SENATE COMMITTEE ON HEALTH
Senator Akilah Weber Pierson, Chair

BILL NO: AB 1864
AUTHOR: Berman
VERSION: May 18, 2026
HEARING DATE: June 10, 2026
CONSULTANT: Natalie Gehred

SUBJECT: Gene synthesis equipment manufacturers and providers

SUMMARY: Requires 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 adheres to the federal Framework for Nucleic Acid Synthesis Screening as revised by the National Science and Technology Council in 2024. Makes a provider or manufacturer who violates this bill subject to a civil penalty of up to $1,000.

Existing law:
1) 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. [EDC §66361]

2) Establishes the following definitions:
   a) "Gene synthesis product" is double-stranded DNA, double-stranded nucleic acids, RNA, or oligonucleotides, designed and created without an existing DNA template.
   b) "Gene synthesis equipment" is equipment needed to produce gene synthesis products that is not readily used for any other purpose.
   c) "Gene synthesis provider" is an entity that does any of the following:
      i) An entity that creates gene synthesis products for delivery to a customer;
      ii) A distributor of gene synthesis products, including, but not limited to, entities that manufacture gene synthesis products for use by other parties, both inside and outside of the entity; or,
      iii) 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. [EDC §66360]

3) Clarifies that "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 or an entity that manufactures gene synthesis products for the entity's own use. [EDC §66360]

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.

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.

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) 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 $1,000 per day that the violation continues. Requires any penalty to be recovered in a civil action brought only by the Attorney General.

7) 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.

8) Makes the provisions of this bill severable.

FISCAL EFFECT: According to the Assembly Committee on Appropriations, the Department of Justice (DOJ) estimates costs of $1.2 million in fiscal year (FY) 2026-27 and $2.3 million per year in FY 2027-28 and ongoing (General Fund). DOJ states it will work with an expert to assess when there is a violation and to litigate violations of this bill. DOJ projects it will need three deputy attorneys general, two legal secretaries, and $1 million for external consultant costs. They also expect cost pressures of an unknown amount to the courts in additional workload to adjudicate additional filings resulting from this bill. Costs will depend on the number of cases filed and the amount of court time needed to resolve each case (Trial Court Trust Fund, General Fund). It generally costs approximately $1,000 to operate a courtroom for one hour. Although courts are not funded based on workload, increased pressure on the Trial Court Trust Fund may create a demand for increased funding for courts from the General Fund**.**

PRIOR VOTES:

Assembly Floor:	78 - 0
Assembly Appropriations Committee:	11 - 0
Assembly Judiciary Committee	12 - 0
Assembly Health Committee:	16 - 0

COMMENTS:

1) *Author's statement.* According to the author, 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.

2) *Synthetic nucleic acids.* According to the National Human Genome Research Institute, nucleic acids like DNA and RNA are polymers of molecules called nucleotides, specifically adenine, guanine, cytosine, and thymine (replaced by uracil in RNA). These four nucleotides can be assembled into any sequence, some of which have the potential to encode functional RNA or proteins. In nature, nucleic acids are replicated using preexisting templates. However, 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, underpinning advances such as the construction of minimal bacterial genomes, disease diagnostics, crop improvement, and the manufacturing of biofuels, according to a 2025 *Applied Biosafety* article.

3) *Growing risks of synthetic biology.* In June 2018, in response to a request from the Department of Defense, the National Academy of Sciences released "Biodefense in the Age of Synthetic Biology." According to this report, synthetic biology and related biotechnologies expand the landscape of potential biodefense concerns. These capabilities could enable new modes of attack, some of which may not be detectable or treatable with

current approaches to disease containment and biodefense mitigation. The age of synthetic biology also lowers some of the barriers to developing and using biological and chemical weapons, potentially putting such weapons within the reach of adversaries with relatively low expertise, financing, and access to scientific equipment and resources. The advent of sophisticated algorithms and artificial intelligence (AI) have also heightened biosecurity risks by reducing the scientific expertise required to create bioweapons. 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 large language model was able to outperform 94% of expert virologists on questions of troubleshooting complex virology laboratory protocols, according to a 2025 preprint.

4) *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 (meaning the database record with the highest sequence similarity for any unique start/stop location in a query sequence in a sequence alignment) 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. The framework states that single- or double-stranded DNA or RNA sequences 200 nucleotides or longer should be screened for SOC, and as of October 13, 2026, this window will be decreased to any sequence 50 nucleotides or longer. As of October 13, 2026, providers must also consider how multiple synthetic nucleic acids in a single order or across multiple orders from the same customer could be constructed to form SOC when ligated together.

   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.

5) *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, which was created in response to President Biden's Executive Order 14110, "Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence," which called on the federal government to reduce the risks of misuse of synthetic nucleic acids and improve related biosecurity measures. The framework heavily references and incorporates 2023 guidance from the U.S. Department of Health and Human Services, the "Screening Framework Guidance for Providers and Users of Synthetic Nucleic Acids." 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 encourages the use of verified user accounts or forms that require self-attestation

of SOC that would trigger the customer to provide information that would reduce the burden of verification on the provider or manufacturer. 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, "Improving the Safety and Security of Biological Research." This Executive Order requires the existing framework to be revised or replaced within 90 days, and requires all agencies that fund life science research to ensure that synthetic nucleic acid procurement is conducted through providers or manufacturers who adhere to the updated framework. However, nothing has yet been produced to replace the NSTC 2024 framework, which remains the federal government's most recent guidance on the topic.

6) *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.

7) *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.

8) *Double referral.* This bill is double referred. Should it pass out of this committee, it will be referred to the Senate Committee on Judiciary.

9) *Prior legislation.* AB 1963 (Salas, Chapter 179, Statutes of 2022) requires CSU, and requests UC, to develop systemwide guidance for purchasing gene synthesis equipment or gene synthesis 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 the IGSC criteria in their guidance.

   AB 70 (Salas of 2021) would have required a gene synthesis provider and manufacturer of gene synthesis equipment to either be a member of the IGSC or be verified by the California Department of Public Health (CDPH) as using customer and sequence screening protocols that are equivalent to or stronger than the IGSC's Harmonized Screening Protocol. *AB 70 was vetoed by Governor Newsom, who wrote, in part: "In order to fund the establishment of the program, the bill would authorize CDPH to begin charging fees from the entities to be regulated before the program is established and before businesses are required to be in compliance. This structure is not implementable and General Fund resources needed to support the establishment of a new regulatory program should be considered in the annual budget process. Furthermore, consideration should be given to whether a patchwork of state and federal regulations on biosecurity is the most effective way to approach an issue of international magnitude."*

   AB 1966 (Salas of 2019) would have required CDPH to develop gene sequence and customer screening guidelines and a certification process for gene synthesis providers and manufacturers of gene synthesis equipment operating in California. AB 1966 would have required any recipient of state resources to purchase gene synthesis products or equipment from certified providers and manufacturers, and specified penalties for failure to comply with these requirements. *AB 1966 was not heard in the Assembly Health Committee.*

10) *Support.* Encode AI and The Secure AI Project are the co-sponsors of this bill. A coalition letter with the sponsors 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 would create 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 protections such as screening. CITED and the California Federation of Teachers write that in the past, creating a live virus or engineered bacterium from genetic material required specialized expertise. They claim that now there is growing evidence 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.

SUPPORT AND OPPOSITION:

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

Oppose: None received

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