Office of Senate Floor Analyses
(916) 651-4171

THIRD READING

Bill No: AB 1864
Author: Berman (D)
Amended: 8/13/26 in Senate
Vote: 21

SENATE HEALTH COMMITTEE: 10-0, 6/10/26
AYES: Weber Pierson, Valladares, Caballero, Durazo, Grove, Menjivar, Padilla, Pérez, Rubio, Smallwood-Cuevas
NO VOTE RECORDED: Gonzalez

SENATE JUDICIARY COMMITTEE: 13-0, 6/23/26
AYES: Umberg, Niello, Allen, Ashby, Caballero, Durazo, Laird, Reyes, Stern, Valladares, Wahab, Weber Pierson, Wiener

SENATE APPROPRIATIONS COMMITTEE: 7-0, 8/13/26
AYES: Cervantes, Seyarto, Cabaldon, Dahle, Grayson, Richardson, Wahab

ASSEMBLY FLOOR: 78-0, 5/26/26 - See last page for vote

SUBJECT: Gene synthesis equipment manufacturers and providers

SOURCE: Encode AI Corporation
Secure AI Project

DIGEST: This bill prohibits manufacturers of benchtop nucleic acid synthesis equipment and providers of synthetic nucleic acid sequences from producing, selling, or distributing the equipment or nucleic acids within the state unless the provider or manufacturer adheres to the federal Framework for Nucleic Acid Synthesis Screening as revised by the National Science and Technology Council in 2024, and attests to doing so on a public website. This bill also makes a provider or manufacturer who violates this bill subject to a civil penalty of up to $5,000.

ANALYSIS:

Existing law requires the California State University (CSU), and requests the University of California (UC), to develop systemwide guidance for purchasing gene synthesis equipment or products from gene synthesis providers who prevent the misuse of synthetic genes and safeguard the benefits of gene synthesis technology while minimizing risk, and to consider including International Gene Synthesis Consortium (IGSC) criteria in their guidance. [Education Code (EDC) §66361]

This bill:

1) Defines "framework" as the Framework for Nucleic Acid Synthesis Screening ("the framework") guidance document issued by the Fast Track Action Committee on Synthetic Nucleic Acid Procurement Screening of the National Science and Technology Council as revised in September 2024. States that the September 2024 version of the framework is the sole operative version and prohibits any subsequent revisions, supplements, or successors issued by a federal entity from modifying or being incorporated into the meaning of "framework" unless the Legislature expressly amends the meaning of "framework."

2) Establishes the following definitions:

   a) "Benchtop nucleic acid synthesis equipment" means equipment sold by manufacturers that is intended to be used to synthesize nucleic acids for use within a research laboratory or within an institution. While it may not necessarily be small enough to be placed on a benchtop, it is still considered benchtop equipment if it is sold with the intent that it will be used by researchers individually or in a core facility at an institution;

   b) "Customer" means an individual or entity (such as an institution) that orders or requests synthetic nucleic acids from a provider, or that purchases nucleic acid synthesis equipment from a manufacturer;

   c) "Manufacturer" means an entity that produces and distributes benchtop equipment for synthesizing nucleic acids. Manufacturers may provide equipment to a customer or third-party vendor;

   d) "Provider" means an entity that synthesizes and distributes synthetic nucleic acids. Providers may provide nucleic acids to a customer or third-party vendor. A provider is understood to be synthesizing and distributing nucleic

acids as a transactional service, rather than as a research scientist collaborating with a colleague; and,

e) "Synthetic nucleic acids subject to screening" means single-or double-stranded DNA or RNA, 200 nucleotides or longer (including the corresponding amino acid sequence, if applicable). As of October 13, 2026, this screening window will be decreased to 50 nucleotides, and providers should implement screening mechanisms that detect the potential for shorter nucleotides to be assembled into Sequences of Concern (SOC) when multiple synthetic nucleic acids are ordered by the same customer in a bulk order or in multiple orders over time.

3) Prohibits a manufacturer from producing benchtop nucleic acid synthesis equipment in the state or selling or delivering such equipment to a customer in the state unless the manufacturer adheres to the framework and attests to their compliance through a statement posted on a public website.

4) Prohibits a provider from producing synthetic nucleic acids subject to screening in the state or selling or delivering such nucleic acids to a customer in the state unless the provider adheres to the framework and attests to their compliance through a statement posted on a public website.

5) Specifies that if the framework uses the term "should," it is a requirement for a provider or manufacturer, and if the framework uses the term "encouraged," it is a recommendation, but not a requirement, for a provider or manufacturer.

6) Specifies that if the framework states a provision takes effect only on or after October 13, 2026, the provision will have no effect under this bill until October 13, 2027.

7) Makes a provider or manufacturer who violates this bill subject to a civil penalty in an amount dependent on the severity of the violation up to $5,000 per day that the violation continues. Requires any penalty to be recovered in a civil action brought only by the Attorney General.

8) Specifies that this bill does not regulate the activities of a customer who is not a provider or manufacturer, including, but not limited to, activities related to medical or pharmaceutical research and development or manufacturing, drug screening assays, reagent production, tests employed in preclinical and clinical studies, manufacturing of biologics, gene therapy, and RNA therapeutics.

9) Makes the provisions of this bill severable.

Background

According to the author of this bill:

> From Silicon Valley to Biotech Beach, California is the undisputed cradle of innovation, which has led to great technological advancements and the development of lifesaving vaccines and treatments. However, innovation cannot come at the expense of protecting public health and we must implement enforceable guardrails to ensure that gene synthesis technology is not misused to create dangerous bioweapons. This bill would protect Californians against the misuse of gene synthesis technology by requiring providers of synthetic genes and manufacturers of gene synthesis equipment to screen customer orders for dangerous pathogen sequences and confirm the legitimacy of customers. This bill is a commonsense approach to require federally recognized best practices in order to keep Californians safe and defend against biological threats.

Synthetic nucleic acids. Nucleic acids like DNA and RNA are polymers of molecules called nucleotides, some of which have the potential to encode functional RNA or proteins. As described in a perspective article published in *Cold Spring Harbor Perspectives in Biology*, scientists began developing chemical synthesis and ligation methods in the mid-1960s that enabled the assembly of nucleotides into custom nucleic acid sequences for molecular biology research. The ability to synthesize nucleic acids has since transformed the life sciences, according to a 2025 *Applied Biosafety* article.

Growing risks of synthetic biology. According to the National Academy of Science's "Biodefense in the Age of Synthetic Biology" report, synthetic biology and related biotechnologies expand the landscape of potential biodefense concerns. The advent of sophisticated algorithms and artificial intelligence (AI) have also heightened biosecurity risks; the *California Report on Frontier AI Policy* highlights that AI models can help users access dual-use biological knowledge, allowing novices to create known biological threats. Open AI's o3 model was able to outperform 94% of expert virologists on questions of troubleshooting complex virology laboratory protocols, according to a 2025 preprint.

SOC and nucleic acid sequence screening. According to the framework, SOC include a nucleotide sequence or its corresponding amino acid sequence that is a best match to a sequence of federally regulated agents (i.e., the Biological Select

Agents and Toxins List or the Commerce Control List), except when the sequence is also found in an unregulated organism or toxin. After October 13, 2026, this definition expands to include sequences known to contribute to pathogenicity or toxicity, even when not derived from or encoding regulated biological agents. Several computational tools are available to screen these sequences, including both commercial and free options. According to a 2025 article in *Applied Biosafety* that compared how six different screening tools screened and labeled a test dataset compiled by the National Institutes of Standards and Technology, there is general agreement between the tools, and all tools had a baseline performance of greater than 95% sensitivity and 97% accuracy. All programs were capable of screening windows of 50 nucleotides, and half were capable of screening 30-nucleotide sequences or less.

The Framework for Nucleic Acid Synthesis Screening. The Framework for Nucleic Acid Synthesis Screening referenced in this bill is the product of the National Science and Technology Council's (NSTC) Fast Track Action Committee on Synthetic Nucleic Acid Procurement Screening. Adherence with the guidance is required for firms providing equipment or synthetic nucleic acids to the government or recipients of federal funding, although compliance is self-attested. The framework takes a sequential approach to screening. First, the nucleotide sequences are screened for SOC as described above. Second, for orders containing SOC, the provider must verify customer legitimacy, including that the customer is affiliated with a legitimate life sciences-oriented institution and has a legitimate need to use synthetic nucleic acids. The framework consists of the following six requirements for synthetic nucleic acid providers and benchtop synthesis equipment manufacturers:

a) Attest to implementing this screening framework through a statement that either is posted on a public website or provided to the federally funded customer and federal funding agency upon request;

b) Screen purchase orders for synthetic nucleic acids to identify SOCs;

c) Screen customers submitting purchase orders of synthetic nucleic acids with SOCs, and purchase orders of benchtop nucleic acid synthesis equipment, to verify legitimacy;

d) Report potentially illegitimate purchase orders of synthetic nucleic acids involving SOCs or of benchtop nucleic acid synthesis equipment;

e) Retain records relating to purchase orders for synthetic nucleic acids and benchtop nucleic acid synthesis equipment; and,

f) Take steps to ensure cybersecurity and information security.

While Executive Order 14110 was rescinded by President Trump in January 2025, the intent to encourage synthetic nucleic acid screening was reiterated in the May 2025 Executive Order 14292. This Executive Order requires the existing framework to be revised or replaced within 90 days, but nothing has yet been produced to replace the NSTC 2024 framework, which remains the federal government's most recent guidance on the topic.

IGSC Harmonized Screening Protocol. IGSC is an industry-led group of gene synthesis companies and organizations that formed in 2009 to design and apply a common protocol to screen synthetic nucleic acid sequences and the customers who place them. IGSC members agree to adhere to the IGSC Harmonized Screening Protocol, which requires members to screen all synthetic nucleic acid orders against the IGSC's comprehensive curated Regulated Pathogen Database, which is compiled from international pathogen and toxin sequence databases. IGSC members also perform customer screening measures to review the individual and organization placing the order, and agree to only provide orders containing sequences for regulated pathogens or toxins to verified government laboratories, universities, and industrial laboratories demonstrably engaged in legitimate research. The Harmonized Screening Protocol additionally establishes best practices related to record-keeping, order refusal and reporting, regulatory compliance, and consortium collaborative activities. Version 3 of the IGSC Harmonized Screening Protocol incorporates the NSTC framework, so that IGSC members should be in compliance with the federal framework. According to IGSC's website, their members represent approximately 80% of commercial gene synthesis capacity world-wide.

Compliance concerns. The Johns Hopkins Center for Health Security's Gene Synthesis Screening Information Hub website maintains a list of biotechnology companies that publicly attest to following the NSTC framework, and CSU and UC have posted a public spreadsheet of various nucleic acid synthesis providers that publicly attest to gene synthesis screening protocols compliant with AB 1963 (Salas, Chapter 179, Statutes of 2022). Although both lists include many large providers and manufacturers, many firms on the UC/CSU list did not provide an attestation upon request (with the caveat that most requests were issued in 2023 and may not reflect changes since the publication of the NSTC 2024 framework). The International Biosecurity and Biosafety Initiative for Science's 2025 Global DNA Synthesis Map reveals a large gap in screening practices, with only 69 providers and manufacturers out of over 700 confirming screening implementation. According to the Engineering Biology Research Consortium, they performed a

study that stress-tested providers' screening protocols by ordering SOC to customers of varying legitimacy and found that IGSC membership or self-attestation of compliance is insufficient to ensure that SOC are not shipped to fraudulent companies or residential addresses.

FISCAL EFFECT: Appropriation: No Fiscal Com.: Yes Local: No

According to the Senate Appropriations Committee:

- Unknown ongoing General Fund costs, likely low millions, for the California Department of Justice for state administration. This would include costs for increased workload to work with an expert to assess when there is a violation, and to litigate violations of the law.
- No fiscal impact for the California Department of Public Health for state administration.
- Unknown, potential workload costs to the courts related to enforcement of civil penalties under the bill (Trial Court Trust Fund, General Fund). While the courts are not funded on a workload basis, an increase in workload could result in delayed court services and would put pressure on the General Fund to increase the amount appropriated for trial court operations.

SUPPORT: (Verified 8/14/26)

Encode AI Corporation (co-source)
Secure AI Project (co-source)
American Nurses Association\California
Anthropic
California Federation of Teachers
California Initiative for Technology & Democracy, a project of California Common Cause
California Medical Association
Kapor Center Advocacy
Eleven individuals

OPPOSITION: (Verified 8/14/26)

None received

ARGUMENTS IN SUPPORT: Encode AI and The Secure AI Project are the co-source of this bill. A coalition letter with the sources and other organizations like the California Initiative for Technology & Democracy (CITED), Kapor Center Advocacy, and the American Nurses Association\California claim that advances in

artificial intelligence are accelerating the risk of gene synthesis technology being misused to produce dangerous pathogens or toxins. They point out that the current systems of voluntary compliance create an uneven playing field that punishes responsible companies and leaves a gap that bad actors can exploit, and that many prominent voices in biotechnology, biosecurity, and AI have called for mandatory gene synthesis screening and customer verification. They claim that by empowering the Attorney General to seek civil penalties, this bill creates an enforcement mechanism that would level the playing field for responsible firms, ultimately protecting Californians from severe public health threats as well as the biotechnology industry against incidents that could jeopardize public trust and result in backlash. Anthropic writes that the same advances in AI that will help cure disease are also lowering the barrier to designing dangerous biology, which is why safeguards must be built into models and paired with screening. CITED and the California Federation of Teachers also highlight that AI systems could help novices create biological weapons, citing the *California Report on Frontier AI Policy*. They view this bill as an opportunity for California to lead efforts to protect public health and defend the public against biological threats.

ASSEMBLY FLOOR: 78-0, 5/26/26
AYES: Addis, Aguiar-Curry, Ahrens, Alanis, Alvarez, Arambula, Ávila Farías, Bains, Bauer-Kahan, Bennett, Berman, Boerner, Bonta, Bryan, Calderon, Caloza, Carrillo, Castillo, Chen, Connolly, Davies, DeMaio, Dixon, Elhawary, Ellis, Flora, Fong, Gabriel, Gallagher, Garcia, Gipson, Jeff Gonzalez, Mark González, Hadwick, Haney, Harabedian, Hart, Hoover, Irwin, Jackson, Johnson, Kalra, Krell, Lackey, Lee, Lowenthal, Macedo, McKinnor, Nguyen, Ortega, Pacheco, Papan, Patel, Patterson, Pellerin, Petrie-Norris, Quirk-Silva, Ramos, Ransom, Michelle Rodriguez, Rogers, Blanca Rubio, Sanchez, Schiavo, Schultz, Sharp-Collins, Solache, Soria, Stefani, Ta, Tangipa, Valencia, Wallis, Ward, Wicks, Wilson, Zbur, Rivas
NO VOTE RECORDED: Muratsuchi, Celeste Rodriguez

Prepared by: Natalie Gehred / HEALTH / (916) 651-4111
8/17/26 10:42:56

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