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An act to amend Sections 65057 and 65059 of the Government Code,
relating to public health.



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

SECTION 1. Section 65057 of the Government Code is amended to read:

65057. (a) The California Initiative to Advance Precision Medicine is hereby established in the office. In establishing the initiative, the office shall incorporate agreements and partnerships regarding precision medicine entered into by the office prior to January 1, 2016.

(b) (1) The office shall develop, implement, and evaluate demonstration projects on precision medicine in collaboration with public, nonprofit, and private entities. A demonstration project may focus on one or more disease areas, and an award of funds under any appropriation of funds to the office for precision medicine shall be based on criteria that include, but are not limited to, the following:

(A) The potential for tangible benefit to patients within two to five years, including the likelihood that the study will have an immediate impact on patients.

(B) The depth and breadth of data available in the disease focus areas across institutions.

(C) The prospects for efficient and effective data integration and analysis.

(D) The expertise of potential team members.

(E) The resources available for the project outside of the initiative, including the potential for leveraging nonstate funding.

(F) The clinical and commercial potential of the project.

(G) The potential to reduce health disparities.

(H) The potential to scale and leverage multiple electronic health records systems.

(I) The potential to develop the use of tools, measurements, and data, including publicly generated and available data.

(2) A demonstration project that is selected by the office shall advance greater understanding in at least one of the following areas, or in another area that is determined by the office to be necessary to advance precision medicine:

(A) The application of precision medicine to specific disease areas.

(B) The challenges of system interoperability.

(C) Economic analysis.

(D) Standards for sharing data or protocols across institutions.

(E) The federal and state regulatory environment.

(F) The clinical environment.

(G) Challenges relating to data, tools, and infrastructure.

(H) The protection of privacy and personal health information.

(I) The potential for reducing health disparities.

(J) Methods and protocols for patient engagement.

(3) The office shall develop concrete metrics and goals for demonstration projects, monitor their progress, and comprehensively evaluate projects upon completion.

(4) (A) ~~On or before January 1, 2017, and annually thereafter, the~~ The office shall annually submit a report to the Legislature that provides an update of the demonstration projects selected. Upon completion of a demonstration project, the office shall submit an evaluation of the demonstration project to the Legislature. A demonstration project is deemed complete when it has completed the agreed upon tasks and deliverables, and the project funding has been completed.



(B) A written report made pursuant to subparagraph (A) shall be made in compliance with Section 9795.

(c) The office shall develop an inventory of precision medicine assets, including projects, data sets, and experts. In developing the inventory, the office shall assemble knowledge across broad disease areas. The office shall use the inventory to inform strategic areas for the future development of precision medicine-related projects.

(d) The office may enter into agreements with public entities, or with nonprofit or not-for-profit organizations for the purpose of jointly administering the programs established under the initiative or to administer any provision of this section.

(e) The office shall create and post on a publicly available-Internet-Web-site internet website guidelines for an award of funds made under any appropriation of funds to the office for precision medicine. The guidelines shall include, but are not limited to, the following:

- (1) Eligibility requirements.
 - (2) A competitive, merit-based application process that allows public and private academic and nonprofit institutions to submit proposals as principal investigators.
 - (3) A comprehensive peer-reviewed selection process.
 - (4) Requirements regarding the use of awarded funds.
 - (5) Requirements regarding the use and sharing of research data and findings.
 - (6) Requirements for the protection of privacy and personal health information.
- (f) The office shall solicit public, nonprofit, and private sector input for any additional guidelines for an award of funds made pursuant to this section.

(g) The office shall establish standards that require a grant to be subject to an intellectual property agreement that balances the opportunity of the state to benefit from the patents, royalties, and licenses that result from basic research, therapy development, and clinical trials against the need to ensure that the agreement does not unreasonably hinder essential medical research.

(h) The office may receive nonstate funds in furtherance of the initiative. "In furtherance of the initiative" means that funds may be used to award additional demonstration projects under the same terms and conditions as state funds in the initiative, held in reserve for follow-on funding of any awardees, or used to fund other nondemonstration project activities in a proportion no greater than 20 percent of the total of nonstate funds received over the term of the commitment. The office shall return unexpended nonstate funds to the source before January 1, ~~2020~~, 2026.

(i) Up to 30 percent of any amount appropriated to the office for precision medicine may be held by the office until an equivalent amount of nonstate matching funds is identified and received. Amounts subject to nonstate match may be released in increments as determined by the office.

(j) Up to 10 percent of any amount appropriated to the office for precision medicine may be used by the office for administrative costs.

(k) The office shall recruit a precision medicine expert selection committee to represent various precision medicine-related skills, such as bioinformatics, statistics, health economics, patient engagement, and genomics. The Legislature may make nominations for the selection committee to the office for consideration.

(l) Members of the selection committee shall be deemed to not be interested in any contract, including any award of funds by the committee, pursuant to this section.



(m) Prior to the selection committee's deliberative process, the office shall notify the Legislature of the selection of the committee members.

(n) The selection committee established in subdivision (k) shall comply with the Bagley-Keene Open Meeting Act (Article 9 (commencing with Section 11120) of Chapter 1 of Part 1 of Division 3 of Title 2), except during the deliberative process as it relates to reviewing and ranking proposals and making final selections.

(o) The selection committee shall report on the justification for selecting the demonstration projects that are awarded funding and provide a list of the demonstration projects that were not selected. This report shall be posted on the ~~Internet Web site~~ internet website created in subdivision (e).

(p) Notwithstanding the rulemaking provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2), the office may implement or interpret this article without taking any regulatory action.

SEC. 2. Section 65059 of the Government Code is amended to read:

65059. This article shall remain in effect only until January 1, ~~2020~~, 2026, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, ~~2020~~, 2026, deletes or extends that date.



LEGISLATIVE COUNSEL'S DIGEST

Bill No.
as introduced, _____.
General Subject: California Initiative to Advance Precision Medicine.

Existing law establishes, until January 1, 2020, the California Initiative to Advance Precision Medicine within the Office of Planning and Research in the Governor's office for the purpose of developing, implementing, awarding funding to, and evaluating demonstration projects on precision medicine in collaboration with public, nonprofit, and private entities. Existing law requires the office to annually report to the Legislature about the initiative and authorizes the office to receive nonstate funds in furtherance of the initiative. Existing law requires the office to return unexpended nonstate funds to the source before January 1, 2020.

This bill would extend the repeal date of the California Initiative to Advance Precision Medicine to January 1, 2026, and extend the requirements and authorizations relating to the initiative.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

