

NOTICE OF PROPOSED REGULATION AMENDMENTS

California Code of Regulations

Title 17. – Public Health

Division 4 - California Institute for Regenerative Medicine

Chapter 8, Section 100800 (and document incorporated by reference)

Date: February 12, 2016

Deadline for Submission of Written Comment: March 28, 2016 – 5:00 p.m.

Public Hearing Date: None Scheduled

Subject Matter of Proposed Amendments:

Loan Administration Policy

Sections Affected: The proposed regulatory action amends Chapter 8, Section 100800, of Title 17 of the California Code of Regulations.

Authority: Article XXXV of the California Constitution and Health and Safety Code Section 125290.40, subdivision (j).

Reference: Sections 125290.40, 125290.70, 125292.10, Health and Safety Code.

Informative Digest/Policy Statement Overview:

The California Institute for Regenerative Medicine (“Institute” or “CIRM”) was established in 2005 after the passage in 2004 of Proposition 71 (the “Act”), 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 29-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. The Act charges the ICOC with developing standards and criteria to make grant and loan awards and to develop standards and criteria for proper oversight of these grants and loans.

Public-private partnerships involving research and development activities among industry, government, and universities can play an instrumental role in introducing key new technologies and valuable products to the commercial marketplace. Experience shows that partnerships involving government participation in research and development activities with industry, universities, and government laboratories can greatly facilitate the translation of basic research discoveries to products with societal benefits.

The mission of the CIRM is to foster and promote stem cell research with the aim of improving human health. A secondary goal is to strengthen California’s biotechnology industry and create

collateral economic benefits such as high-paying jobs and increased tax revenues. CIRM believes that the funding of commercial research organizations focused on stem cell-related projects is a key component to achieving the overall mission of the Institute. Increased interest by the commercial research sector in stem cell-related research projects and the successful translation of basic research discoveries into commercial products for public use are primary success indicators (among others) that can be used by CIRM to track benefits of commercial sector funding.

To achieve the goal of commercializing stem cell research-related products, CIRM will fund non-profit and for-profit (commercial) research institutions in California via options that include grants and loans. As required by law, all CIRM-funded research activities must be conducted in the State of California. The goal of a loan program is to fund the translation of research into research tools, medical diagnostics and devices, and therapeutic products. These loans will be targeted at the funding gaps in product development that will serve to leverage participation by follow-on investors, such as venture capital and other capital markets, and result in more products that enter the market. For the State and CIRM, the advantage of a loan program versus a grant is the ability to recycle CIRM research funds, potentially enlarging the return for each CIRM research dollar expended. In addition to loan principal and interest, loans may also feature warrant coverage, depending on the type of loan, which will constitute additional interest-based return on the investment in light of risk posed.

Early stage companies and pre-commercialization entities would be the prime targets for a loan program in light of the lack of funding available in what is known as the “valley of death” for translational development of products. Established companies indicate a loan program would be valuable because there are more research and product development projects worthy of pursuit than can be funded with existing funds available to the companies.

The document incorporated by reference, the Loan Administration Policy (LAP) works from the Non-Profit Grants Administration Policy (Regulation 100500) and setting out the modified policies that apply to CIRM loan funding of for-profit organizations. Note that this LAP does not incorporate the For-Profit GAP, which continues to apply to for-profit organizations to the extent that CIRM funds them through grants. Where differences between grants and loans warrant different treatment, this LAP provides the modified sections that apply to loans. All other provisions of the Non-Profit GAP apply to loans. When Non-Profit GAP provisions are applied to loans, “Loan” replaces “Grant” and “Loan Recipient” replaces “Grantee.”

The proposed amendments affect not regulation 100800 itself, but the document incorporated by reference, the “CIRM Loan Administration Policy, Eff 8/29/2012.”

In the event that the CIRM-funded project is not a successful, a Product-Backed Loan is automatically forgiven if, among other things, the loan recipient complies with reporting requirements and abandons the project. Under these circumstances the loan recipient’s obligation to repay the loan is extinguished. However, a loan that has been forgiven will automatically be reinstated in the event that the loan recipient obtains revenue arising in whole or in part from the CIRM-Funded Project. If the Loan Recipient’s obligation to repay has been forgiven and if further activity results in a repayment obligation, the Product Backed Loan will automatically be reinstated under terms that the Intellectual Property and Industry Subcommittee

approves. Because of this springing obligation, a loan recipient whose loan has been forgiven may be required to continue to carry the loan as a liability on its books indefinitely.

To provide clarity regarding future obligations, CIRM proposes giving existing loan recipients whose loan has been forgiven by CIRM the option to convert their loan to a grant and forego reinstatement of a forgiven loan. In this way, loan recipients will be automatically governed by the revenue sharing (and other) principles of the agency's intellectual property regulations in the event future revenue streams are realized. This will be particularly important in the event future revenues are realized after CIRM has exhausted its funding.

Document Incorporated by Reference

California Institute for Regenerative Medicine's Loan Administration Policy, Effective date based upon filing with the Secretary of State by OAL.

Anticipated Benefits of the Proposed Regulation:

The primary objective of the regulation is to provide relief from unforeseen financial circumstances that can linger for a CIRM Loan Recipient even though the loan is forgiven. Because CIRM has learned that even a forgiven loan may yet be required to be carried on a recipient's books, CIRM will allow the recipient to convert the forgiven loan to a Grant. This ensures that CIRM loan funds are attractive to later stage companies by not saddling them with potential debt that may never be extinguished.

Consistency with Existing State Regulations:

After performing an evaluation for any other regulations in this area, CIRM has determined that these are the only regulations dealing with recipients of CIRM loan funds, and therefore the proposed regulations are neither inconsistent nor incompatible with existing state regulations.

DISCLOSURES REGARDING THE PROPOSED AMENDMENTS:

CIRM has made the following initial determinations:

Mandate on local agencies and school districts: None.

Submittal of Comments:

Any interested party may present comments in writing about the proposed amendments to the agency contact person named in this notice. Written comments must be received no later than 5:00 p.m. on March 28, 2016. Comments regarding this proposed action may also be transmitted via e-mail to lapcomments@cirm.ca.gov.

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, he or she must do so in writing no later than March 14, 2016.

Effect on Small Business:

CIRM has determined that the proposed amendment will have no impact on small businesses. The regulation implements conditions on awarding and administering grants for stem cell research. This research is conducted almost exclusively by large public and private nonprofit institutions. As such, the amendments to the regulation are 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 amendments do 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 amendments 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 amendments.

Costs or Savings to State Agencies:

CIRM has determined that no savings or increased costs to any agency will result from the proposed amendments.

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 amendments.

Effect on Housing Costs:

CIRM has determined that the proposed amendments will have no effect on housing costs.

Significant Statewide Adverse Economic Impact Directly Affecting Businesses:

CIRM has made an initial determination that the proposed amendments 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 these amendments 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 necessarily incur in reasonable compliance with the proposed amendments.

Results of Economic Impact Analysis:

Under section 3 of the “California Stem Cell Research and Cures Act,” which established the California Institute for Regenerative Medicine, funds for this agency are continuously appropriated without regard to fiscal year and not subject to budgetary control. The Act requires CIRM adopt rules to apply to Grants and Loans made by the agency.

CIRM has determined that that proposed regulatory action has no direct impact on small businesses. Virtually all applicants for CIRM funding are either large academic nonprofit institutions or well-capitalized biotechnology ventures. As such, the regulation is not expected to adversely impact small business as defined in Government Code section 11343.610. Application

for grant funds is voluntary and grant awards are required by Proposition 71 to include a prescribed additional amount to cover any costs associated with administration of the grant by grant recipients.

This action is not expected to have a direct impact on the creation or elimination of jobs, nor the creation of new businesses or elimination of existing businesses, nor the expansion of business currently doing business within the State of California because the regulation affect only administrative requirements regarding use of loan and grant funds. The use of loan funds is required neither by law nor these regulations. To the extent the regulation facilitates use of the funds and encourage development of intellectual property and return to the state as required by law, and to the extent California institutions apply for and receive research funds, such requirements are indirectly attributable to increased economic activity spurred by the investment research funds in the state and resultant positive business and employment development. Also, to the extent the regulation makes it possible for the expenditure of research funds in the state, and to the extent that research results in medical treatments and cures for chronic disease and injury, the regulation indirectly benefit the health and welfare of California residents who will benefit from such treatments and cures. Finally, to the extent that a loan recipient with a forgiven loan is able to convert that potential liability to a grant and remove the debt from its accounting, that will help loan recipients improve their financial standing.

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 amendments 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 amendments, all of the information upon which the amendments are based, 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 holding the hearing and considering all timely and relevant comments, CIRM may adopt the proposed amendments 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 may be directed to:

Scott Tocher
Deputy General Counsel
California Institute for Regenerative Medicine
1999 Harrison Street, Suite 1650
Oakland, CA 94612
(415) 396-9100

Questions on the substance of the proposed regulatory action may be directed to:

Amy Cheung
California Institute for Regenerative Medicine
(415) 396-9100

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.

*****END*****