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### HEALTH AND SAFETY CODE - HSC

**DIVISION 110. California Initiative to Advance Precision Medicine [130300 - 130304]** ( *Division 110 added by Stats. 2024, Ch. 41, Sec. 54.* )

**130300.** The Legislature finds and declares all of the following:

(a) Over the past three decades, the United States has been a leader in biological research and medicine that describes fundamental biological structures and processes in unprecedented detail and that has led to breakthroughs in therapies and treatments. Advances in information technology and computing have also furthered our ability to gather important data to better understand disease functions. However, we are now at a point where our capacity to collect information has outpaced our capacity to integrate and analyze it and to convert data to new knowledge.

(b) According to a 2011 report from the National Academy of Sciences, entitled "Toward Precision Medicine: Building a Knowledge Network for Biomedical Research and a New Taxonomy of Disease," the aggregation, integration, and analysis of data from research, clinical, personal, and population health settings are critical to creating a new knowledge network that will enable us to deliver more precise medicine, whether by targeting existing therapies more safely and effectively to patients, or by developing new therapies based on new insights into disease. Precision medicine, which embodies efforts to create this new knowledge network through data infrastructure, technology tools, and diagnostics, holds promise to transform health, health care, and biomedical research.

(c) Precision medicine, particularly in the form of better diagnostic tools for infectious disease, has the potential to alleviate the burdens of pandemics through early detection, faster response, and better countermeasures.

(d) California, with its vast scientific, medical, and technological resources, is positioned to lead advances in the field of precision medicine, which is gaining both national and international prominence. By establishing a California Initiative to Advance Precision Medicine, the state can help coordinate public, private, and nonprofit partners to advance this important intersection between science, research, and medicine, and to foster the creation of new technologies and therapies that can improve the health of Californians. A California Initiative to Advance Precision Medicine will bring together state precision medicine leaders as well as complete projects that demonstrate the power and application of precision medicine to the people of the State of California.

*(Added by Stats. 2024, Ch. 41, Sec. 54. (SB 164) Effective June 29, 2024. Repealed as of June 30, 2029, pursuant to Sec. 130304.)*

**130301.** As used in this division, "California Initiative to Advance Precision Medicine" or "initiative" means the California Initiative to Advance Precision Medicine established in Section 130302.

*(Added by Stats. 2024, Ch. 41, Sec. 54. (SB 164) Effective June 29, 2024. Repealed as of June 30, 2029, pursuant to Sec. 130304.)*

**130302.** (a) The California Initiative to Advance Precision Medicine is hereby established in the California Health and Human Services Agency. In establishing the initiative, the California Health and Human Services Agency shall incorporate agreements and partnerships regarding precision medicine entered into prior to January 1, 2016.

(b) (1) The California Health and Human Services Agency shall develop, implement, and evaluate demonstration or nondemonstration projects on precision medicine in collaboration with public, nonprofit, and private entities. A demonstration project may focus on one or more disease areas or a subset of a population, and an award of funds under any appropriation of funds to the office for precision medicine may 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 prospects of preventing or alleviating the impact of a pandemic through pathways including, but not limited to, tracking of emerging pathogens, early infectious disease outbreak detection, rapid outbreak response, and transmission reduction.

- (C) The depth and breadth of data available in the disease focus areas across institutions.
- (D) The prospects for efficient and effective data integration and analysis.
- (E) The expertise of potential team members.
- (F) The resources available for the project outside of the initiative, including the potential for leveraging nonstate funding.
- (G) The clinical and commercial potential of the project.
- (H) The potential to reduce health disparities.
- (I) The potential to scale and leverage multiple electronic health records systems.
- (J) 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 California Health and Human Services Agency shall advance greater understanding in at least one of the following areas, or in another area that is determined by the California Health and Human Services Agency to be necessary to advance precision medicine:

- (A) The application of precision medicine to specific disease areas.
- (B) The feasibility of the technology in preventing, mitigating, or monitoring pandemics or other large-scale disease outbreaks.
- (C) The challenges of system interoperability.
- (D) Economic analysis.
- (E) Standards for sharing data or protocols across institutions.
- (F) The federal and state regulatory environment.
- (G) The clinical environment.
- (H) Challenges relating to data, tools, and infrastructure.
- (I) The protection of privacy and personal health information.
- (J) The potential for reducing health disparities.
- (K) Methods and protocols for patient engagement.

(3) The California Health and Human Services Agency shall develop concrete metrics and goals for demonstration projects, monitor their progress, and comprehensively evaluate projects upon completion.

(4) (A) The California Health and Human Services Agency shall annually submit a report to the Legislature that provides an update of the demonstration projects selected. Upon completion of a demonstration project, the California Health and Human Services Agency 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 of the Government Code.

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

(d) The California Health and Human Services Agency 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 California Health and Human Services Agency shall create and post on a publicly available internet website guidelines for an award of funds made under any appropriation of funds to the California Health and Human Services Agency 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 California Health and Human Services Agency shall solicit public, nonprofit, and private sector input for any additional guidelines for an award of funds made pursuant to this section.

(g) The California Health and Human Services Agency 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) (1) The California Health and Human Services Agency 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.

(2) The California Health and Human Services Agency may work with external stakeholders to receive nonstate funds that enable the initiative to develop new demonstration projects that look to prevent or mitigate future infectious disease outbreaks and pandemics.

(i) Up to 30 percent of any amount appropriated for precision medicine may be held by the California Health and Human Services Agency 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 California Health and Human Services Agency.

(j) Up to 10 percent of any amount appropriated to the California Health and Human Services Agency for precision medicine for demonstration projects may be used by the California Health and Human Services Agency for administrative costs.

(k) The California Health and Human Services Agency 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 California Health and Human Services Agency 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 California Health and Human Services Agency 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 of the Government Code), 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 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 of the Government Code), the California Health and Human Services Agency may implement or interpret this division without taking any regulatory action.

*(Added by Stats. 2024, Ch. 41, Sec. 54. (SB 164) Effective June 29, 2024. Repealed as of June 30, 2029, pursuant to Sec. 130304.)*

**130303.** It is the intent of the Legislature that the office make awards in compliance with the following:

(a) The awards are made to demonstration projects in California.

(b) The awards are prioritized for public and private nonprofit entities.

(c) The awards include, but are not limited to, awards to public institutions in both northern and southern California.

*(Added by Stats. 2024, Ch. 41, Sec. 54. (SB 164) Effective June 29, 2024. Repealed as of June 30, 2029, pursuant to Sec. 130304.)*

**130304.** This division shall remain in effect only until June 30, 2029, and as of that date is repealed.

*(Added by Stats. 2024, Ch. 41, Sec. 54. (SB 164) Effective June 29, 2024. Repealed as of June 30, 2029, by its own provisions. Note: Repeal affects Division 110, commencing with Section 130300.)*