

**State of California  
Office of Administrative Law**

**In re:  
Department of Corrections and  
Rehabilitation**

**Regulatory Action:**

**Title 15, California Code of Regulations**

**Adopt sections: 3349.1, 3349.2, 3349.3,  
3349.4, 3349.5, 3349.6,  
3349.7, 3349.8, 3349.9**

**Amend section: 3349**

**Repeal sections:**

**DECISION OF DISAPPROVAL OF  
REGULATORY ACTION**

**Government Code Section 11349.3**

**OAL Matter Number: 2016-1104-02**

**OAL Matter Type: Regular (S)**

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**SUMMARY OF REGULATORY ACTION**

On November 4, 2016, the California Department of Corrections and Rehabilitation (Department) submitted to the Office of Administrative Law (OAL) proposed regulations to implement the lethal injection process. On December 21, 2016, OAL notified the Department of the disapproval of this regulatory action.

**DECISION**

The reasons for the disapproval were because the Department did not meet the standards set forth in Government Code section 11349.1 and the procedural requirements of the California Administrative Procedure Act (chap. 3.5 (commencing with sec. 11340) of tit. 2, div. 3, of the Gov. Code). Specifically, the regulations did not meet the Clarity, Consistency and Necessity standards of Government Code section 11349.1, and the Department failed to comply with all required Administrative Procedure Act procedures. 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, 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.<sup>1</sup> 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. OAL reserves the right to conduct a complete review for compliance with the procedural and substantive requirements of the APA.

### 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:

- (a) A regulation shall be presumed not to comply with the “clarity” standard if any of the following conditions exists:
  - (1) the regulation can, on its face, be reasonably and logically interpreted to have more than one meaning; or
  - (2) the language of the regulation conflicts with the agency’s description of the effect of the regulation; or
  - (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
  - (4) the regulation uses language incorrectly. This includes, but is not limited to, incorrect spelling, grammar or punctuation; or
  - (5) the regulation presents information in a format that is not readily understandable by persons “directly affected;” or

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<sup>1</sup> OAL notes that Penal Code section 3604.1, as enacted by initiative Proposition 66, section 11, provides “The Administrative Procedure Act shall not apply to standards, procedures, or regulations promulgated pursuant to Section 3604.” However, on December 20, 2016, prior to OAL’s decision on this proposed rulemaking, the Supreme Court of California issued an order in case S238309. That order states: “In order to provide time for further consideration of the amended petition for writ of mandate and to permit the filing and consideration of papers in opposition to the petition, the implementation of all provisions of Proposition 66, approved by the voters on November 8, 2016, as certified by the Secretary of State on December 16, 2016, is hereby stayed.”

- (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, a number of proposed regulatory provisions fail to comply with the “clarity” standard. These provisions are discussed below in the order in which they appear in the proposed regulation text unless the context requires otherwise. All clarity concerns must be addressed by the Department prior to resubmission of this rulemaking to OAL

**Issue 1.** Proposed section 3349.2, subdivision (a), pertains to the recruitment and selection process for Lethal Injection Team members. Subdivision (a)(2)(A) provides:

After the Panel selects the Lethal Injection Team members, the Team Administrator shall assign each member to one of the following Sub-Teams: Intravenous Sub-Team, Infusion Sub-Team, or Record Keeping Sub-Team pursuant to the criteria as set forth in subsection (d) below. **Each sub-team shall have a minimum number of four members.** [Emphasis added.]

Subdivision (a)(2)(B) provides in part:

The Team Administrator shall select an Intravenous Sub-Team leader from among **the four** Intravenous Sub-Team members. [Emphasis added.]

Subdivision (a)(2)(C) provides in part:

The Team Administrator shall select an Infusion Sub-Team leader from among **the four** infusion Sub-Team members. [Emphasis added.]

Use of the language “minimum of four members” in subdivision (a)(2)(A) for the sub-teams is inconsistent with use of the definitive language “the four” when referring to the sub-teams in subdivision (a)(2)(B) and (C). This internal inconsistency creates a clarity issue in violation of Government Code section 11349, subdivision (c), and subdivision (a)(1) of section 16 of title 1 of the CCR.

**Issue 2.** Proposed section 3349.4, subdivision (c), provides:

(c) The **Lethal Injection Facility safe** shall be permanently mounted within the Infusion Control Room.

(1) The combination to the **Infusion Control Room safe** shall be known only by the San Quentin Warden, the San Quentin Chief Deputy Warden, and the Team Administrator.

(2) The combination to the **Infusion Control Room safe** shall be changed after each execution to maintain quality control, accountability, and security of Lethal Injection Chemical. [Emphasis added.]

Based on the references to both a “Lethal Injection Facility safe” and “Infusion Control Room safe,” it is unclear from the proposed regulation text whether there are two separate safes in the Infusion Control Room or whether both terms are being used to refer to the same safe. This ambiguity creates a clarity issue in violation of Government Code section 11349, subdivision (c), and subdivision (a)(1) of section 16 of title 1 of the CCR.

**Issue 3.** Proposed section 3349.4, subdivision (e), provides:

The Team Supervisor shall conduct and document monthly security and operational inspections of the Lethal Injection Facility.

This provision raises two clarity issues. First, the regulation does not contain a description of how the Team Supervisor is required to document the inspections, nor is there any description of what information about the inspection is to be documented. This ambiguity creates a clarity issue in violation of Government Code section 11349, subdivision (c), and subdivision (a)(1) of section 16 of title 1 of the CCR.

Second, while the regulation includes a broad requirement that the Team Supervisor conduct monthly security and operational inspections of the Lethal Injection Facility, there is no description of what these inspections entail. Although the regulation contains only general terms, the Initial Statement of Reasons (ISR) includes language definitively stating: “This inspection shall include ensuring the equipment is functioning, supply inventory, and building maintenance.” (ISR at p. 22.) This expansion of the regulation requirements in the ISR creates a conflict between the language of the regulation and the Department’s description of the effect of the regulation in violation of Government Code section 11349, subdivision (c), and subdivision (a)(2) of section 16 of title 1 of the CCR.

**Issue 4.** Proposed section 3349.5, subdivision (f)(5), provides:

(f) The San Quentin Warden shall:

...

(5) Ensure the Team Administrator, the Team Supervisor and all Lethal Injection Team members involved in the lethal injection process understand their roles in the scheduled execution.

While the proposed regulation text is silent as to how the San Quentin Warden shall complete this requirement, the ISR’s description of the effect of this provision states:

The San Quentin Warden has the responsibility to ensure that a scheduled execution is performed and to ensure that all Lethal Injection Team members are prepared to carry out their duties during a scheduled execution. The San Quentin Warden has the discretion to determine the preparedness of a specific Lethal Injection Team member. The San Quentin Warden may consider the training session performance assessments by the Intravenous Sub-Team leader, the Infusion Sub-Team leader, and Team Supervisor; any concerns expressed by the Team Administrator, Team Supervisor, or any Lethal Injection Team member; recent performance in job duties, to include personnel evaluations or corrective and adverse action taken against the specific Lethal Injection Team member; and any other information that causes the San Quentin Warden to believe that the specific Lethal Injection Team member may be unprepared or unable to perform the duties required by these regulations during a scheduled execution. [ISR at p. 26.]

The ambiguity in this subdivision and the expanded meaning as set forth in the ISR create clarity issues in violation of Government Code section 11349, subdivision (c), and subdivisions (a)(1) and (a)(2) of section 16 of title 1 of the CCR.

**Issue 5.** Proposed section 3349.6, subdivision (a)(4) provides, in part:

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

Two clarity issues arise from this provision. First, as written, this provision requires notification by the San Quentin Warden only if both the San Quentin Warden and Warden at the institution where the inmate is housed have good reason to believe the inmate has become insane. In response to a comment questioning what happens if the two wardens disagree on whether the inmate is insane, the Department responds that “[a] single opinion questioning the inmate’s sanity is sufficient to trigger the statutory requirements mandating that the warden must call such fact to the attention of the District Attorney.” (Final Statement of Reasons (FSR) at Exh. G, Response to Comment 30401(219), p. 613.) The Department’s description of the effect of this regulation therefore conflicts with the language of the proposed text in violation of subdivision (a)(2) of section 16 of title 1 of the CCR.

Second, although the phrase “good reason to believe the inmate has become insane” is not defined, the Department sets out clear parameters for determining “good reason to believe” in response to comments. For example, in response to a comment questioning what happens if there is disagreement on the part of the alienists as to the sanity of the inmate in the 20-Day Pre-Execution Report or 7-Day Pre-Execution Report, the Department states:

Penal Code section 3701, specifically states that if, after his delivery to the warden for execution, there is good reason to believe that a defendant, under judgment of death, has become insane, the warden must call such fact to the

attention of the district attorney of the county in which the prison is situated, whose duty it is to immediately file in the superior court of such county a petition, stating the conviction and judgment, and the fact that the defendant is believed to be insane, and asking that the question of his sanity be inquired into. Each alienist will be provided any and all information pertinent to the inmate's sanity that is known from any source. Each alienist will perform an independent evaluation and report which summarizes their individual conclusions. **A single opinion questioning the inmate's sanity is sufficient to trigger the statutory requirements mandating that the warden must call such fact to the attention of the District Attorney.** [FSR at Exh. G, pp. 897-898 (Response to Comment 30403 (38)) (Emphasis added).]

The requirement that a single alienist opinion triggers the notification requirements of the San Quentin Warden to the district attorney is not discernable from a plain reading of the regulation text. This expansion of the meaning of the regulation text creates a conflict between the language of the regulation and the Department's description of the effect of the regulation in violation of Government Code section 11349, subdivision (c), and subdivision (a)(2) of section 16 of title 1 of the CCR.

**Issue 6.** Proposed section 3349.6, subdivision (b), provides that "[a]pproximately ten calendar days prior to the scheduled execution" several specific tasks and events must occur, including, among other things, a second interview of the inmate and submission of a "7-Day Pre-Execution Report" by each of the three alienists. "Approximately ten calendar days" lacks clarity because the phrase can reasonably and logically be interpreted to have more than one meaning in violation of subdivision (a)(1) of section 16 of title 1 of the CCR. "Approximately ten days" implies that the events listed in subdivision (b) need not adhere to an exact time schedule. Merriam Webster's Collegiate Dictionary defines "approximate" as meaning "located close together" and "nearly correct or exact." (Merriam-Webster's Collegiate Dict. (11<sup>th</sup> ed. 2007) p. 61.) Use of the term "approximately" therefore creates an unspecified amount of leeway in interpreting the regulation and members of the directly affected public could reasonably interpret this time frame to mean different things. How will the Department or other members of the directly affected public know if they are complying with this provision? Would an alienist's 7-Day Pre-Execution Report be in compliance with subdivision (b) if it was prepared eleven days before the execution? Would twelve days be compliant?

In support of this provision, the ISR states that "CDCR determined that ten days is necessary to allow the Alienists approximately three calendar days to complete the duties required by the second evaluation of the inmate's sanity...." (ISR at p. 30.) This language indicates the Department's intent that the stated events occur specifically at ten days, which is inconsistent with "approximately ten days" as set forth in section 3349.6, subdivision (b). This creates a conflict between language of the regulation and the Department's description of the effect of the regulation in violation of Government Code section 11349, subdivision (c), and subdivision (a)(2) of section 16 of title 1 of the CCR.

**Issue 7.** Proposed section 3349.6, subdivision (d), provides that "[a]pproximately five calendar days prior to the scheduled execution, the following shall occur...." Following this provision are several actions that must be taken "approximately" five calendar days before the scheduled execution. Similar to section 3349.6, subdivision (b), use of the term "approximately" creates an

unspecified amount of leeway in interpreting the regulation and when these actions must be taken. This ambiguity makes the regulation reasonably and logically susceptible to more than one meaning and is therefore in violation of Government Code section 11349, subdivision (c), and subdivision (a)(1) of section 16 of title 1 of the CCR.

**Issue 8.** Proposed section 3349.6, subdivisions (d)(6)(A) and (B), provide:

(6) Religious accommodations.

(A) State employed Chaplains and Spiritual Advisors selected by the inmate shall be allowed to perform their spiritual functions at the inmate's cell front on either **second or third watch** and by telephone at any time.

(B) Pre-approved non-state employed Chaplains and Spiritual Advisors may visit the inmate utilizing the visitor process and shall be allowed to perform their spiritual functions at the inmate's cell front on either **second or third watch** or by telephone at any time. [Emphasis added.]

Although the ISR defines the terms "second watch" and "third watch" as "second watch (6 a.m. to 2 p.m.)" and "third watch (2 p.m. to 10 p.m.)" these terms are not defined in regulation and are reasonably and logically subject to more than one meaning. Nor has the Department demonstrated in the rulemaking record that these terms have a meaning generally familiar to those directly affected by the regulation, including not only Department staff, but the inmate, chaplains, spiritual advisors, etc. Thus, these provisions are in violation of Government Code section 11349, subdivision (c), and subdivisions (a)(1), (a)(2) and (a)(3) of section 16 of title 1 of the CCR.

**Issue 9.** Proposed section 3349.6, subdivision (e), provides that "[a]pproximately three calendar days prior to the scheduled execution" certain actions be taken by the Department. Similar to section 3349.6, subdivision (b), use of the term "approximately" creates an unspecified amount of leeway in interpreting the regulation and when these actions must be taken. This ambiguity makes the regulation reasonably and logically susceptible to more than one meaning and is therefore in violation of Government Code section 11349, subdivision (c), and subdivision (a)(1) of section 16 of title 1 of the CCR.

**Issue 10.** Proposed section 3349.6, subdivision (f), provides that "[a]pproximately 24 hours prior to the scheduled execution" specified actions must be taken by the Department. Similar to section 3349.6, subdivision (b), use of the term "approximately" creates an unspecified amount of leeway in interpreting the regulation and when these actions must be taken. This ambiguity makes the regulation reasonably and logically susceptible to more than one meaning and is therefore in violation of subdivision (a)(1) of section 16 of title 1 of the CCR. In addition, the description in the ISR for this provision states that the "CDCR determined 24 hours is necessary" indicating the Department's intent that this provision mean 24 hours and not approximately 24 hours. (ISR at p. 34.) This creates a conflict between the regulation text and the description of the effect of the regulation in violation of Government Code section 11349, subdivision (c), and subdivision (a)(2) of section 16 of title 1 of the CCR.

**Issue 11.** Proposed section 3349.6, subdivision (f)(1), provides:

The San Quentin Warden shall confirm that all Lethal Injection Team members are fully prepared and ready to perform their assigned duties.

The regulations are silent on how the San Quentin Warden shall perform this task, leaving this requirement open to interpretation. In describing the necessity and effect of this provision, the ISR states:

This is necessary because the San Quentin Warden has the legal duty to carry out the execution and must be confident the necessary Lethal Injection Team members are ready and able to perform their assigned duties and responsibilities. The San Quentin Warden has the discretion to determine the preparedness of a specific Lethal Injection Team member. The San Quentin Warden may consider performance during training sessions, any concerns expressed by the Intravenous Sub-Team leader, Infusion Sub-Team leader, Team Administrator, Team Supervisor, or any Lethal Injection Team member; recent performance in job duties, to include personnel evaluations or corrective and adverse action taken against the specific Lethal Injection Team member; and any other information that causes the San Quentin Warden to believe that the specific Lethal Injection Team member may be unprepared or unable to perform the duties required by these regulations during a scheduled execution. [ISR at p. 34.]

The ambiguity in this subdivision and the expanded meaning as set forth in the ISR create clarity issues in violation of Government Code section 11349, subdivision (c), and subdivisions (a)(1) and (a)(2) of section 16 of title 1 of the CCR.

**Issue 12.** Proposed section 3349.6, subdivision (g), provides “[a]pproximately six hours prior to the scheduled execution” specified actions must be taken. Use of the term “Approximately” creates ambiguity as to when the events subsequently listed are required to be performed and can be reasonably and logically interpreted to have more than one meaning. For example, subdivision (g)(F)(2), states that “[v]isiting, with the exception of an Attorney and a state employed or pre-approved non-state employed Chaplain or Spiritual Advisor shall cease.” Would members of the inmate’s family or the inmate’s loved ones be permitted to visit less than six hours before the execution? Can the Department cease all visitation more than six hours before the execution if pre-execution tasks are running ahead of schedule? Reference to the ISR calls the meaning of this provision further into question in that when describing this provision, the ISR refers to this time period in definitive, not approximate terms: “The CDCR determined six hours is necessary to accommodate and complete the specific requirements in the provisions.” (ISR at p. 35.) The ambiguity in this subdivision and the conflict between the regulation text and the effect of the regulation as described in the ISR create clarity issues in violation of Government Code section 11349, subdivision (c), and subdivisions (a)(1) and (a)(2) of section 16 of title 1 of the CCR.

**Issue 13.** Proposed section 3349.6, subdivision (g)(2), provides: “No visitation shall occur on first watch.” “First watch” is not defined in the regulations. However, in the ISR, “first watch” is defined as 10 p.m. to 6 a.m. (ISR at p. 35.) The lack of definition and expansion of the effect of the regulations as described in the ISR create clarity issues in violation of Government Code



section 11349, subdivision (c), and subdivisions (a)(1) and (a)(2) of section 16 of title 1 of the CCR.

**Issue 14.** Proposed section 3349.6, subdivision (h), provides that “[a]pproximately three hours prior to the scheduled execution” specific actions shall be taken. Use of “approximately” creates ambiguity as to when the events subsequently listed are required to be performed and can be reasonably and logically interpreted to have more than one meaning. In describing this provision, the ISR states definitively that “all visiting shall cease three hours prior to the execution,” thereby creating a conflict between the language of the regulation and the agency’s description of the effect of the regulation. The ambiguity in this subdivision and the conflict between the regulation text and the effect of the regulation as described in the ISR create clarity issues in violation of Government Code section 11349, subdivision (c), and subdivisions (a)(1) and (a)(2) of section 16 of title 1 of the CCR.

**Issue 15.** Proposed section 3349.6, subdivision (h)(2)(B), provides:

**A sedative is available upon request.** If requested by the inmate, the sedative shall be administered under the direction and approval of a **physician**.  
[Emphasis added.]

San Quentin State Prison Lethal Injection Team Administrator/Team Leader Execution Log, form CDCR 2181 (10/15), which is incorporated by reference, at Step 4, includes a requirement to:

Inform the inmate that a sedative is available. **Valium or its equivalent** will be administered under the direction and approval of a **clinician**. [Emphasis added.]

These provisions raise two clarity issues. First, it is unclear what sedative options are available. To the extent that form CDCR 2181 (10/15) further defines the meaning of “sedative” as “Valium or its equivalent”, it is unclear what is meant by “or its equivalent.” This term can reasonably and logically be interpreted to have multiple meanings, such as Valium, sedatives consisting of the same chemical make-up as Valium, generics, or sedatives in the same drug category as Valium. The Department’s response to comment 30401 (126) states:

The plain reading of the proposed regulations does not limit the physician’s choice of sedative, route of administration of the sedative, or the dose or number of doses. [FSR at Exh. G, pp. 537-538.]

This response indicates broad latitude on the part of the physician which conflicts with form CDCR 2181 (10/15)’s reference to “Valium or its equivalent.”

Second, the Department’s reference to the sedative being “administered under the direction and approval of a **physician**” in section 3349.6, subdivision (h)(2)(B), conflicts with the language on form CDCR 2181(10/15) that the sedative “will be administered under the direction and approval of a **clinician**.” Use of separate terms in the regulation and form create ambiguity as to who the

sedative will be administered under the direction and approval of. Merriam Webster defines clinician as “a person qualified in the clinical practice of medicine, psychiatry or psychology as distinguished from one specializing in laboratory or research techniques or theory.” (Merriam-Webster’s Collegiate Dict. (11<sup>th</sup> ed. 2007) p. 232.) A physician is defined as “a person skilled in the art of healing; one educated, clinically experienced, and licensed to practice medicine as usually distinguished from surgery.” (Id. at 935.) Although there may be similarities between clinicians and physicians, the term “clinician” is defined more broadly than “physician” and therefore the terms do not have the same meaning.

The ambiguities and inconsistencies between the regulation text and form CDCR 2181 (10/15), as well as the conflicting description of the effect of the regulation with regard to the administration of the sedative create clarity issues in violation of Government Code section 11349, subdivision (c), and subdivisions (a)(1) and (a)(2) of section 16 of title 1 of the CCR.

**Issue 16.** Proposed section 3349.6, subdivision (h)(3)(D), provides:

The Lethal Injection Chemical shall be mixed according to the **manufacturer’s instructions**. [Emphasis added.]

When responding to comments questioning the availability of manufacturer’s instructions when the Lethal Injection Chemical is received from a compounding pharmacy and not the manufacturer, the Department responds by stating:

If a compounding pharmacy is utilized to compound the Lethal Injection Chemical, a licensed compounding pharmacy would provide the mixing instructions. [FSR at Exh. G, p. 384 [Comment 30390 (32)]; Id. at pp. 665-666 [Comment 30401 (285).]

The regulations, however, do not include procedures for when the Lethal Injection Chemical is obtained from compounding pharmacies. Therefore, the Department’s explanation expands the meaning of this regulatory provision and creates an inconsistency between the regulation text and the effect of the regulation as described by the agency. The conflict between the regulation text and the effect of the regulation as described by the Department create clarity issues in violation of Government Code section 11349, subdivision (c), and subdivisions (a)(1) and (a)(2) of section 16 of title 1 of the CCR.

**Issue 17.** Proposed section 3349.6, subdivision (i), provides that specified actions be taken “[a]pproximately two hours prior to the scheduled execution.” Use of “approximately” creates ambiguity as to when the events subsequently listed are required to be performed and can be reasonably and logically interpreted to have more than one meaning. The ambiguity in this subdivision creates a clarity issue in violation of Government Code section 11349, subdivision (c), and subdivision (a)(1) of section 16 of title 1 of the CCR.

**Issue 18.** Proposed section 3349.6, subdivision (j), provides that specified actions be taken “[a]pproximately one hour prior to the scheduled execution.” Use of “approximately” creates ambiguity as to when the events subsequently listed are required to be performed and can be reasonably and logically interpreted to have more than one meaning. The ambiguity in this subdivision creates a clarity issue in violation of Government Code section 11349, subdivision (c), and subdivision (a)(1) of section 16 of title 1 of the CCR.

**Issue 19.** Proposed section 3349.6, subdivision (j)(2), provides that “[a]pproximately 45 minutes before a scheduled execution, the San Quentin Warden shall order the inmate to be prepared for the execution.” Use of “approximately” creates ambiguity as to when the events subsequently listed are required to be performed and can be reasonably and logically interpreted to have more than one meaning. The ambiguity in this subdivision creates a clarity issue in violation of Government Code section 11349, subdivision (c) and subdivision (a)(1) of section 16 of title 1 of the CCR.

**Issue 20.** Proposed section 3349.6, subdivision (j)(5), provides:

- (5) Approximately 15 minutes before a scheduled execution, the San Quentin Warden shall:
  - (A) Order the inmate escorted to the Lethal Injection Room.
  - (B) Order the inmate to be secured to the gurney with restraints.
  - (C) Order the inmate’s hands to be secured to the arm rests on the gurney with medical tape.

Use of “approximately” creates ambiguity as to when the events subsequently listed are required to be performed and can be reasonably and logically interpreted to have more than one meaning. The ambiguity in this subdivision creates a clarity issue in violation of Government Code section 11349, subdivision (c), and subdivision (a)(1) of section 16 of title 1 of the CCR.

**Issue 21.** Proposed section 3349.7, subdivision (c), provides in part:

(c) Infusion.

...

(3) A Record Keeping Sub-Team member in the Infusion Control Room shall **initiate a ten minute count down at the start of the infusion of syringe #1.**

(4) Beginning with Tray A and using the primary intravenous catheter, the Lethal Injection Chemical shall be administered as follows:

(A) #1-60cc syringe containing the specified amount of the designated Lethal Injection Chemical shall be administered, followed by a consciousness assessment of the inmate; the Intravenous Sub-Team Member shall brush the back of his/her hand over the inmate’s eyelashes, and speak to and gently shake the inmate. Observations shall be documented. If the inmate is

unresponsive, it will demonstrate that the inmate is unconscious. The process shall continue as follows:

(B) #2-60cc syringe containing the specified amount of the designated Lethal Injection Chemical shall be administered.

(C) #3-60cc syringe containing the specified amount of the designated Lethal Injection Chemical shall be administered.

(D) #4-60cc syringe containing the specified amount of the designated Lethal Injection Chemical shall be administered.

(E) #5-60cc syringe containing the specified amount of the designated Lethal Injection Chemical shall be administered.

(F) #6-60cc syringe containing the saline flush.

(5) If, following the administration of syringe #1 the assessment indicates the inmate is not unconscious, the Intravenous Sub-Team member shall check the catheter for patency. After checking for patency, syringe #2 shall be administered followed by a second consciousness assessment of the inmate in the same manner as described in subsection (c)(4)(A). If the assessment indicates the inmate is not unconscious, the San Quentin Warden shall direct that the injection through the primary intravenous catheter be discontinued and the entire sequence re-initiated with the Lethal Injection Chemical on Tray B using the designated backup intravenous catheter.

(6) If, at any time during the infusion of the Lethal Injection Chemical the primary intravenous catheter fails, the San Quentin Warden shall:

(A) Direct the lethal injection process using the primary intravenous catheter and the chemical on Tray A be discontinued.

(B) Direct the Lethal Injection Chemical administration process set forth in subsections (4) and (5) begin again, but using the backup intravenous catheter and the Lethal Injection Chemical on Tray B.

(7) The inmate's heart activity shall be monitored by an electrocardiogram.

(8) The attending physician shall monitor the electrocardiogram. Death shall be determined and declared by a physician. Once death is declared, infusion of any remaining Lethal Injection Chemical shall cease.

**(9) In the event all six syringes from Tray A have been administered, ten minutes has elapsed and death has not been declared, the Record Keeping Sub-Team member shall advise the Team Supervisor, who shall then advise the Team Administrator and the San Quentin Warden. The San Quentin Warden shall direct the Lethal Injection Chemical administration process set forth in subsections (4) - (8) be repeated, but using the backup intravenous catheter and the six syringes from Tray B.**

**(10) In the event all six syringes from Tray B have been administered, ten minutes has elapsed and death has not been declared, or an intravenous site cannot be established or maintained at either the primary or backup site, the Record Keeping Sub-Team member shall advise the Team Supervisor, who shall then advise the Team Administrator and the San Quentin Warden. The San Quentin Warden shall direct the Lethal Injection Chemical**

**administration process set forth in subsections (4) and (5) be repeated, but using the alternate backup site and Tray C. [Emphasis added.]**

A clarity issue exists as to how the Department determines when “ten minutes has elapsed” in relation to the administration of the syringes on Tray B pursuant to subdivision (c)(10). For Tray A, subdivision (c)(3) requires a Record Keeping Sub-Team member to begin a ten minute countdown at the start of the infusion of syringe #1. For the administration of Tray B, however, subdivision (c)(9) states that only subdivisions (c)(4) through (c)(8) shall be repeated, thereby eliminating the requirement that a Record Keeping Sub-Team member begin a ten minute countdown as set forth in (c)(3). Based on the regulation text, it is unclear when the ten minute countdown required by subdivision (c)(10) commences, thereby making this provision reasonably and logically subject to more than one meaning. For example, does the ten minute countdown begin when syringe # 1 of Tray B is first infused, or does the ten minute countdown begin after syringe # 6 of Tray B has been infused? The ambiguity in this subdivision creates a clarity issue in violation of Government Code section 11349, subdivision (c), and subdivision (a)(1) of section 16 of title 1 of the CCR.

**Issue 22.** Proposed section 3349.7, subdivision (d)(5), provides:

**(5) In the event all six syringes from Tray C have been administered, ten minutes has elapsed and death has not been declared,** the San Quentin Warden shall direct the Infusion Sub-Team to prepare a set of five additional syringes of Lethal Injection Chemical, each containing 1.5 grams of Lethal Injection Chemical. The Lethal Injection Chemical shall be mixed according to the manufacturer’s instructions. A medically trained Infusion Sub-Team member shall prepare the syringes. A separate medically trained Infusion Sub-Team member or Intravenous Sub-Team member shall verify proper preparation of each syringe. The Warden shall direct the Infusion Sub-Team to administer a syringe containing 1.5 grams of the Lethal Injection Chemical in the alternate backup intravenous line, and wait for ten minutes. If the inmate’s death has not been declared by the end of that ten-minute period, the San Quentin Warden shall direct the Infusion Sub-Team to administer another syringe containing 1.5 grams of Lethal Injection Chemical in the alternate backup intravenous line and wait ten minutes. The same process shall be followed until the five syringes have been administered. If at any time during this process the inmate is declared dead, the administration of Lethal Injection Chemical shall stop.... [Emphasis added.]

As discussed above, in the event that the syringes from Tray B do not result in death of the inmate, subdivision (c)(10) requires in part, that the “San Quentin Warden shall direct the Lethal Injection Chemical administration process set forth in subsections (4) – (8) be repeated, but using the backup intravenous catheter and the six syringes from Tray C.” For Tray A, subdivision (c)(3) requires a Record Keeping Sub-Team member to begin the ten minute countdown at the start of the infusion of syringe #1. For the administration of Tray C, however, subdivision (c)(10) states that only subdivisions (c)(4) through (c)(8) shall be repeated, thereby eliminating the requirement that a Record Keeping Sub-Team member begin a ten minute countdown as set

forth in (c)(3). Based on the regulation text, it is unclear when the ten minute countdown required by subdivision (d)(5) commences leaving this provision reasonably and logically subject to more than one meaning. For example, does the ten minute countdown begin when syringe # 1 of Tray C is first infused, or does the ten minute countdown begin after syringe # 6 of Tray C has been infused? The ambiguity in this subdivision creates a clarity issue in violation of Government Code section 11349, subdivision (c), and subdivision (a)(1) of section 16 of title 1 of the CCR.

**Issue 23.** On Request for Approval of Witnesses, form CDCR 1801-C (10/15), incorporated by reference in these regulations, the first paragraph of the form provides: "Per Penal Code Section 3605, I am requesting that the following person(s) be permitted to witness the execution. I understand that all requested witnesses must meet all guidelines applied to normal visiting. All persons not meeting these guidelines will not be approved." Based on the text in this form, it is unclear what "guidelines" CDCR is referring to and what "normal visiting" means. Are there guidelines for visiting inmates sentenced to death that are different than visiting inmates not sentenced to death? The ambiguity in this subdivision creates a clarity issue in violation of Government Code section 11349, subdivision (c), and subdivision (a)(1) of section 16 of title 1 of the CCR. Any clarifying language added to this form must meet all APA standards, including the consistency standard.

### **CONSISTENCY**

OAL is mandated by Government Code section 11349.1, subdivision (a)(4), to review each regulation adopted pursuant to the APA to determine whether the regulation complies with the "consistency" standard. Government Code section 11349, subdivision (d), defines "consistency" to mean "being in harmony with, and not in conflict with or contradictory to, existing statutes, court decisions, or other provisions of law." As discussed below, aspects of the proposed regulations fail to comply with the consistency standard of the APA.

**Issue 1.** Penal Code section 3701 provides:

If, after his delivery to the warden for execution, there is good reason to believe that a defendant, under judgment of death, has become insane, the warden must call such fact to the attention of the district attorney of the county in which the prison is situated, whose duty it is to immediately file in the superior court of such county a petition, stating the conviction and judgment, and the fact that the defendant is believed to be insane, and asking that the question of his sanity be inquired into. Thereupon the court must at once cause to be summoned and impaneled, from the regular jury list of the county, a jury of 12 persons to hear such inquiry.

Therefore, if the San Quentin Warden has good reason to believe the defendant has become insane, such fact must be called to the attention of the district attorney.

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

If the **San Quentin Warden and the Warden at the institution where the inmate is housed** have good reason to believe the inmate has become insane

after reviewing the 20-Day Pre-Execution Report, the San Quentin Warden shall notify the District Attorney pursuant to Penal Code Section 3701. [Emphasis added.]

If after reviewing the “20-Day Pre-Execution Report,” the San Quentin Warden alone has good cause to believe the inmate has become insane, then pursuant to Penal Code section 3701, the San Quentin Warden must bring such fact to the district attorney. As written, however, proposed section 3349.6, subdivision (a)(4), requires such fact to be brought to the district attorney only if “the San Quentin Warden *and* Warden at the institution where the inmate is housed have good reason to believe the inmate has become insane.” By making such notification mandatory only if both wardens “have good reason to believe the inmate has become insane,” subdivision (a)(4) is inconsistent with Penal Code section 3701.

**Issue 2.** As discussed above in Issue 1, Penal Code section 3701 requires the San Quentin Warden to call to the attention of the district attorney if the warden has good reason to believe the inmate has become insane. Proposed section 3349.6, subdivision (b)(3), provides:

**“If the San Quentin Warden and the Warden at the institution where the inmate is housed** have good reason to believe the inmate has become insane after reviewing the 7-day Pre-Execution Report, the San Quentin Warden shall notify the district Attorney pursuant to Penal Code Section 3701. [Emphasis added.]

Similar to proposed section 3349.6, subdivision (a)(4), by making such notification to the district attorney mandatory only if both wardens “have good reason to believe the inmate has become insane,” subdivision (b)(3) is inconsistent with Penal Code section 3701.

**Issue 3.** Penal Code section 3605, subdivision (a), provides:

(a) The warden of the state prison where the execution is to take place shall be present at the execution and shall, subject to any applicable requirement or definition set forth in subdivision (b), invite the presence of the Attorney General, the members of the immediate family of the victim or victims of the defendant, and at least 12 reputable citizens, to be selected by the warden. **The warden shall, at the request of the defendant, permit those ministers of the Gospel, not exceeding two, as the defendant may name, and any persons, relatives or friends, not to exceed five,** to be present at the execution, together with those peace officers or any other Department of Corrections employee as he or she may think expedient, to witness the execution. **But no other persons than those specified in this section may be present at the execution,** nor may any person under 18 years of age be allowed to witness the execution. [Emphasis added.]

In proposed section 3349.5, subdivision (e)(6), the Department incorporates by reference form CDCR 1801-C (10/15), Request for Approval of Witnesses. CDCR 1801-C (10/15) violates the consistency standard in two respects.

First, while Penal Code section 3605, subdivision (a), allows a defendant to name any persons, relatives or friends, not to exceed five, to witness the execution, form CDCR 1801-C (10/15) provides space for the inmate to request "Family and Loved Ones" to witness the execution. By limiting the requested witnesses to "Family and Loved Ones," form CDCR 1801-C (10/15) is narrowing the scope of allowable witnesses and is in conflict with Penal Code section 3605(a).

Second, while Penal Code section 3605, subdivision (a), requires the warden to "permit those ministers of the Gospel, not exceeding two" as named by the defendant to witness the execution, form CDCR 1801-C (10/15) provides space for two "Spiritual Advisors." "Spiritual Advisor" is defined in proposed regulation section 3349.1, subdivision (q), as "a person who, by profession or practice, provides spiritual advice, assistance, or guidance." Inclusion of the term "Spiritual Advisors," as defined by section 3349.1, subdivision (q), on form CDCR 1801-C (10/15) conflicts with Penal Code section 3605, subdivision (a), and is in violation of the consistency standard.

The Department must ensure that all inconsistencies are remedied before resubmitting this action to OAL.

### **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:

- (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 in proposing the regulation in the ISR, pursuant to Government Code section 11346.2, subdivision (b).

In this rulemaking action, many proposed amendments to the CCR and forms incorporated by reference are not supported by substantial evidence in the rulemaking record. The Department must resolve all necessity issues before resubmittal to OAL.

**Issue 1.** Proposed section 3349.6, subdivision (d)(7), provides:

(7) The Team Administrator along with the Food Manager shall interview the inmate to confirm what request, if any, the inmate may have for a last meal as noted on the CDCR Form 1801-D (10/15), Last Meal Request.

(A) Accommodations for the last meal shall be reasonable and not exceed a fifty dollar (\$50.00) limit.

(B) The Food Manager shall determine if food services can fulfill the request or make arrangements to obtain the requested menu items.

The ISR explains the purpose and necessity for this provision as follows:

**New Subsections 3349.6(d)(7) through 3349.6(d)(7)(B) are adopted** to establish provisions regarding the inmate's last meal and to establish that the Food Manager shall make a determination if food services can fulfill the request or if other arrangements need to be made. It is necessary to establish a cost limit for the meal to ensure fiscal responsibility with taxpayer dollars. It is also necessary to ensure food services can fulfill the request or make arrangements to obtain the requested menu items. [ISR at p. 33; bolding original.]

The Department has discretion to set limits on the inmate's last meal. However, while the above language from the ISR explains the purpose of placing a \$50.00 limit on the last meal, there is no evidence or explanation demonstrating how the Department determined that this \$50.00 limit ensures "fiscal responsibility with taxpayer dollars." The Department's conclusory statement does not demonstrate by substantial evidence the need for the regulation, and therefore, does not satisfy the necessity standard.

**Issue 2.** Proposed section 3349.6, subdivision (h)(2)(B), provides:

A sedative is available upon request. If requested by the inmate, the sedative shall be administered under the direction and approval of a physician.

San Quentin State Prison Lethal Injection Team Administrator/Team Leader Execution Log, form CDCR 2181 (10/15), Step 4, includes a requirement to:

Inform the inmate that a sedative is available. Valium or its equivalent will be administered under the direction and approval of a clinician.

The Department's explanation for these provisions, as set forth in the ISR, provides:

**New Subsections 3349.6(h)(2) through 3349.6(h)(2)(B) are adopted** to establish the San Quentin Warden and the Team Administrator shall meet with the inmate in the Lethal Injection Facility Holding Area and advise the inmate that a written last statement can be prepared and made available after the execution. The inmate shall also be informed that a sedative is available upon request. This subsection is necessary to ensure the inmate is offered the opportunity to prepare a written last statement to express his or her thoughts, as well as to ensure the inmate is informed of the option to have a sedative available to the inmate upon request. [ISR at pp. 36-37; bolding original.]

The language in the ISR explaining the necessity for these provisions is a restatement of the purpose of the regulation, to wit, "to ensure the inmate is informed of the option to have a sedative." There is no rationale provided for why a sedative is being made available to the inmate at this point in the execution process. Moreover, there is no discussion of why the Department has chosen "Valium or its equivalent" as the options available to the inmate for a sedative. The Department's explanation does not demonstrate by substantial evidence the need for the regulation, and therefore, does not satisfy the necessity standard.

**Issue 3.** Proposed section 3349.6, subdivision (h)(3), provides the following with regard to the preparation of the Lethal Injection Chemical:

(3) Preparation of the Lethal Injection Chemical shall be as follows:

(A) The Lethal Injection Chemical that has been designated pursuant to Subsection 3349.5(f)(1)(C) shall be prepared for administration by means of five syringes. Each syringe shall contain 1.5 grams of the designated Lethal Injection Chemical for a total of 7.5 grams. A sixth syringe shall be prepared with a saline flush.

(B) The Infusion Sub-Team shall prepare the Lethal Injection Chemical as follows:

1. Three Identical trays shall be prepared. Each tray shall contain a total of 7.5 grams of the 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 colored-coded blue and shall be the backup tray.

4. Tray C shall be color-coded yellow and shall be the alternate backup tray.

(C) Trays A and B and C shall have six color-coded syringes each to match the tray and be labeled by content and sequence of administration as follows:

# 1 60cc syringe containing the specified amount of designated Lethal Injection Chemical.

# 2 60cc syringe containing the specified amount of designated Lethal Injection Chemical.

# 3 60cc syringe containing the specified amount of designated Lethal Injection Chemical.

# 4 60cc syringe containing the specified amount of designated Lethal Injection Chemical.

# 5 60cc syringe containing the specified amount of designated Lethal Injection Chemical.

# 6 60cc syringe containing saline flush.

(D) The Lethal Injection Chemical shall be mixed according to the manufacturer's instructions.

**Issue 3.1. Use of 7.5 grams of Lethal Injection Chemical:** Subdivision (h)(3)(A) of section 3349.6 provides for the preparation of a total of 7.5 grams of the Lethal Injection Chemical. The rationale provided in the ISR states as follows:

**New Subsections 3349.6(h)(3) through 3349.6(h)(3)(E) are adopted** to establish how the designated Lethal Injection Chemical is labeled for each tray with the corresponding total amount of Lethal Injection Chemical to utilize and the amount of Lethal Injection Chemical each syringe shall contain. Each tray is comprised of five syringes each containing 1.5 grams of the designated Lethal Injection Chemical. A sixth syringe shall be prepared containing saline. 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; **bolding original.**]

The explanation provided in the ISR and the identified documents relied upon 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 dosage amount to 7.5 grams, which is 2.5 grams greater than the stated lethal dosage, is not supported by substantial evidence. While the ISR states that "CDCR chose to increase the dosage to 7.5 grams to take into account Lethal Injection Chemical tolerance, size or weight of the inmate" there is no explanation in the record to demonstrate that a 2.5 gram increase is necessary to address these potential variables. For example, what evidence is the Department relying on in determining that, for each of the four listed barbiturates, successful administration of 5 grams may be insufficient to result in a lethal dose? Similarly, assuming there is a need to increase the amount of Lethal Injection Chemical to account for these variables, what is the basis for increasing the dosage for each of the four listed barbiturates by 2.5 grams? The Department's explanation does not demonstrate by substantial evidence the need for the regulation, and therefore, does not satisfy the necessity standard.

**Issue 3.2. Preparation of Syringes.** Proposed section 3349.6, subdivision (h)(3)(C), requires preparation of three trays (A, B and C) using five “60 cc syringe[s] containing the specified amount of designated Lethal Injection Chemical.” The rationale for preparing the syringes in this manner is as follows:

The Infusion Sub-Team shall prepare three identical trays which shall be color coded and lettered A, B, or C for distinction. The three color-coded trays shall have six color-coded syringes each to match the tray and be labeled by content and numbered sequence of administration, i.e. five separate 60cc syringes, each containing the specified amount of designated Lethal Injection Chemical and one 60cc syringe containing the saline flush. A saline flush is necessary to ensure that the Lethal Injection Chemical is fully delivered through the IV tubing. The Lethal Injection Chemical shall be prepared according to the manufacturer’s instructions. The syringes on each tray shall be prepared by a medically trained Infusion Sub-Team member and a separate medically trained Infusion Sub-Team or Intravenous Sub-Team member shall verify proper preparation of the syringes for each tray.

This subsection is necessary to ensure the preparation and verification of the Lethal Injection Chemical is completed by medically-trained Lethal Injection Team staff members according to the manufacturer’s instructions, thus ensuring the Lethal Injection Chemical is ready for proper administration consistent with these regulations. Additionally, these provisions are necessary to ensure accountability and establish the procedures for the proper preparation of the Lethal Injection Chemical. The color coding and lettering of the Lethal Injection Chemical trays is necessary to visually aid in distinguishing the primary, backup and alternate backup. [ISR at p37.]

The record does not explain why or how the Department determined that five 60cc syringes are necessary for administration of 7.5 grams of each of the four barbiturates identified as a Lethal Injection Chemical if selected for use in an execution. Do the manufacturer’s instructions (as referenced in subdivision (h)(3)(D)) for each of the four listed barbiturates require or recommend use of a specified size and number of syringes, such as five 60cc syringes? The Department’s explanation does not demonstrate by substantial evidence the need for the regulation, and therefore, does not satisfy the necessity standard.

### **FAILURE TO FOLLOW APA PROCEDURES**

**Issue 1. Final Statement of Reasons - Summary and Response to Comments.** Government Code section 11346.9, subdivision (a)(3), provides:

Every agency subject to this chapter shall do the following:

(a) Prepare and submit to the office with the adopted regulation a final statement of reasons that shall include all of the following:

...

(3) A summary of each objection or recommendation made regarding the specific adoption, amendment, or repeal proposed, together with an explanation of how the proposed action has been changed to accommodate each objection or recommendation, or the reasons for making no change. This requirement applies only to objections or recommendations specifically directed at the agency's proposed action or to the procedures followed by the agency in proposing or adopting the action. The agency may aggregate and summarize repetitive or irrelevant comments as a group, and may respond to repetitive comments or summarily dismiss irrelevant comments as a group. For the purposes of this paragraph, a comment is "irrelevant" if it is not specifically directed at the agency's proposed action or to the procedures followed by the agency in proposing or adopting the action.

The Department's rulemaking record includes over 35,000 written comments received in response to this rulemaking. While the vast majority of the comments were properly summarized and responded to, some of the of the comments were either not included in the FSR or were not adequately responded to. Examples of such comments are set forth below. Upon resubmission, all comments must be adequately summarized and responded to.

**Example 1.** Issue (5), in comments 3134-3136, as set forth in the FSR, states the following:

Drug Experimentation: The regulations name two drugs (amobarbital and secobarbital) that have never been used in lethal injection. If the CDCR is planning to resume executions, it should at the very least not be using methods that are untested and poorly understood. I do not support my tax dollars being used in this type of "innovation," which amounts to nothing more than human experimentation. [FSR at Exh. B, p. 52.]

The Department's response states:

**Response:** The United States Supreme Court noted in *Glossip v. Gross* (2015) U.S., [135 S.Ct 2726, 2732-2733], that decisions in this area of law recognize that because it is settled that capital punishment is constitutional, "[i]t necessarily follows that there must be a [constitutional] means of carrying it out." quoting *Baze v. Rees* (2008) 553 U.S. 35, 47. While *Baze* upheld the most common three-drug protocol that states use to carry out the death penalty as constitutional, the United States Supreme Court pointed out that, by upholding the three-drug protocol, they were not saying that other protocols or methods of execution were unconstitutional and that adoption of that argument would hamper the adoption of new and potentially more humane methods of execution and prevent States from adapting to changes in the availability of suitable drugs. *Id.* At 2745. CDCR considers the listed chemicals equally effective in carrying out the purpose of the proposed lethal injection regulations. Accommodation: None. [FSR at Exh. B, p. 52.]

The Department's response does not address the issue of using "methods that are untested and poorly understood" or "human experimentation" as it pertains to the use of amobarbital and

secobarbital for lethal injection purposes as raised by the commenter. The response does not include the reason for making no changes to the regulations as required by Government Code section 11346.9, subdivision (a), and is therefore inadequate.

**Example 2.** Comment letter 30713 states the following:

**30713(2)**

Specifically, I am concerned about the following in the new proposed regulations. The regulations: • Lack safeguards to prevent the execution of inmates who suffer from severe mental illness or other problems that could render them legally incompetent to be executed.

**Response:** Prior to promulgating regulations, CDCR referred to its lethal injection procedures as Operational Procedure 770. Operational Procedure 770 was reviewed by the court in *Morales v. Tilton* (N.D. Cal. 2006) 465 F.Supp.2d 972. In December 2006, the Morales court issued a memorandum of intended decision and found that, while "Defendants' implementation of the lethal injection is broken, it can be fixed." Although the rest of the comment does pertain to some aspect of the proposed regulations, the comment is of such a generalized nature that no meaningful response can be formulated to refute or accommodate the comment. Accommodation: None. [FSR at Exh. H, p. 1031.]

The Department's response to comment 30713(2) does not address the commenter's concerns regarding a "Lack safeguards to prevent the execution of inmates who suffer from severe mental illness or other problems that could render them legally incompetent to be executed." The response is nonresponsive and inadequate.

**Example 3.** Comment number 30834 (7) states that the proposed regulations:

Discriminate against non-religious/non-spiritual inmates by failing to allow special visitation for non-religious/nonspiritual advisor or counselor. [FSR at Exh. H, pp. 1616-1617.]

In response, the Department discusses a number of various procedural issues, including transportation of female inmates and restrictions in the hours leading up to the execution, however, the Department does not address the specific issue raised by the commenter regarding failing to allow special visitation for a non-religious/non-spiritual advisor. Although lengthy, the Department's response is non-responsive and inadequate.

**Example 4.** Comment 30398 (5) states:

5. CDCR should electronically send a copy of the Alienist report to counsel immediately upon receipt of the report from the Alienist, without a request from counsel. [FSR at Exh. G, p. 419.]

The Department's response to this comment includes a lengthy description of the Alienist's role and the procedures used to determine the sanity of the inmate, however, the response does not

provide an explanation for why the Department is rejecting the commenter's request to include language in the regulations to require the Department to electronically send a copy of the Alienist report to counsel immediately upon receipt of the report from the Alienist, without a request from counsel. The Department's response is non-responsive and inadequate.

**Example 5.** Comment 30403 (46) states:

The Proposed Regulations Are Not Supported by an Adequate Record. The Initial Statement of Reasons provided by CDCR describes the effect of the proposed regulations but fails to provide information explaining the need for each of the provisions in the proposed text. In order to provide the public with an opportunity to review and comment upon an agency's proposal as well as whether the proposed action truly represents the more effective and less burdensome manner for fulfilling the need the agency is seeking to address, the APA requires the agency to: (1) provide an estimate of cost or savings, with supporting data; (2) provide a description of reasonable alternatives considered and the reasons for rejecting them; (3) provide supporting data for its initial determinations about adverse economic impacts on business; and (4) describe in the Initial Statement of Reasons why the proposed action is reasonably necessary to carry out the purpose for which it is proposed. [FSR at Exh. G, p. 907.]

The Department's response to this comment is as follows:

**Response:** Although the comment does pertain to some aspect of the proposed regulations, the comment is of such a generalized nature that no meaningful response can be formulated to refute or accommodate the comment. Accommodation: None. [FSR at Exh. G, p. 907.]

The Department's response to this comment is inadequate. The comment is directed at the rulemaking procedures followed by the Department because it is directed at the ISR and an alleged lack of necessity for the proposed regulations. The Department's response does not address the issue raised in this comment and does not provide any explanation for rejecting the comment.

**Example 6.** Comment 33802(4) states:

I'm concerned about the administration of these drugs by people who aren't sufficiently trained. [FSR at Exh. J, p. 2004.]

The Department's response is as follows:

**Response:** Capital punishment is an authorized sentence under the law and is constitutional *Glossip v. Gross* (June 29, 2015, No. 14-7955) 576 U.S. [135 S.Ct. 2726, 2732]. Penal Code §3600, et seq. authorizes the CDCR to carry out capital punishment sentences. CDCR has no authority to depart from existing law or change a conviction sentence. CDCR has no authority to

eliminate the death penalty. Although the comment does pertain to some aspect of the proposed regulations, the comment is of such a generalized nature that no meaningful response can be formulated to refute or accommodate the comment.  
Accommodation: None. [FSR at Exh. J, p. 2004.]

The Department's response to this comment is inadequate because it does not address the specific issue being raised by the commenter regarding the administration of lethal injection drugs by people who are not sufficiently trained. The comment is directed at the proposed regulations and the Department's response does not address any of the issues raised in this comment and does not provide any explanation for rejecting the comment.

**Issue 2. Incomplete Record.** Government Code section 11349.3, subdivision (b)(6), requires that the rulemaking record include all "data and other factual information, any studies or written reports, and written comments submitted to the agency in connection with the adoption, amendment, or repeal of the regulation." Although a summary and response has been provided in the FSR, copies of comments 23,200 through 23,260 and comment 30887 are not included in the record. Copies of these comments must be included in the rulemaking record.

**Issue 3. Final Statement of Reasons - Forms Incorporated by Reference.** When incorporating document by reference, CCR, title 1, section 20, subdivision (c) requires:

- (1) The agency demonstrates in the final statement of reasons that it would be cumbersome, unduly expensive, or otherwise impractical to publish the document in the California Code of Regulations.
- (2) The agency demonstrates in the final statement of reasons that the document was made available upon request directly from the agency, or was reasonably available to the affected public from a commonly known or specified source. In cases where the document was not available from a commonly known source and could not be obtained from the agency, the regulation shall specify how a copy of the document may be obtained.

The Department's FSR does not comply with this subdivision because it does not contain the necessary demonstrations as required. Upon resubmission, the Department will need to submit a revised FSR containing the necessary demonstrations.

**Issue 4. Authority and Reference Citations.** Government Code section 11346.2, subdivision (a)(2), requires that proposed text include "the specific statutes or other provisions of law being implemented, interpreted, or made specific" by the proposed regulations. The Authority citations listed for proposed section 3349.5 include case citations along with explanatory parentheticals. While case citations are permitted, such explanatory information is not a "provision of law" and therefore must be removed from the citations.



**CONCLUSION**

For the reasons set forth above, OAL has 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.

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

Date: December 28, 2016



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