C) "GENE SYNTHESIS EQUIPMENT" MEANS EQUIPMENT NEEDED TO PRODUCE GENE SYNTHESIS PRODUCTS THAT IS NOT READILY USED FOR ANY OTHER PURPOSE, AS SPECIFIED BY THE DEPARTMENT.

(D) "GENE SYNTHESIS PRODUCT" MEANS DOUBLE–STRANDED DNA, DOUBLE–STRANDED NUCLEIC ACIDS, RNA, OR OLIGONUCLEOTIDES, DESIGNED AND CREATED WITHOUT AN EXISTING DNA TEMPLATE.

(E) (1) "GENE SYNTHESIS PROVIDER" MEANS AN ENTITY THAT:

(I) CREATES GENE SYNTHESIS PRODUCTS FOR DELIVERY TO A CUSTOMER; OR

(II) DISTRIBUTES GENE SYNTHESIS PRODUCTS.

(2) "GENE SYNTHESIS PROVIDER" INCLUDES:

(I) AN ENTITY THAT MANUFACTURES GENE PRODUCTS FOR USE BY OTHER PARTIES, BOTH INSIDE AND OUTSIDE OF THE ENTITY; OR

(II) 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, COMPLETES, MODIFIES, OR PURIFIES GENE SYNTHESIS PRODUCTS.

(3) "GENE SYNTHESIS PROVIDER" DOES NOT INCLUDE A RESEARCH SCIENTIST MAKING GENE SYNTHESIS PRODUCTS FOR THE RESEARCH SCIENTIST'S OWN USE OR FOR USE BY ANOTHER RESEARCH SCIENTIST.

17–802.

(A) ON OR BEFORE JANUARY 1, 2023, THE DEPARTMENT SHALL, WITH INPUT FROM INDUSTRY STAKEHOLDERS, DEVELOP GENE SEQUENCE AND CUSTOMER SCREENING GUIDELINES FOR GENE SYNTHESIS PROVIDERS AND MANUFACTURERS OF GENE SYNTHESIS EQUIPMENT TO:

(1) INCREASE GENE SYNTHESIS SECURITY; AND

(2) IMPROVE BIOSECURITY EFFORTS TO PREVENT, DETER, DETECT, ATTRIBUTE, AND MITIGATE THE MISUSE OF GENE SYNTHESIS PRODUCTS IN THE STATE.

(B) THE GUIDELINES DEVELOPED UNDER SUBSECTION (A) OF THIS SECTION SHALL 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.

17–803.

(A) (1) THE DEPARTMENT SHALL DEVELOP A PROCESS TO CERTIFY THAT GENE SYNTHESIS PROVIDERS AND MANUFACTURERS OF GENE SYNTHESIS EQUIPMENT ARE IN COMPLIANCE WITH THE GUIDELINES DEVELOPED UNDER § 17–802 OF THIS SUBTITLE.

(2) THE CERTIFICATION PROCESS SHALL INCLUDE A REVIEW OF EACH ENTITY'S COMPLIANCE WITH THE GUIDELINES, AT MINIMUM, ONCE EVERY 2 YEARS.

(B) ON OR AFTER JANUARY 1, 2024, THE DEPARTMENT SHALL CERTIFY GENE SYNTHESIS PROVIDERS AND MANUFACTURERS OF GENE SYNTHESIS EQUIPMENT OPERATING IN THE STATE THAT MEET THE GUIDELINES ESTABLISHED IN § 17–802 OF THIS SUBTITLE.

17–804.

(A) ON OR AFTER JANUARY 1, 2024, A GENE SYNTHESIS PROVIDER OR MANUFACTURER OF GENE SYNTHESIS EQUIPMENT MUST RECEIVE CERTIFICATION FROM THE DEPARTMENT UNDER § 17–803(B) OF THIS SUBTITLE BEFORE:

(1) THE GENE SYNTHESIS PROVIDER MAY:

(I) CREATE GENE SYNTHESIS PRODUCTS FOR DELIVERY TO A CUSTOMER IN THE STATE; OR

(II) DISTRIBUTE GENE SYNTHESIS PRODUCTS IN THE STATE; OR

(2) THE MANUFACTURER OF GENE SYNTHESIS EQUIPMENT MAY MANUFACTURE EQUIPMENT NEEDED TO PRODUCE GENE SYNTHESIS PRODUCTS IN THE STATE.

(B) A GENE SYNTHESIS PROVIDER OR MANUFACTURER OF GENE SYNTHESIS EQUIPMENT THAT IS NOT CERTIFIED, OR THAT FAILS TO MAINTAIN ITS CERTIFICATION, WHILE PERFORMING THE FUNCTIONS DESCRIBED IN SUBSECTION (A) OF THIS SECTION, IS SUBJECT TO A CIVIL PENALTY OF $1,000 PER DAY THAT THE ENTITY IS NOT CERTIFIED.

17–805.

(A) THIS SECTION APPLIES TO:

(1) AN ENTITY THAT RECEIVES STATE RESOURCES, INCLUDING FUNDS OR THE USE OF FACILITIES, MATERIALS, AND LABOR, WHETHER OR NOT THE RESOURCES ARE RECEIVED AS PART OF A PROJECT WITH ANOTHER ENTITY THAT DOES NOT RECEIVE STATE RESOURCES; AND

(2) A GENE SYNTHESIS PROVIDER OR 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.

(B) ON OR AFTER JANUARY 1, 2024, AN ENTITY SUBJECT TO THIS SECTION THAT IS THE RECIPIENT OF STATE RESOURCES MAY PURCHASE GENE SYNTHESIS PRODUCTS ONLY FROM A GENE SYNTHESIS PROVIDER, AND GENE SYNTHESIS EQUIPMENT FROM A MANUFACTURER OF GENE SYNTHESIS EQUIPMENT, THAT IS CERTIFIED UNDER THIS SUBTITLE.

(C) AN ENTITY SUBJECT TO THIS SECTION THAT DOES NOT COMPLY WITH THIS SECTION MAY HAVE ACCESS TO ALL STATE RESOURCES REVOKED FOR THE DURATION OF THE NONCOMPLIANCE.

17–806.

(A) THE DEPARTMENT SHALL DEVELOP AN APPEALS PROCESS FOR GENE SYNTHESIS PROVIDERS AND MANUFACTURERS OF GENE SYNTHESIS EQUIPMENT SUBJECT TO A CIVIL PENALTY UNDER § 17–804(B) OF THIS SUBTITLE AND FOR ENTITIES SUBJECT TO STATE RESOURCE REVOCATION UNDER § 17–805(C) OF THIS SUBTITLE.

(B) THE APPEALS PROCESS SHALL ENSURE THAT APPELLANTS ARE PROVIDED WITH DUE PROCESS.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2021.