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118TH CONGRESS
2D SESSION

H. R. 8065

To require the Secretary of Health and Human Services, acting through the Assistant Secretary for Preparedness and Response, to carry out a program under which the Secretary requires each regulated seller of a highly infectious agent to comply with certain logbook requirements, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 18, 2024

Mr. COSTA (for himself and Mr. KILEY) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To require the Secretary of Health and Human Services, acting through the Assistant Secretary for Preparedness and Response, to carry out a program under which the Secretary requires each regulated seller of a highly infectious agent to comply with certain logbook requirements, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Preventing Illegal Laboratories and Protecting Public Health Act of 2024''.

SEC. 2. REQUIRING CERTAIN SELLERS OF HIGHLY INFECTIOUS AGENTS TO KEEP A LOGBOOK OF SALES.

(a) PROGRAM.—The Secretary of Health and Human Services, acting through the Assistant Secretary for Preparedness and Response, shall carry out a program under which the Secretary requires each regulated seller of a highly infectious agent to comply with the logbook requirements of subsection (c).

(b) LIST OF HIGHLY INFECTIOUS AGENTS.—

(1) DEVELOPMENT.—The Secretary shall develop and maintain a list of all agents that meet the definition of a highly infectious agent in subsection (e).

(2) INITIAL LIST.—The Secretary shall develop the initial list required by paragraph (1) not later than 12 months after the date of enactment of this Act.

(3) PERIODIC REVIEW.—The Secretary shall periodically review and update the list required by paragraph (1).

(4) CONSULTATION; CONSIDERATION.—In developing and updating the list required by paragraph (1), the Secretary shall—

(A) consult with relevant agencies, including the Centers for Disease Control and Pre-

vention, the National Institutes of Health, and the Department of Homeland Security;

(B) take into consideration the latest edition of ''Biosafety in Microbiological and Biomedical Laboratories'' published by the Centers for Disease Control and Prevention and the National Institutes of Health (or any successor to such publication); and

(C) take into consideration the latest edition of ''NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules'' published by the National Institutes of Health (or any successor to such publication).

(c) LOGBOOK REQUIREMENTS.—

(1) IN GENERAL.—Each regulated seller shall maintain, in accordance with criteria issued by the Secretary, an electronic list (in this section referred to as a ''logbook'') of the sales by such seller of each highly infectious agent on the list under subsection (b) that identifies—

(A) the agent by name;

(B) the quantity sold;

(C) the name and address of each purchaser, including relevant identifying business

information as deemed necessary by the Secretary;

(D) a short description of the purchaser's intended use of the agent; and

(E) the date and time of the sale.

(2) SALE REQUIREMENTS.—In the case of a sale to which the requirement of paragraph (1) applies, the regulated seller shall not sell the highly infectious agent unless—

(A) the prospective purchaser—

(i) presents an identification card that provides a photograph and is issued by a State or the Federal Government, or a document that, with respect to identification, is considered acceptable for purposes of sections 274a.2(b)(1)(v)(A) and 274a.2(b)(1)(v)(B) of title 8, Code of Federal Regulations (or successor regulations); and

(ii) signs the logbook and enters in the logbook—

(I) the purchaser's name and address;

(II) a short description of the purchaser's intended use of the agent; and

(III) the date and time of the sale; and

(B) the regulated seller—

(i) determines that the name entered in the logbook corresponds to the name provided on such identification and that the date and time entered are correct; and

(ii) enters in the logbook the name of the highly infectious agent and the quantity sold.

(3) CONTENTS.—The regulated seller shall include in the logbook, in accordance with criteria of the Secretary, a notice to purchasers that entering false statements or misrepresentations in the logbook may subject the purchasers to criminal penalties under section 1001 of title 18, United States Code, which notice specifies the maximum fine and term of imprisonment under such section.

(4) DURATION OF MAINTENANCE OF ENTRIES.—The regulated seller shall maintain each entry in the logbook for not fewer than five years after the date on which the entry is made.

(5) DISCLOSURE OF LOGBOOKS.—The Secretary shall establish restrictions on disclosure of information in logbooks. Such regulations shall—

(A) provide for the disclosure of the information as appropriate to the Secretary and to Federal, State, and local law enforcement agencies; and

(B) prohibit accessing, using, or sharing information in the logbooks for any purpose other than to ensure compliance with this section or to protect public health and safety.

(d) FALSE STATEMENTS OR MISREPRESENTATIONS BY PURCHASERS.—For purposes of section 1001 of title 18, United States Code, entering information in a logbook shall be considered a matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States.

(e) DEFINITIONS.—In this section:

(1) The term ''highly infectious agent'' means an infectious agent that meets the criteria of ''risk group 3'' or ''risk group 4'' as such risk groups are defined in the latest edition of ''NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules'' published by the National In-

stitutes of Health (or any successor to such publication).

(2) The term ''regulated seller'' means a seller of highly infectious agents, except that such term does not include an employee or agent of such a seller.

(3) The term ''Secretary'' means the Secretary of Health and Human Services, acting through the Assistant Secretary for Preparedness and Response.

SEC. 3. EVALUATION OF HIGH-CONTAINMENT LABORATORIES.

(a) IN GENERAL.—The National Security Advisor, in consultation with the Secretary of Health and Human Services, the Secretary of Agriculture, the Secretary of Defense, the Secretary of Homeland Security, the National Intelligence Council, and such other Federal officials as the National Security Advisor determines appropriate, shall identify a single Federal official to oversee a periodic strategic evaluation of high-containment laboratories in the United States.

(b) TOPICS.—Each strategic evaluation under subsection (a) shall include—

(1) an assessment of—

(A) the number, location, and mission of high-containment laboratories;

(B) the capacity of such existing laboratories to effectively meet national goals to counter threats to biosafety and biosecurity;

(C) the aggregate risks associated with—

(i) such existing laboratories; and

(ii) expanding the numbers and facilities of such laboratories; and

(D) the type of oversight needed for high-containment laboratories; and

(2) up-to-date national standards, developed by the Federal official designated under subsection (a) in consultation with the scientific community, for the design, construction, commissioning, operation, and long-term maintenance of high-containment laboratories.

(c) REPORTING.—Upon completion of each strategic evaluation under subsection, (a), the Federal official designated under subsection (a) shall submit to the President and the Congress a report on the results of such evaluation and include in each such report recommendations on—

(1) addressing gaps in Federal oversight of high-containment laboratories; and

(2) utilizing high-containment laboratories for protecting public health and ensuring biosecurity in the United States.

(d) PUBLIC HEALTH AND BIOSECURITY TEAM.—

(1) IN GENERAL.—The Federal official designated under subsection (a) shall maintain a team, to be known as the Public Health and Biosecurity Team, to serve as a single point of contact for State and local agencies regarding questions of public health relating to laboratory biosafety and biosecurity.

(2) ESTABLISHMENT.—The Federal official designated under subsection (a) shall establish the Public Health and Biosecurity Team, as required by paragraph (1), not later than one year after such official is first designated.

(3) DUTIES.—The Public Health and Biosecurity Team shall be the primary point of contact in the Federal Government for State and local agencies on—

(A) issues related to—

(i) oversight of high-containment laboratories;

(ii) the impact of high-containment laboratories on public health; or

(iii) connecting State and local officials with the relevant Federal agency or agencies on matters related to high-containment laboratories; and

(B) other issues as determined necessary by the Federal official designated under subsection (a).

(e) FEASIBILITY STUDY.—

(1) IN GENERAL.—The Federal official designated under subsection (a) shall conduct a feasibility study on establishing and maintaining a database on existing high-containment laboratories in the United States and making such database accessible to State and local officials.

(2) DATABASE DESCRIBED.—The database to be studied under paragraph (1) should be designed to include, with respect to each high-containment laboratory, the following information:

(A) The identity of the owners of the laboratory.

(B) The status of any licensing or certification of the laboratory required under Federal, State, or local law.

(C) Any legal violations by, and disciplinary action taken against, the laboratory.

(3) REPORT TO CONGRESS.—Upon completion of the feasibility study under this subsection, the Federal official designated under subsection (a) shall submit to the Congress a report on the results of such study.

(f) DEFINITION.—In this section, the term ''high-containment laboratory'' means laboratories that are suitable for ''biosafety level 3'' or ''biosafety level 4'' procedures as defined in the latest edition of ''Biosafety in Microbiological and Biomedical Laboratories'' published by the Centers for Disease Control and Prevention and the National Institutes of Health (or any successor to such publication).

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