

An act to amend the heading of Article 6 (commencing with Section 65055) of Chapter 1.5 of Division 1 of Title 7 of, to amend, renumber, and add Section 65055 of, to amend and repeal Sections 65056, 65057, and 65058 of, to add Sections 65053, 65054, 65056.1, 65056.2, and 65056.3 to, and to repeal Section 65059 of, the Government Code, relating to precision medicine.



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

## SECTION 1. Section 65053 is added to the Government Code, to read:

65053. (a) The office shall establish a nonprofit corporation named the California Institute to Advance Precision Health and Medicine (CIAPHM). The institute shall be under the direction of a board of directors, which shall function as the board of directors for the purposes of the Nonprofit Corporation Law (Division 2 (commencing with Section 5000) of Title 1 of the Corporations Code). The purpose of the institute is to improve the health and health care of Californians through better use of advanced computing, technology, and data science.

(b) The board of directors (CIAPHM Board) shall consist of 19 directors comprising the following:

(1) The director of the Office of Planning and Research, or his or her designee.

(2) Sixteen directors, who are professionally active in precision health- and medicine-related fields, shall be appointed by the Governor. Each appointed director shall represent a subarea of precision health and medicine and the appointed directors shall be selected so as to represent, to the greatest extent possible, the diverse elements of precision health- and medicine-related fields. At a minimum, four directors shall represent different public academic research institutions, and four directors shall represent different private nonprofit entities.

(3) One director, who shall be a public member, shall be appointed by the Senate Rules Committee.

(4) One director, who shall be a public member, shall be appointed by the Speaker of the Assembly.

(c) With the exception of the director of the Office of Planning and Research, a director shall not serve for more than two consecutive terms. For purposes of this subdivision, the phrase "two consecutive terms" does not include partial terms.

(d) Except for the original directors, all directors shall serve four-year terms. One-third of the directors originally appointed shall serve a two-year term, one-third of the directors originally appointed shall serve a three-year term, and the remaining one-third shall serve a four-year term.

(e) The directors shall elect two co chairs, one of whom shall be affiliated with a public higher education academic institution. Co chairs shall be elected at least every two years, with no limitation on how many terms a director may serve as a co chair.

(f) The institute may lease space from the office or another state agency.

(g) All institute meetings shall be held in California, although meetings may be held by teleconference and other technology and include locations other than California.

(h) No person shall receive compensation for serving as a director, but each director shall receive reimbursement for reasonable expenses incurred while on authorized institute business.

(i) Institute meetings shall be subject to the requirements of the Bagley-Keene Open Meeting Act (Article 9 (commencing with Section 11120) of Chapter 1 of Part 1 of Division 3 of Title 2). Closed session meetings may be held for deliberative discussions on grant awards, intellectual property, matters for which competitive content should not be disclosed, and as otherwise allowed by law.

(j) The executive director of the institute shall serve as secretary to the institute, a nonvoting position, and shall keep the minutes and records of all institute meetings.



SEC. 2. Section 65054 is added to the Government Code, to read:

65054. (a) The institute shall be a separate, independent California nonprofit corporation. Except as provided through agreements with the office, the staff of the institute shall be employees solely of the institute, and the procedures adopted by the institute shall not be subject to the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2).

(b) Directors and employees of the institute are not responsible individually in any way whatsoever to any person for any good faith activity of the institute.

(c) The CIAPHM Board shall adopt procedures concerning the operation of the institute within the first three months of operation, which shall also be exempt from the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2).

(d) The institute shall be administered by an executive director. For the first six months of operation, the director of the Office of Planning and Research shall recommend an individual to serve as the executive director, who shall be approved by the Governor. Thereafter, an individual who serves as the executive director shall be recommended by a vote of the CIAPHM Board. The executive director shall serve at the pleasure of the CIAPHM Board.

(e) The executive director shall report to the CIAPHM Board and shall implement the institute's strategic implementation plan.

(f) The CIAPHM Board may permit the executive director to maintain a dual appointment with the institute and another private nonprofit entity or public agency, from whom the executive director has negotiated a term of leave or partial leave, if any potential conflicts of interest are addressed to the satisfaction of the CIAPHM Board.

(g) The salary and benefits of the executive director shall be determined by the CIAPHM Board, based upon industry standards.

SEC. 3. The heading of Article 6 (commencing with Section 65055) of Chapter 1.5 of Division 1 of Title 7 of the Government Code is amended to read:

Article 6. California-Initiative Institute to Advance Precision Health and Medicine

SEC. 4. Section 65055 of the Government Code is amended and renumbered to read:

~~65055.~~

65052. 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) California, with its vast scientific, medical, and technological resources, is positioned to lead advances in the field of precision health and medicine, which is gaining both national and international prominence. By establishing a California Initiative Institute to Advance Precision Health and 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~~ technologies, tools, and therapies that can improve the health and health care of Californians. A California Initiative Institute to Advance Precision Health and Medicine will bring together state precision health and medicine leaders as well as complete projects that demonstrate the power and application of precision medicine to the people of the State of California. medicine, and facilitate future integration of precision health and medicine into health care.

SEC. 5. Section 65055 is added to the Government Code, to read:

65055. (a) (1) The institute shall annually provide a report to the CIAPHM Board on the activities and budget of the institute including, but not limited to, revenue, including charitable, income, or in-kind support, and expenses, the fund balance, a summary of the strategic implementation plan, and a report of progress in achieving the goals set forth in the plan. The institute shall additionally publically post that report on its Internet Web site. The portions of the report that pertain to the institute's revenues, expenses, and the fund balance, as well as those other portions that the institute may deem appropriate, shall be reviewed by the Office of Planning and Research.

(2) The institute's annual budget shall be subject to the review and approval of the CIAPHM Board.

(b) (1) The institute shall prepare a strategic implementation plan. In developing the plan, the institute shall utilize, as appropriate, the advice and recommendations of the advisory committee or committees established pursuant to subdivision (d). The institute may amend the plan at any institute meeting, but shall update the plan no less than every two years. All expenditures by the institute shall be consistent with the plan.

(2) The plan prepared pursuant to paragraph (1) shall include, but not be limited to, both of the following:

(A) An evaluation of the institute's budget and activities, including annual budget expenditures and projection for future activities.

(B) Review of California precision health and medicine trends, conditions, and opportunities.

(c) Before final adoption of the plan, the institute shall provide notice of the availability of the plan and suitable opportunity, which may include public meetings, to review the plan and to comment upon it. The institute shall take into consideration any recommendations submitted, except that the final determination as to the nature, extent, and substance of the plan shall in all respects rest solely within the ultimate discretion of the institute. The final adoption of the plan shall be subject to the approval of the CIAPHM Board.



(d) The institute may establish one or more advisory committees, which may include nondirectors as members. The advisory committee or committees shall be structured so that, in the aggregate, they include, to the maximum extent feasible and reasonable, representation from different geographic regions of the state and, as appropriate, various segments of precision health and medicine related fields. The institute shall establish procedures for the operation of advisory committees that will provide appropriate opportunity for various geographic regions of the state and various segments of precision health and medicine related fields to offer advice and recommendations to the institute relative to the development of its strategic implementation plan.

(e) The institute may also establish from time to time any other committees it deems appropriate, and may appoint nondirectors to the committees.

(f) The institute may accept private funds, in-kind support, and other revenue, and may charge membership dues or fees for participation in the board's professional activities, convenings, or services, if these activities, convenings or services further the purpose of the institute and are approved by the CIAPHM Board.

SEC. 6. Section 65056 of the Government Code is amended to read:

65056. (a) As used in this article, "California Initiative to Advance Precision Medicine" or "initiative" means the California Initiative to Advance Precision Medicine established in Section 65057.

(b) This section shall become inoperative on October 1, 2018, and, as of January 1, 2019, is repealed.

SEC. 7. Section 65056.1 is added to the Government Code, to read:

65056.1. (a) As used in this article, "California Institute to Advance Precision Health and Medicine" or "institute" means the California Institute to Advance Precision Health and Medicine established in Section 65053.

(b) To the extent possible and subject to the approval of the CIAPHM Board, the institute shall adopt and incorporate agreements and partnerships regarding precision medicine entered into by the office, or its subcontractors, under the California Initiative to Advance Precision Medicine established by Section 29 of Chapter 24 of the Statutes of 2016.

SEC. 8. Section 65056.2 is added to the Government Code, to read:

65056.2. (a) The institute may undertake the following activities, in addition to other activities approved by the CIAPHM Board:

(1) Develop criteria for new grant awards for demonstration projects in precision health and medicine.

(2) Provide oversight of all awarded demonstration projects in process or newly awarded after July 1, 2018, made under the California Initiative to Advance Precision Medicine.

(3) Promote successful demonstration project outcomes and incorporate them into the health care setting.

(4) Facilitate payer reimbursement of proven advances in precision health and medicine.

(5) Coordinate the sharing of datasets and other precision medicine assets.

(6) Facilitate additional public-private partnerships in precision health and medicine.

(7) Further advance the application of data science in health and health care.



(b) (1) The institute may grant awards to demonstration projects on precision health and medicine in one or more disease areas, based on criteria that may include, but are not limited to, the following:

(A) The potential for near-term tangible benefit to patients, 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 institute shall advance greater understanding in at least one of the following areas, or in another area that is determined by the institute to be necessary to advance precision health and medicine:

(A) The application of precision health and 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 institute shall develop concrete metrics and goals for demonstration projects, monitor their progress, and comprehensively evaluate projects upon completion.

(4) The institute shall create and post on its publicly available Internet Web site guidelines for demonstration projects, which shall include, but are not limited to, all of the following:

(A) Eligibility requirements.

(B) A competitive, merit-based application process.

(C) A peer-reviewed selection process.

(D) Requirements regarding the use of awarded funds.

(E) Requirements regarding the use and sharing of research data and findings.

(F) Requirements for the protection of privacy and personal health information.

(5) The office shall solicit broad input for any additional guidelines for demonstration projects.

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



(7) Members of the expert committee shall be deemed to be not interested in any contract, including any award of funds made to the demonstration projects, pursuant to this subdivision.

(8) The meetings of the expert committee shall not be subject to the requirements of the Bagley-Keene Open Meeting Act (Article 9 (commencing with Section 11120) of Chapter 1 of Part 1 of Division 3 of Title 2).

(c) The institute shall establish standards that require a demonstration project grant to be subject to an intellectual property agreement that balances 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.

SEC. 9. Section 65056.3 is added to the Government Code, to read:

65056.3. It is the intent of the Legislature that, for funds appropriated in the 2017 or 2018 Budget Acts, any award of demonstration projects be made 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 are made to entities that include, but are not limited to, public institutions in both northern and southern California.

SEC. 10. 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 office shall 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 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.

(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 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.

(q) This section shall become inoperative on October 1, 2018, and, as of January 1, 2019, is repealed.

SEC. 11. Section 65058 of the Government Code is amended to read:

65058. (a) It is the intent of the Legislature that the office make awards in compliance with the following:

(a)

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

(b)

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

(c)

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

(b) This section shall become inoperative on October 1, 2018, and, as of January 1, 2019, is repealed.

SEC. 12. Section 65059 of the Government Code is repealed.

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



## LEGISLATIVE COUNSEL'S DIGEST

Bill No.  
as introduced, \_\_\_\_\_.  
General Subject: Precision health and medicine.

Existing law establishes, until January 1, 2020, the California Initiative to Advance Precision Medicine in the Office of Planning and Research for the purpose of developing, implementing, awarding funding to, and evaluating demonstration projects on precision medicine in collaboration with public, nonprofit, and private entities, as specified. Existing law specifies criteria that would make a project eligible to receive funds, and requires the office to develop and post on a publicly available Internet Web site guidelines regarding the application for and use of awarded funds. Existing law requires the office to establish standards that require a grant to be subject to an intellectual property agreement, as specified. Existing law requires the office to annually report to the Legislature to update and provide evaluations on selected demonstration projects, as specified.

This bill would make those provisions inoperative on October 1, 2018. The bill would require the Office of Planning and Research to establish the California Institute to Advance Precision Health and Medicine as a nonprofit corporation. The bill would require the board of the institute to be comprised of specified individuals, including, among others, the Director of the Office of Planning and Research. The bill would require the institute to annually provide a report on the activities and budget of the institute to board of the institute, as specified. The bill would authorize the institute to grant awards to demonstration projects on precision health and medicine in one or more disease areas, based on specified criteria. The bill would require the institute to create and post on its publicly available Internet Web site guidelines for demonstration projects. The bill would require the institute to establish standards that require a grant to be subject to an intellectual property agreement, as specified. The bill would authorize the institute to accept private funds, in-kind support, and other revenue, and to charge membership dues or fees for participation in the board's professional activities, convenings, or services, if these activities, convenings, or services further the purpose of the institute and are approved by the board.

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

