

**State of California
Office of Administrative Law**

**In re:
California Institute for Regenerative
Medicine**

**Regulatory Action: Title 17
California Code of Regulations**

**Adopt sections:
Amend sections: 100600, 100601, 100602,
100608**

Repeal sections:

**DECISION OF DISAPPROVAL OF
REGULATORY ACTION**

Government Code Section 11349.3

OAL File No. 2013-0911-01 S

SUMMARY OF REGULATORY ACTION

The California Institute for Regenerative Medicine (CIRM) proposed this action to amend sections 100600, 100601, 100602, and 100608 under title 17 of the California Code of Regulations. These sections pertain to intellectual property rights and revenue sharing requirements for non-profit and for-profit grantees of CIRM-funded projects. The proposed amendments refine existing procedures and requirements related to the use of CIRM research funds and exploitation of CIRM-funded intellectual property.

DECISION

On September 11, 2013, CIRM submitted the above-referenced regulatory action to the Office of Administrative Law (OAL) for review in accordance with the Administrative Procedure Act (APA). On October 23, 2013, OAL notified CIRM that OAL disapproved the proposed action because CIRM failed to meet the necessity and clarity standards of Government Code section 11349.1 and failed to provide a sufficient economic impact assessment that complied with Government Code section 11346.3(b)(1).

DISCUSSION

CIRM's regulatory action must satisfy requirements established by the part of the APA that governs rulemaking by a state agency. Any regulation adopted by a state agency to implement, interpret, or make specific the law enforced or administered by it, or to govern its procedure, is subject to the APA unless a statute expressly exempts the regulation from APA coverage. (Gov. Code, sec. 11346.)

Before any regulation subject to the APA may become effective, the regulation is reviewed by OAL for compliance with the procedural requirements of the APA and for compliance with the standards for administrative regulations in Government Code section 11349.1. Generally, to satisfy APA standards, a regulation must be legally valid, supported by an adequate record, and easy to understand. In this review, OAL is limited to the rulemaking record and may not substitute its judgment for that of the rulemaking agency with regard to the substantive content of the regulation. This review is an independent check on the exercise of rulemaking powers by executive branch agencies intended to improve the quality of regulations that implement, interpret, and make specific statutory law, and to ensure that the public is provided with a meaningful opportunity to comment on regulations before they become effective.

A. The Amendment of Section 100601(v) Fails to Meet the Necessity Standard.

Government Code section 11349.1 (a)(1) requires OAL to review all regulations for compliance with the necessity standard. Government Code section 11349 (a), defines “necessity” to mean:

(a) ... the record of the rulemaking proceeding demonstrates by substantial evidence the need for a regulation to effectuate the purpose of the statute, court decision, or other provision of law that the regulation implements, interprets, or makes specific, taking into account the totality of the record. For purposes of this standard, evidence includes, but is not limited to, facts, studies, and expert opinion.

To further explain the meaning of substantial evidence in the context of the necessity standard, title 1, California Code of Regulations, section 10(b) provides:

(b) In order to meet the “necessity” standard of Government Code section 11349.1, the record of the rulemaking proceeding shall include:

(1) A statement of the specific purpose of each adoption, amendment, or repeal;
and

(2) information explaining why each provision of the adopted regulations is required to carry out the described purpose of the provision. Such information shall include, but is not limited to, facts, studies, or expert opinion. When the explanation is based upon policies, conclusions, speculation, or conjecture, the rulemaking record must include, in addition, supporting facts, studies, expert opinion, or other information. An “expert” within the meaning of this section is a person who possesses special skill or knowledge by reason of study or experience which is relevant to the regulation in question.

In order to provide the public with an opportunity to review and comment upon an agency’s perceived need for a regulation, the APA requires that the agency describe the need for the regulation in the initial statement of reasons. Specifically, Government Code section 11346.2(b)(1) states, in part:

(b) An initial statement of reasons ... shall include ... :

(1) A statement of the specific purpose of each adoption, amendment, or repeal, the problem the agency intends to address, and the rationale for the determination by the agency that each adoption, amendment, or repeal is reasonably necessary to carry out the purpose and address the problem for which it is proposed. The statement shall enumerate the benefits anticipated from the regulatory action, including the benefits or goals provided in the authorizing statute.

In short, CIRM's initial statement of reasons for this action must state the problems CIRM intends to address, the purpose for the adoption or amendment, and the rationale for the adoption or amendment for each regulatory provision. More simply put, the initial statement of reasons must include a statement, for each regulatory provision, explaining "why" the proposed regulation is needed and "how" this regulation fills that need. The initial statement of reasons must then be submitted to OAL with the initial notice of the proposed action and made available to the public during the public comment period, along with all the information upon which the proposal is based. (Gov. Code, sec. 11346.2, subd. (b) and sec. 11346.5, subs. (a)(16) and (b).) In this way the public is informed of the basis of the regulatory action and may comment knowledgeably.

Here, CIRM failed to comply with the necessity standard. Among other things, the proposed amendments in the 45-day text revised two existing definitions and added two definitions in a definitions section, section 100601. The only statement of necessity CIRM provided in their initial statement of reasons for all four definitions was "[t]o make specific the language and terminology used in formulating these regulations." The necessity for most of these definitions is self-evident; however, the amendment of the definition of licensing revenue in section 100601(v) (re-numbered from subdivision (t)) amounts to a completely rewritten definition that contains several regulatory provisions. As proposed in the 45-day text, the amendment to section 100601(v) provides:¹

(v) Licensing Revenue. The consideration received from the license of a CIRM-Funded Invention or CIRM-Funded Technology (provided however that with respect to a For-Profit Grantee or For-Profit Collaborator, Licensing Revenue does not include pre-commercial revenues such as development milestones and upfront payments). Licensing revenue excludes any additional grants, loans and other forms of research funding obtained to support the Project.

Calculation: Revenue is calculated by subtracting a proportion of expenses reasonably incurred in prosecuting, defending and enforcing related patent rights equal to CIRM's percentage of support for development of such CIRM-Funded Invention and/or CIRM-Funded Technology from total consideration rendered, except to the extent that such expenses are recoverable from a third party as provided in Section 100605(c) or otherwise. In the case of non-profit Grantees and non-profit Collaborators, Licensing Revenue is calculated by subtracting amounts due to the Inventor pursuant to existing institutional policies from total consideration rendered.

¹ Section 100601(v) was modified in subsequent modifications to the 45-day text.

The single necessity statement quoted above from CIRM's initial statement of reasons does not suffice to explain the reasons for the regulatory provisions in section 100601(v). It does not state the problem CIRM intends to address, the purpose for the amendment of section 100601(v), and the rationale for the amendment of section 100601(v), and therefore fails the necessity standard. In other words, CIRM did not answer "why" the amended definition is needed and "how" the amendment fills that need.

Thus, before this regulatory action is resubmitted to OAL, CIRM must draft a supplemental statement of reasons to correct the lack of necessity in the initial statement of reasons for the initially proposed amendment to section 100601(v). CIRM must ensure that they comply with the necessity standard for each regulatory provision in the amendment. Pursuant to Government Code section 11347.1, this supplemental statement of reasons, which would provide the necessity missing from the initial statement of reasons, must be made available to the public for at least 15 days prior to CIRM's adoption, amendment or repeal of the regulations. Additionally, any comments made in relation to the supplemental statement of reasons must be summarized and responded to in the final statement of reasons. (Gov. Code, sec. 11347.1, subd. (d).)

B. A Regulatory Provision in Proposed Section 100601(v) Fails to Meet the Clarity Standard.

In adopting the APA, the Legislature found that the language of many regulations was unclear and confusing to persons who must comply with the regulations. (Gov. Code, sec. 11340, subd. (b).) Government Code section 11349.1(a)(3) requires that OAL review all regulations for compliance with the clarity standard. Government Code section 11349(c) defines "clarity" to mean "written or displayed so that the meaning of the regulations will be easily understood by those persons directly affected by them."

In proposed section 100601(v), CIRM amended the definition for licensing revenue, as follows:

(v) Licensing Revenue. The consideration received from the license of a CIRM-Funded Invention or CIRM-Funded Technology (provided however that with respect to a For-Profit Grantee or For-Profit Collaborator, Licensing Revenue does not include pre-commercial revenues such as development milestones and upfront payments). Licensing revenue excludes any additional grants, loans and other forms of research funding obtained to support the Project.

Calculation: Revenue is calculated by subtracting a proportion of expenses reasonably incurred in prosecuting, defending and enforcing related patent rights equal to CIRM's percentage of support for development of such CIRM-Funded Invention and/or CIRM-Funded Technology from total consideration rendered, except to the extent that such expenses are recoverable from a third party as provided in Section 100605(c) or otherwise. In the case of non-profit Grantees and non-profit Collaborators, Licensing Revenue is calculated by subtracting

amounts due to the Inventor pursuant to existing institutional policies from total consideration rendered.²
[Emphasis added.]

In the above-quoted text, the directly affected public would not know what policies are being referred to in the phrase “pursuant to existing institutional policies.” This language, therefore, fails to comply with the clarity standard of the APA. CIRM will need to clarify what the phrase “pursuant to existing institutional policies” means by modifying the text of section 100601(v) in a 15-day notice pursuant to Government Code section 11346.8(c). Additionally, CIRM must have the modified text adopted by its statutory governing body, the Independent Citizens’ Oversight Committee, before resubmitting these regulations to OAL.

B. CIRM Failed to Provide in the Rulemaking Record a Sufficient Economic Impact Assessment that Complies with Government Code Section 11346.3(b)(1).

Government Code Section 11346.3(b)(1) provides the following:

- (b)(1) All state agencies proposing to adopt, amend, or repeal a regulation ... shall prepare an economic impact assessment that assesses whether and to what extent it will affect the following:
 - (A) The creation or elimination of jobs within the state.
 - (B) The creation of new businesses or the elimination of existing businesses within the state.
 - (C) The expansion of businesses currently doing business within the state.
 - (D) The benefits of the regulation to the health and welfare of California residents, worker safety, and the state’s environment.

On October 5, 2012, CIRM published a public notice of proposed action, which commenced this regulatory action. The above-quoted APA requirement for an economic impact assessment (EIA) provision was in effect at that time. Therefore, CIRM was statutorily mandated to prepare an assessment of the economic impacts described in subdivisions (b)(1)(A) through (C), and the benefits of the regulation described in subdivision (b)(1)(D), of Government Code section 11346.3.

The EIA that CIRM provided to OAL in the rulemaking record does not contain a sufficient EIA that complies with all of the elements addressed by subdivisions (b)(1)(A) through (D) of Government Code section 11346.3(b). The EIA provided includes an assessment that addresses the EIA elements required in subdivisions (b)(1)(A) and (b)(1)(D) of Government Code section 11346.3; however, it does not contain the assessments that address the EIA elements required in subdivisions (b)(1)(B) and (C) of Government Code section 11346.3. Government Code section 11346.3, subdivision (b)(1) requires an *assessment* of all four elements addressed by subdivisions (b)(1)(A) through (D). In its EIA, CIRM must perform an analysis explaining why and how it made the initial determinations stated in its 45-day notice that it is unlikely the

² This version of section 100601(v) was subsequently modified from the version made available with the 45-day text. Although section 100601(v) was subsequently modified, this version illustrates the clarity issue involved because the underlined text was not modified. All versions of section 100601(v) contain the same clarity issue.

proposed action will impact the creation or elimination of businesses (subdivision (b)(1)(B)) or will impact the expansion of businesses currently doing business (subdivision (b)(1)(C)) within the State of California, to address the missing elements of its EIA.

CIRM will need to prepare an EIA that assesses all of the required elements addressed in Government Code section 11346.3, subdivision (b)(1). CIRM must then make this revised EIA available to the public for at least 15 days and add it to the rulemaking record before adopting the regulations and resubmitting these regulations to OAL. (Gov. Code, sec. 11347.1.) Additionally, any comments made in relation to this revised EIA must be summarized and responded to in the final statement of reasons. (Gov. Code, sec. 11347.1, subd. (d).)

CONCLUSION

OAL disapproved this proposed regulatory action for the reasons set forth above.

Date: October 30, 2013



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