

An act to amend Section 13988.4 of, and to add and repeal Article 6 (commencing with Section 65055) of Chapter 1.5 of Division 1 of Title 7 of, the Government Code, and to amend Section 10340 of the Public Contract Code, relating to state government.



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

SECTION 1. Section 13988.4 of the Government Code is amended to read:

13988.4. (a) This chapter shall not apply to intellectual property or intellectual property related agreements administered by the Regents of the University of California, the subcontractors of the Regents of the University of California, and the Trustees of the California State University. This chapter shall apply to a funding agreement from a state agency for the performance of research, and these funding agreements shall be subject to the model contract provisions developed pursuant to Chapter 14.27 (commencing with Section 67325) of Part 40 of Division 5 of Title 3 of the Education Code.

(b) This chapter shall not apply to intellectual property agreements governed by the California Stem Cell Research and Cures Bond Act (Chapter 3 (commencing with Section 125290.10) of Part 5 of Division 106 of the Health and Safety Code).

(c) This chapter shall not apply to an intellectual property agreement entered into by the California Initiative to Advance Precision Medicine pursuant to subdivision (f) of Section 65057.

SEC. 2. Article 6 (commencing with Section 65055) is added to Chapter 1.5 of Division 1 of Title 7 of the Government Code, to read:

Article 6. California Initiative to Advance Precision Medicine

65055. 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 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.

65056. 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.

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:

(A) Eligibility requirements.

(B) A competitive, merit-based application process that allows public and private academic and nonprofit institutions to submit proposals as principal investigators.

(C) A comprehensive 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.



(f) 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.

(g) 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.

(h) 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.

65058. 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.

SEC. 3. Section 10340 of the Public Contract Code is amended to read:

10340. (a) Except as provided by subdivision (b), state agencies shall secure at least three competitive bids or proposals for each contract.



(b) Three competitive bids or proposals are not required in any of the following cases:

(1) In cases of emergency where a contract is necessary for the immediate preservation of the public health, welfare, or safety, or protection of state property.

(2) When the agency awarding the contract has advertised the contract in the California State Contracts Register and has solicited all potential contractors known to the agency, but has received less than three bids or proposals.

(3) (A) The contract is with another state agency, a local governmental entity, an auxiliary organization of the California State University, an auxiliary organization of a California community college, a foundation organized to support the Board of Governors of the California Community Colleges, or an auxiliary organization of the Student Aid Commission established pursuant to Section 69522 of the Education Code. These contracts, however, ~~may~~ shall not be used to circumvent the competitive bidding requirements of this article.

(B) Notwithstanding subparagraph (A), until January 1, ~~2019~~, 2020, an interagency agreement that is in effect pursuant to ~~the~~ an amount appropriated to the Office of Planning and Research ~~under Item 0650-001-0001 of the Budget Act of 2014,~~ for precision medicine, including a contract between the Office of Planning and Research, the Regents of the University of California, or an auxiliary organization of the California State University, may include a subcontract not subject to any competitive bidding requirements of this article for the limited purpose of researching or developing precision medicine.



(4) The contract meets the conditions prescribed by the department pursuant to subdivision (a) of Section 10348.

(5) The contract has been awarded without advertising and calling for bids pursuant to Section 19404 of the Welfare and Institutions Code.

(6) Contracts entered into pursuant to Section 14838.5 of the Government Code.

(7) Contracts for the development, maintenance, administration, or use of licensing or proficiency testing examinations.

(8) The contract is for services for the operation, maintenance, repair, or replacement of specialized equipment at facilities of the State Water Resources Development System, as defined in Section 12931 of the Water Code, and meets the conditions established by the Department of Water Resources for those contracts.

(9) The contract meets the conditions prescribed by the Department of Water Resources for contracts subject to Section 10295.6.

(10) Contracts entered into by the Commission on Peace Officer Standards and Training or the Office of Emergency Services solely for the services of instructors for public safety training. For the purpose of this paragraph, "public safety training" includes, but is not limited to, training related to law enforcement, emergency medical response, emergency volunteers, and fire responders.

(c) Any agency ~~which~~ that has received less than three bids or proposals on a contract shall document, in a manner prescribed by the department, the names and addresses of the firms or individuals it solicited for bids or proposals.



LEGISLATIVE COUNSEL’S DIGEST

Bill No.

as introduced, _____.

General Subject: California Initiative to Advance Precision Medicine.

Existing law establishes the Office of Planning and Research in the Governor’s Office that constitutes the comprehensive state planning agency and serves the Governor and his or her Cabinet as staff for long-range planning or research.

This bill would establish, until January 1, 2020, the California Initiative to Advance Precision Medicine in the 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, as specified. The bill would specify criteria that would make a project eligible to receive funds, and would require the office to develop guidelines regarding the application for and use of awarded funds. The bill would require the office to establish standards that require a grant to be subject to an intellectual property agreement, as specified. The bill would require the office to annually report to the Legislature to update and provide evaluations on selected



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demonstration projects, as specified. The bill would authorize the office to receive nonstate funds in furtherance of the initiative, and would authorize up to 30 percent of any amount appropriated to the office for precision medicine to be held by the office until an equivalent amount of nonstate matching funds is identified and received.

Existing law authorizes the Department of General Services to carry out various powers and duties relating to assisting a state agency in the management and development of intellectual property developed by state employees or with state funding.

This bill would provide that those provisions do not apply to an intellectual property agreement entered into by the initiative.

Existing law generally requires state agencies to obtain at least 3 competitive bids for each contract for services. Under existing law, this requirement does not apply under certain circumstances, including, until January 1, 2019, to a subcontract for the limited purpose of researching or developing precision medicine included in an interagency agreement that is in effect pursuant to an amount appropriated to the office under a specific budget item, including a contract between the office, the Regents of the University of California, or an auxiliary organization of the California State University.

This bill would extend that competitive bidding exemption until January 1, 2020, and expand the exemption to include such a subcontract in an interagency agreement in effect pursuant to an amount appropriated to the office for precision medicine.

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

