

NOTICE OF PROPOSED REGULATION

California Code of Regulations

Title 17. - Public Health Division 4 - California Institute for Regenerative Medicine

Chapter 1, Section 100006

Date: January 27, 2023

Deadline for Submission of Written Comment: March 13, 2023 -5:00 p.m.

Public Hearing Date: None Scheduled

Subject Matter of Proposed Regulation: Conflict of Interest Rules Applicable to Non-ICOC Members of the Treatments and Cures Accessibility and Affordability Working Group

Submittal of Comments:

Any interested party may present comments in writing about the proposed regulations to the agency contact person named in this notice. Written comments must be received no later than March 13, 2023. Comments regarding this proposed action may also be transmitted via e-mail to comments@circm.ca.gov or by facsimile transmission to (415) 396-9141.

Public Hearing:

At this time, no public hearing has been scheduled concerning the proposed regulations. If any interested person or the person's representative requests a public hearing, they must do so in writing no later than February 27, 2023.

Sections Affected:

The proposed regulatory action adds Section 100006 to Chapter 5 of Title 17 of the California Code of Regulations.

Informative Digest/Policy Statement Overview:

The California Institute for Regenerative Medicine ("Institute" or "CIRM") was established in 2004 after the passage in 2004 of Proposition 71, the California Stem Cell Research and Cures Initiative. The statewide ballot measure established a new state agency to make grants and provide loans for stem cell research, research facilities and other vital research opportunities. The Independent Citizens' Oversight Committee ("ICOC") is the 35- member governing board for the Institute. The ICOC members are public officials, appointed on the basis of their experience earned in California's leading public universities, non-profit academic and research institutions, patient advocacy groups, and the biotechnology industry. The goal of CIRM is to sponsor and facilitate research in regenerative medicine that will advance scientific understanding and result in the development of therapies and treatments for a wide range of devastating diseases. Under Prop 71, the ICOC receives guidance from three working groups delving into ethical standards, grants review, and facilities funding. Health & Saf. Code, § 125290.50. Each of the working groups has patient advocates from the ICOC, as well as outside experts, among its members.

Proposition 14 (2020) authorized the state to issue \$5.5 billion worth of bonds to fund CIRM and enable it to continue its operations. It also created a fourth working group, the Treatments and Cures Accessibility and Affordability Working Group. *Id.*, § 125290.75.

Because the working groups are purely advisory and have no final decision-making authority, members of the working groups shall not be considered public officials, employees, or consultants for purposes of the Political Reform Act (Title 9 (commencing with Section 81000) of the Government Code), Sections 1090 and 19990 of the Government Code, and Sections 10516 and 10517 of the Public Contract Code. *Id.*, § 125290.50(e)(3). Health and Safety Code section 125290.50(e) requires the Board to adopt conflict of interest rules to govern non-ICOC members of the working groups. *See* Cal. Code Reg. tit. 1, §§ 100001-100004.

Health and Safety Code section 125290.40(m) also authorizes CIRM to adopt interim regulations to take effect immediately and to remain in effect for 270 days unless they are superseded by regulations adopted pursuant to the Administrative Procedure Act prior to this time. In December of 2022, the ICOC determined to establish an interim regulation establishing a conflict of interest policy applicable to non-ICOC members of the AAWG, to go into effect January 15, 2023, to ensure the work of the AAWG moves forward under COI rules while the agency pursues permanent adoption of those rules via formal APA process. This policy is modeled on the regulations of existing CIRM working groups, primarily that of the Grants Working Group (Cal. Code Reg. tit. 1, §100003) but tailored to the specifics of the AAWG members, which are not composed of individual scientists who may engage in collaborative research.

This proposed regulation prohibits non-ICOC members of the AAWG from receiving a benefit from CIRM funding and requires disclosure and disqualification. They are modeled on the working group conflict of interest rules found in Title 1, section 100003 of the California Code of Regulations.

The proposed language identifies three types of potential conflicts of interest: 1) Financial; 2) Professional; and 3) Personal.

Financial conflicts of interest rules seek to identify circumstances where a financial benefit may accrue to the non-ICOC member or his or her immediate family as a result of a given outcome on an application or contract before the working group. Here, the member will have a conflict if they have an employee of or otherwise has a financial interest in the applicant institution, subcontractor, or other key person on the application. The member also will have a conflict if the member is under consideration for employment with the applicant or key parties on the application or stands to benefit in any amount from the applicant under review. Key terms such as “Subcontractor,” “Partner,” “Key Personnel,” and “Financial Interest” are defined in the policy and are identical to their usage in the Grants Working Group (“GWG”) context, as well.

Professional Conflicts of Interest -A non-ICOC member will have a professional conflict of interest if the member and key person on the application are engaged in or planning to be engaged in a joint project. This rule follows the rule as applied in the GWG context but is modified to exclude rules that reached research collaborations unique to the types of reviewers on the GWG.

Personal Conflicts of Interest -Finally, a non-ICOC member of the AAWG will have a personal COI in two circumstances: 1) where a family member or close friend is a key person on the application; and 2) where there member and a key person have been on opposing sides of a lawsuit or similar

dispute. This provision is identical to the rule applied to the work of the GWG.

Disclosures

To aid in implementing the COI rules, each non-ICOC member will be asked to disclose to CIRM, confidentially, companies, institutions and real property in which the member has an interest that could present a conflict. The categories mirror those of the GWG, and include income or gifts received from a California-based academic or non-profit research organization, income from or investments in a publicly-held biotechnology or pharmaceutical company, income from a privately-held biotechnology company, and certain real property interests in California.

Exceptional Circumstances

In alignment with the Institute's COI policies applicable to the other working groups and advisory panels, the proposed policy allows CIRM's President/CEO to allow participation by an otherwise conflicted member where the need for special expertise of the reviewer outweighs any possible bias. Under such circumstances, the member will be permitted to participate in the discussion but not permitted to vote or participate in the scoring.

Anticipated Benefits of the Proposed Regulation:

The purpose and intent section of Proposition 14 provides that by "enacting this Initiative, it is the purpose and intent of the people of the State of California to continue to support stem cell research to mitigate and/or cure chronic disease and injury and thereby reduce or mitigate human suffering and the cost of care and improve the health and productivity of Californians" including by "[r]equiring strict accountability and transparency, including rigorous conflict of interest rules that are updated every four years. Proposition 14, § 3D. This regulation will ensure that members of the AAWG abide by rigorous conflict of interest rules as intended by the voters.

Consistency and Compatibility with Existing State Regulations:

This proposed regulation is the first regulation concerning the AAWG, established by Proposition 14 in 2020. *See* Health & Saf. Code, § 125290.75.

The proposed regulation is also consistent with the Political Reform Act and Fair Political Practices Commission's (FPPC) conflict of interest regulations. Those regulations generally exempt purely advisory bodies from conflict of interest rules unless the body to which they report routinely adopts the advisory body's recommendations without substantive change. In this case, Proposition 14 expressly recognizes that CIRM's working groups are advisory and hence not subject to the Political Reform Act, so instead, Proposition 14 required CIRM to adopt this proposed regulation.

This proposed regulation is consistent with existing CIRM regulations regarding conflicts of interest. Health and Safety Code section 125290.50, subdivision (e), provides the ICOC shall adopt conflict of interest rules to govern the participation of non-ICOC working group members. CIRM previously promulgated regulations on conflict of interest rules for members of the working groups. Cal. Code Reg. tit. 1, §§ 100001-100004. This proposed regulation models these rules.

Therefore, the proposed regulation is not inconsistent nor incompatible with any other existing state regulations.

Incorporated by Reference Documents: None

DISCLOSURES REGARDING THE PROPOSED AMENDMENTS:

CIRM has made the following initial determinations:

Mandate on local agencies and school districts: None.

Effect on Small Business: CIRM has determined that the proposed regulation will have no impact on small businesses. The regulation proposes conflict of interest rules for non-ICOC members of the AAWG. As such, the proposed regulation is not expected to adversely impact small business as defined in Government Code Section 11342.610.

Impact on Local Agencies or School Districts: CIRM has determined that the proposed regulation does not impose a mandate on local agencies or school districts, nor do they require reimbursement by the state pursuant to Part 7 (commencing with Section 17500) of Division 4 of the Government Code because the proposed regulation do not constitute a "new program or higher level of service of an existing program" within the meaning of Section 6 of Article XIII of the California Constitution. CIRM has also determined that no nondiscretionary costs or savings to local agencies or school districts will result from the proposed regulation.

Costs or Savings to State Agencies: CIRM has determined that no savings or increased costs to any agency will result from the proposed regulation.

Effect on Federal Funding to the State: CIRM has determined that no costs or savings in federal funding to the state will result from the proposed regulation.

Effect on Housing Costs: CIRM has determined that the proposed regulation will have no effect on housing costs.

Significant Statewide Adverse Economic Impact Directly Affecting Businesses: CIRM has made an initial determination that the proposed regulation will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states.

Cost Impacts on Representative Private Persons or Businesses: CIRM has made an initial determination that the adoption of this regulation will not have a significant cost impact on representative private persons or businesses. CIRM is not aware of any cost impacts that a representative private person or business would incur in reasonable compliance with the regulation.

Results of Economic Impact Analysis: CIRM does not anticipate that this proposed regulation will have any economic impact, including on the creation or elimination of jobs or businesses within the State of California or any impact on the expansion of business in the State of California, nor any impact on the health and welfare of California residents, worker safety, or the state's environment. This analysis is based on that fact that the proposed regulation does not impose new requirements on existing business operations or functions of other agencies or individuals but implements a conflict of interest policy for non-ICOC members of the AAWG. However, to the extent that the amendments ensure a fair and thorough process for screening conflicts of interest, and thereby ensure the integrity of the grant evaluation process, the welfare of California residents is enhanced. In addition, to the extent that the applications for funding are evaluated not on the basis of bias but on the basis of scientific merit, and to the extent that the regulation ensures that is the case, the welfare of California residents is enhanced by ensuring that only the best scientific proposals receive funding, which ultimately may lead to the reduction of suffering if the research projects are ultimately successful and help California patients.

Consideration of Alternatives: In accordance with Government Code section 11346.5, subdivision (a)(13), CIRM must determine that no reasonable alternative it considered, or that has otherwise been identified and brought to its attention, would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of the law than the proposal described in this Notice. CIRM invites interested persons to present statements or arguments with respect to alternatives to the proposed regulation at the scheduled hearing or during the written comment period.

Availability of Statement of Reasons and Text of Proposed Regulations: CIRM has prepared an Initial Statement of Reasons and has available the express terms of the proposed regulation and a rulemaking file. A copy of the Initial Statement of Reasons and the proposed text of the regulation may be obtained from the agency contact person named in this notice. The information upon which CIRM relied in preparing this proposal and the rulemaking file are available for review at the address specified below.

Availability of Changed or Modified Text: After considering all timely and relevant comments, CIRM may adopt the proposed regulation substantially as described in this notice. If CIRM makes modifications that are sufficiently related to the originally proposed text of the amendments, it will make the modified text (with the changes clearly indicated) available to the public for at least 15 days before it adopts the regulations as amended. Requests for the modified text should be addressed to the agency contact person named in this notice. CIRM will accept written comments on any changes for 15 days after the modified text is made available.

Agency Contact: Written comments about the proposed regulatory action; requests for a copy of the Initial Statements of Reasons, the proposed text of the amendments; and inquiries regarding the rulemaking file, and questions on the substance of the proposed regulatory action may be directed to:

C. Scott Tocher
Counsel for the California Institute for Regenerative Medicine
stocher@cirm.ca.gov
(510) 340-9101

Ben Huang
Deputy General Counsel for the California Institute for Regenerative Medicine
bhuang@cirm.ca.gov
(510) 340-9101

The Notice of Proposed Regulatory Amendment, the Initial Statement of Reasons and any attachments, and the proposed text of the amendments and existing regulation are also available on CIRM's website, www.cirm.ca.gov.

Availability of Final Statement of Reasons: Following its preparation, a copy of the Final Statement of Reasons mandated by Government Code Section 11346.9, subdivision (a), may be obtained from the contact person named above.

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