State of California
Office of Administrative Law

In re: **Department of Corrections and Rehabilitation**	**DECISION OF DISAPPROVAL OF REGULATORY ACTION**
Regulatory Action:	**Government Code Section 11349.3**
Title 15, California Code of Regulations	**OAL Matter Number: 2017-0825-03**
Adopt sections: 3349.1, 3349.2, 3349.3, 3349.4, 3349.5, 3349.6, 3349.7, 3349.8, 3349.9 **Amend section: 3349**	**OAL Matter Type: Regular Resubmittal (SR)**

SUMMARY OF REGULATORY ACTION

On August 25, 2017, the California Department of Corrections and Rehabilitation (Department) submitted to the Office of Administrative Law (OAL) proposed regulations to implement the lethal injection process. This action is a resubmittal of previously disapproved action, OAL matter number 2016-1104-02S. On October 9, 2017, OAL notified the Department of the disapproval of this regulatory action.

DECISION

The reasons for the disapproval were because the Department's resubmission did not meet the Clarity and Necessity standards of Government Code section 11349.1. This Decision of Disapproval of Regulatory Action details the reasons for OAL's action. The Department will have 120 days from receipt of this written decision to remedy the issues set forth herein and resubmit this regulatory action to OAL.

DISCUSSION

Regulations adopted by the Department must generally be adopted pursuant to the rulemaking provisions of the California Administrative Procedure Act (APA), Chapter 3.5 of Part 1 of Division 3 of title 2 of the Government Code (secs. 11340-11361). Pursuant to section 11346 of the Government Code, any regulatory action a state agency adopts through the exercise of quasi-legislative power delegated to the agency by statute is subject to the requirements of the APA, unless a statute expressly exempts or excludes the regulation from compliance with the APA. No

exemption or exclusion applies to the present regulatory action under review.[1] Consequently, before these regulations may become effective, the regulations and rulemaking record must be reviewed by OAL for compliance with the substantive standards and procedural requirements of the APA, in accordance with Government Code section 11349.1.

Pursuant to Government Code section 11349.4, subdivision (b), "[u]pon resubmission of a disapproved regulation to the office pursuant to subdivision (a), the office shall only review the resubmitted regulation for those reasons expressly identified in the written opinion required by subdivision (b) of Section 11349.3, or for those issues arising as a result of a substantial change to a provision of the resubmitted regulation or as a result of intervening statutory changes or intervening court orders or decisions."

CLARITY

OAL must review regulations for compliance with the "clarity" standard of the APA, as required by Government Code section 11349.1. Government Code section 11349, subdivision (c), defines "clarity" as meaning "...written or displayed so that the meaning of regulations will be easily understood by those persons directly affected by them."

The "clarity" standard is further defined in section 16 of title 1 of the California Code of Regulations (CCR), OAL's regulation on "clarity," which provides the following:

> In examining a regulation for compliance with the "clarity" requirement of Government Code section 11349.1, OAL shall apply the following standards and presumptions:
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> (a) A regulation shall be presumed not to comply with the "clarity" standard if any of the following conditions exists:
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> (1) the regulation can, on its face, be reasonably and logically interpreted to have more than one meaning; or
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> (2) the language of the regulation conflicts with the agency's description of the effect of the regulation; or
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> (3) the regulation uses terms which do not have meanings generally familiar to those "directly affected" by the regulation, and those terms are defined neither in the regulation nor in the governing statute; or
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> (4) the regulation uses language incorrectly. This includes, but is not limited to, incorrect spelling, grammar or punctuation; or
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> (5) the regulation presents information in a format that is not readily understandable by persons "directly affected;" or

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[1] OAL notes that Penal Code section 3604.1, as enacted by initiative Proposition 66 (Gen. Elec. (Nov. 8, 2016), sec. 11), provides: "The Administrative Procedure Act shall not apply to standards, procedures, or regulations promulgated pursuant to Section 3604." However, the effective date of Proposition 66, including Penal Code section 3604.1, is stayed pending a final order by the Supreme Court of California in *Briggs v. Brown*, Case No. S238309.

(6) the regulation does not use citation styles which clearly identify published material cited in the regulation.

(b) Persons shall be presumed to be "directly affected" if they:

(1) are legally required to comply with the regulation; or

(2) are legally required to enforce the regulation; or

(3) derive from the enforcement of the regulation a benefit that is not common to the public in general; or

(4) incur from the enforcement of the regulation a detriment that is not common to the public in general.

In this rulemaking action, two similar provisions fail to comply with the "clarity" standard. These clarity issues result from substantial changes made by the Department in response to Clarity Issue 5 identified in OAL's Decision of Disapproval of Regulatory Action, dated December 28, 2016, at pages five through six. All clarity concerns must be addressed by the Department prior to resubmission of this rulemaking to OAL.

Proposed section 3349.6, subdivision (a)(4) provides, in part:

> If the San Quentin Warden or the Warden at the institution where the inmate is housed has **good reason to believe** the inmate has become insane **after reviewing any of the three 20-Day Pre-Execution Reports**, the San Quentin Warden shall notify the District Attorney pursuant to Penal Code Section 3701. [Emphasis added.]

Proposed section 3349.6, subdivision (b)(3) provides, in part:

> If the San Quentin Warden or the Warden at the institution where the inmate is housed has **good reason to believe** the inmate has become insane **after reviewing any of the three 7-Day Pre-Execution Reports**, the San Quentin Warden shall notify the District Attorney pursuant to Penal Code Section 3701. [Emphasis added.]

The Department's description of the above language in the Notice of Change to Text As Originally Proposed (Notice of Change), dated February 28, 2017, at page three, states that "a single Alienist's report questioning the inmate's sanity is sufficient to trigger the requirement that the San Quentin Warden shall notify the District Attorney." The rule that a single alienist opinion questioning the inmate's sanity triggers the notification requirement of the San Quentin Warden to the district attorney is not clear from a plain reading of the regulation text. The regulation text does not contain a requirement that the San Quentin Warden *must* find "good reason to believe" the inmate has become insane if a single alienist's report questions the sanity of the inmate. The conflict between the language of the proposed regulation and the Department's description of the effect of the regulation in the Notice of Change does not meet the clarity standard set forth in subdivision (a)(2) of section 16 of title 1 of the CCR.

NECESSITY

OAL must review regulations for compliance with the "necessity" standard of Government Code section 11349.1. Government Code section 11349, subdivision (a), defines "necessity" as meaning "...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, subdivision (b) of section 10 of title 1 of the CCR provides:

> In order to meet the "necessity" standard of Government Code section 11349.1, the record of the rulemaking proceeding shall include:
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> (1) a statement of the specific purpose of each adoption, amendment, or repeal; and
>
> (2) information explaining why each provision of the adopted regulation 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 need for a regulation, the APA requires a rulemaking agency to describe the need for the regulation, and identify documents relied upon, if any, in proposing the regulation in the Initial Statement of Reasons (ISR), pursuant to Government Code section 11346.2, subdivision (b).

In this rulemaking action, adequate necessity is lacking for the below regulatory provisions. These issues were identified in Necessity Issues 3.1 and 3.2 in OAL's Decision of Disapproval of Regulatory Action, dated December 28, 2016, at pages nineteen through twenty and result from substantial changes to the proposed regulatory provisions made by the Department subsequent to OAL's Decision of Disapproval of Regulatory Action.

Proposed section 3349.6, subdivision (i) provides, in part:

> (i) Three hours prior to the scheduled execution, the following shall be initiated:
>
> ....
>
> (3) The Lethal Injection Chemical shall be prepared according to the instructions provided by the Lethal Injection Chemical Supplier.

(4) Preparation for administration of the Lethal Injection Chemical shall be as follows:
(A) If Pentobarbital is the designated Lethal Injection Chemical, it shall be administered by means of **three syringes for a total of 7.5 grams**. A fourth syringe shall be prepared with a saline flush.
(B) If Thiopental is the designated Lethal Injection Chemical, it shall be administered by means of **five syringes for a total of 7.5 grams**. A sixth syringe shall be prepared with a saline flush.
(C) The Infusion Sub-Team shall prepare the Lethal Injection Chemical for administration as follows:
1. Three identical trays shall be prepared. Each tray shall contain a total of 7.5 grams of Lethal Injection chemical.
2. Tray A shall be color-coded red and shall be the primary tray used for the lethal injection process.
3. Tray B shall be color-coded blue and shall be the backup tray.
4. Tray C shall be color-coded yellow and shall be the alternate backup tray.
(D) **If Pentobarbital has been designated, Trays A, B, and C shall each have three syringes containing the Lethal Injection Chemical**, each color-coded to match the tray; and a fourth syringe, color-coded white, containing the saline flush. The syringes shall be labeled by sequence of administration as follows:
1. **Three syringes, each containing 2.5 grams of Pentobarbital**, shall be labeled #A-1, #A-2, and #A-3 for Tray A, #B-1, #B-2, and #B-3 for Tray B, and #C-1, #C-2, and #C-3 for Tray C.
2. Syringe #4 shall contain a saline flush and be labeled #A-4 for Tray A, #B-4, for Tray B, and #C-4 for Tray C.
(E) **If Thiopental has been designated, Trays A, B, and C shall each have five syringes containing the Lethal Injection Chemical**, each color-coded to match the tray; and a sixth syringe, color-coded white, containing the saline flush. The syringes shall be labeled by sequence of administration as follows:
1. **Five syringes, each containing 1.5 grams of Thiopental,** shall be labeled #A-1, #A-2, #A-3, #A-4, and #A-5 for Tray A, #B-1, #B-2, #B-3, #B-4, and #B-5 for Tray B, and #C-1, #C-2, #C-3, #C-4, and #C-5 for Tray C.
2. Syringe #6 shall contain a saline flush and be labeled #A-6 for Tray A, #B-6, for Tray B, and #C-6, for Tray C. [Emphasis added.]

As set forth above, proposed section 3349.6, subdivision (i), requires administration of 7.5 grams of the designated lethal injection chemical. The Department provides the following rationale in the ISR for choosing 7.5 grams as the necessary amount of lethal injection chemical:

> The Morales Plaintiffs' medical expert has agreed that 5 grams of thiopental is a lethal dose. (Transcript of Proceedings, Morales v. Tilton (N.D. Cal., Sept. 27, 2006, No. C-06-0219-JF) pp. 542-543) All named barbiturates contained in the proposed regulations are equal to, or greater than, Thiopental in strength. (Rulemaking File documents relied upon: Vol. I, Document 26 (pp 29, 50); Vol. III, Document 26 (p 692); Vol. VI, Document 12 (1652), Document 32 (pp 413, 430, 433, 434), Document 33, Document 34 (pp 1,

> 12,14, 15), Document 35 (pp 6, 11, 30).) As a result, CDCR considers the listed chemicals equally effective in carrying out the purpose of these regulations. While CDCR recognizes that 5 grams has been deemed lethal, CDCR chose to increase the dosage to 7.5 grams to take into account Lethal Injection Chemical tolerance, size or weight of the inmate. [ISR at p. 37.]

The Addendum to the Initial Statement of Reasons (ISR-A), dated February 27, 2017, provides:

> Although 5g Thiopental has been recognized as lethal, there is documentation showing that some inmates have continued to breathe after 5g of Thiopental was injected (Rulemaking File documents relied upon: Vol VI, Document 7 (p. 4)). Therefore, in addition to the four 1.5g doses totaling 6g, CDCR has elected to administer an additional 1.5 dose, for a total of 7.5g, to take into account the inmates' Lethal Injection Chemical tolerance, age, size or weight, to ensure a result of death. [ISR-A at p. 2.]

In the Second Notice of Change to Text as Originally Proposed (Second Notice of Change), issued July 17, 2017, the Department provides the following explanation after removing two of the four originally proposed lethal injection chemicals:

> The purpose of the proposed regulations is to administer a fatal dose. Both Pentobarbital and Thiopental are effective in carrying out the purpose of the proposed regulations. Although 5g of Thiopental has been recognized as lethal, there is documentation showing that some inmates have continued to breathe after injection of 5 grams of Thiopental (Rulemaking File documents relied upon: Vol. VI, Document 7, p. 4). CDCR has elected to administer an additional 2.5 grams, beyond the 5 grams recognized as lethal, for a total of 7.5 grams, to take into account the inmates' Lethal Injection Chemical tolerance, age, size, or weight, to carry out the purpose of the proposed regulations. Further, the additional 2.5 grams was selected for simplicity and consistency, allowing an equal dose per syringe of Lethal Injection Chemical. [Second Notice of Change at p. 4.]

The explanations provided in the record lend support to the Department's determination that 5 grams of the named barbiturates is a lethal dose; however, the Department's explanation for choosing to increase the dose amount to 7.5 grams, which is 2.5 grams greater than the stated lethal dose, is not supported by substantial evidence. While the above excerpts state that increasing the dose to 7.5 grams is needed "to take into account the inmates' Lethal Injection Chemical tolerance, age, size, or weight," there is no explanation in the record to demonstrate that a 2.5 gram increase is necessary to address these potential variables. Assuming that there is a need to increase the amount above the stated lethal dose of 5 grams to account for these variables, what is the basis for increasing the dose of the two listed barbiturates by 2.5 grams?

Nor does the Department's assertion that "the additional 2.5 grams was selected for simplicity and consistency, allowing an equal dose per syringe of Lethal Injection Chemical" provide substantial evidence. Even assuming that the need for "simplicity and consistency" warranted

equal doses per syringe, such need does not explain why the Department chose the additional 2.5 grams as opposed to any other amount over the lethal dose of 5 grams that can be equally divided amongst a specified number of syringes. The Department's explanation does not demonstrate by substantial evidence the need for the above regulatory provisions, and therefore, does not satisfy the necessity standard in Government Code, section 11349.1.

CONCLUSION

For the reasons set forth above, OAL disapproved this regulatory action. Pursuant to Government Code section 11349.4, subdivision (a), the Department may resubmit this rulemaking action within 120 days of its receipt of this Decision of Disapproval.

Any changes made to the regulation text to address the clarity issues discussed above must be made available for at least 15 days for public comment pursuant to Government Code section 11346.8 and section 44 of title 1 of the CCR prior to adoption by the Department. Additionally, any supplement to the ISR or other document the Department may create or otherwise propose to add to the record in order to address the necessity or clarity issues discussed above must be made available for at least 15 days for public comment pursuant to Government Code section 11347.1 prior to adoption by the Department. The Department must resolve all issues raised in this Decision of Disapproval before resubmitting to OAL. OAL reserves the right to conduct a complete review for compliance with the procedural and substantive requirements of the APA. A copy of this Decision will be emailed to the Department on the date indicated below.

If you have any questions, please contact me at (916) 323-8916.

Date: October 12, 2017

Kevin D. Hull
Senior Attorney

For: Debra M. Cornez
Director

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