AB-70 Gene synthesis providers. (2021-2022)

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CALIFORNIA LEGISLATURE— 2021–2022 REGULAR SESSION

ASSEMBLY BILL NO. 70

Introduced by Assembly Member Salas
(Coauthor: Assembly Member Lorena Gonzalez)

December 07, 2020

An act to add Chapter 1.5 (commencing with Section 24200) to Division 20 of the Health and Safety Code, relating to gene synthesis.

LEGISLATIVE COUNSEL'S DIGEST

AB 70, Salas. Gene synthesis providers.

Existing law requires the State Department of Public Health to establish an advisory committee to advise the Legislature and the Governor on human cloning and other issues relating to human biotechnology.

This bill would require the department to develop a process, with input from the International Gene Synthesis Consortium (IGSC) and industry stakeholders, to verify that gene synthesis providers and manufacturers of gene synthesis equipment adhere to customer and sequence screening protocols that are equivalent to, or stronger than, the IGSC's Harmonized Screening Protocol. Beginning January 1, 2025, the bill would require a gene synthesis provider and manufacturer of gene synthesis equipment operating in California to be a current member of the IGSC or verified by the department as adhering to the prescribed proper screening protocols. The bill would, beginning January 1, 2022, authorize the department to charge a fee in an amount not to exceed the department's reasonable costs to establish and administer the verification process, as specified. The bill would also require, beginning January 1, 2025, any entity that is the recipient of state resources to purchase gene synthesis products from a

gene synthesis provider, and gene synthesis equipment from a manufacturer of gene synthesis equipment, only if they are a current member of the IGSC or verified by the department, as specified. The bill would impose specified penalties on gene synthesis providers and manufacturers of gene synthesis equipment for failure to comply with those requirements, and would require the department to develop an appeals process to address appeals on the imposition of those penalties.

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: no

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Chapter 1.5 (commencing with Section 24200) is added to Division 20 of the Health and Safety Code, to read:

CHAPTER 1.5. Gene Synthesis Providers

24200. For the purposes of this chapter, the following terms apply:

(a) “Current member” means a current member of the International Gene Synthesis Consortium (IGSC) who is a certified member of that organization and includes voting members, small company members, and nonprofit members. It does not include provisional associate members or any other membership tier where the entity does not implement an IGSC tested and approved screening system.

(b) “Dangerous pathogen” means severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2, also known as COVID-19), a pathogen on the select agents and toxins list maintained by the Federal Select Agent Program, the list of human and animal pathogens and toxins for export control maintained by the Australia Group, and any other regulated pathogen identified by the department.

(c) “Department” means the State Department of Public Health.

(d) “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.

(e) “Gene synthesis product” is double-stranded DNA (dsDNA), double-stranded nucleic acids, RNA, or oligonucleotides, designed and created without an existing DNA template.

(f) (1) “Gene synthesis provider” means an entity that does any of the following:

(A) An entity that creates gene synthesis products for delivery to a customer.

(B) A distributor of gene synthesis products, including, but not limited to, entities who manufacture gene products for use by other parties, both inside and outside of the entity.

(C) 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.

(2) “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.

24201. This chapter shall not be interpreted to regulate medical or pharmaceutical research and development or manufacturing, including drug screening assays, reagent production, tests employed in preclinical and clinical studies, manufacturing of biologics, gene therapy, and RNA therapeutics.

24202. In order to improve biosecurity efforts to prevent, deter, detect, attribute, and mitigate the misuse of gene synthesis products in California, including those products that may contain dangerous pathogen sequences, the department shall develop a verification process, with input from the IGSC and industry stakeholders, to verify that a gene synthesis provider and manufacturer of gene synthesis equipment adhere to customer and sequence screening protocols that are equivalent to, or stronger than, the IGSC’s Harmonized Screening Protocol. The verification process shall include, at a minimum, a review of each entity’s compliance every two years.

24203. (a) Beginning January 1, 2025, gene synthesis providers and manufacturers of gene synthesis equipment operating in California shall either be current members of the IGSC or verified by the department as entities adhering to proper screening protocols pursuant to Section 24202.

(b) A gene synthesis provider or manufacturer of gene synthesis equipment that fails to comply with the requirements of this section shall be subject to a civil penalty of one thousand dollars ($1,000) per day that it is noncompliant.

(c) Beginning January 1, 2022, the department may charge each gene synthesis provider or manufacturer of gene synthesis equipment operating in California a fee in an amount not to exceed the department's reasonable costs to establish and administer the verification process.

24204. (a) Beginning January 1, 2025, any entity that is the recipient of state resources, including, but not limited to, funds, 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, shall purchase gene synthesis products from a gene synthesis provider, and gene synthesis equipment from a manufacturer of gene synthesis equipment, only if they are a current member of the IGSC or are otherwise verified by the department pursuant to Section 24202, whether or not the gene synthesis provider or manufacturer of gene synthesis equipment is operating in California.

(b) An entity that does not comply with subdivision (a) may have access to all state resources revoked for the duration of the noncompliance.

24205. The department shall develop an appeals process for gene synthesis providers and manufacturers subject to a civil penalty pursuant to Section 24203 and for entities subject to state resource revocation pursuant to Section 24204. The appeals process shall ensure that appellants are provided with due process.