

**STATE OF CALIFORNIA  
OFFICE OF ADMINISTRATIVE LAW**

In re:

DEPARTMENT OF PUBLIC HEALTH

REGULATORY ACTION:

Title 22, California Code of  
Regulations

DECISION OF DISAPPROVAL  
OF REGULATORY ACTION  
(Gov. Code, sec. 11349.3)

OAL File No. 2009-0827-02S

AMEND SECTIONS: 70055, 70577, 70703,  
70706, 70707, 70717, 70749, 70751, 70753,  
71053, 71203, 71205, 71503, 71507, 71517,  
71545, 71551, 71553, 72091, 72109, 72303,  
72311, 72315, 72319, 72337, 72413, 72423,  
72433, 72453, 72461, 72471, 72515, 72523,  
72525, 72528, 72543, 72547, 73077, 73089,  
73301, 73303, 73311, 73313, 73315, 73325,  
73329, 73399, 73409, 73449, 73469, 73479,  
73489, 73517, 73519, 73523, 73524, 73543,  
73547, 79315, 79351, 79637, AND 79689

**SUMMARY OF REGULATORY ACTION**

The Department of Public Health (Department) proposed to amend existing regulations contained in title 22 of the California Code of Regulations relating to the scope of practice in General Acute Care Hospitals, Acute Psychiatric Hospitals, Skilled Nursing Facilities, Intermediate Care Facilities, and Chemical Dependency Rehabilitation Hospitals.

**DECISION**

On October 9, 2009, the Office of Administrative Law (OAL) disapproved the above referenced regulatory action for the following reasons: failure to comply with the consistency and clarity standards of Government Code section 11349 and for failure to make a change to the regulations available as required by Government Code section 11346.8(c) and section 44 of title 1 of the California Code of Regulations.

**DISCUSSION**

The adoption of regulations by the Department must satisfy requirements established by the part of the California Administrative Procedure Act (APA) that governs rulemaking by a state agency. Any rule or 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 rule or regulation subject to the APA may become effective, the rule or 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 the standards a rule or 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 rules and regulations that implement, interpret, and make specific statutory law, and to ensure that the public is provided with a meaningful opportunity to comment on rules and regulations before they become effective.

### 1. CONSISTENCY/CLARITY

OAL is mandated to review each regulation adopted pursuant to the APA to determine whether the regulation complies with the “consistency” standard. (Gov. Code, sec. 11349.1(a)(4).) “Consistency” as defined by Government Code section 11349(d) means “being in harmony with, and not in conflict with or contradictory to, existing statutes, court decisions, or other provisions of law.”

OAL is also mandated to review each regulation adopted pursuant to the APA to determine whether the regulation complies with the “clarity” standard. (Gov. Code, sec. 11349.1(a)(3).) “Clarity” as defined by Government Code section 11349(c) means “written or displayed so that the meaning of regulations will be easily understood by those persons directly affected by them.”

The following changes fail to comply with the consistency and/or clarity standards:

- a. Subsection (a) of section 70703 of title 22 as proposed to be amended by this rulemaking would have provided:

Each hospital shall have an organized medical staff responsible to the governing body for the adequacy and quality of the care rendered to patients **subject to the bylaws, rules and regulations of the hospital.** (Emphasis added.)

Subsection (a) of section 71503 of title 22 as proposed to be amended by this rulemaking would have provided:

Each hospital shall have an organized medical staff responsible to the governing body for the fitness, adequacy and quality of the care rendered to patients **subject to the bylaws, rules and regulations of the hospital.** (Emphasis added.)

Section 2282 of the Business and Professions Code provides:

**The regular practice of medicine in a licensed general or specialized hospital having five or more physicians and surgeons on the medical staff, which does not have rules established by the board of directors thereof to govern the operation of the hospital, which rules include, among other provisions, all the following, constitutes unprofessional conduct:**

(a) Provision for the organization of physicians and surgeons licensed to practice in this state who are permitted to practice in the hospital into a formal medical staff with appropriate officers and bylaws and with staff appointments on an annual or biennial basis.

(b) Provision that membership on the medical staff shall be restricted to physicians and surgeons and other licensed practitioners competent in their respective fields and worthy in professional ethics. In this respect the division of profits from professional fees in any manner shall be prohibited and any such division shall be cause for exclusion from the staff.

**(c) Provision that the medical staff shall be self-governing with respect to the professional work performed in the hospital; that the medical staff shall meet periodically and review and analyze at regular intervals their clinical experience; and the medical records of patients shall be the basis for such review and analysis.**

(d) Provision that adequate and accurate medical records be prepared and maintained for all patients. (Emphasis added.)

As proposed to be revised by this rulemaking, sections 70703(a) and 71503(a) would have provided that each hospital shall have organized medical staff responsible for the adequacy and quality of the care rendered to patients subject to the bylaws, rules and regulations of the hospital. As worded, the adequacy and quality of the patient care would appear to be subject to the bylaws, rules and regulations of the hospital. This would conflict with the requirement in Business and Professions Code section 2282(c) that the medical staff be self-governing with respect to the professional work performed in the hospital and be a violation of the "consistency" standard of the APA. One could argue that, since Business and Professions Code section 2282 requires the rules of the hospital to include a provision that the medical staff shall be self-governing in this regard, there is no conflict between revised sections 70703(a) and 71503(a) and Business and Professions Code section 2282. This is not at all clear in the text of the regulations, however. A person directly affected by sections 70703(a) and 71503(a) would not easily understand from the regulations, as proposed to be revised, that the hospital rules cannot govern the professional work performed at the hospital by the medical staff and would result in a violation of the "clarity" standard of the APA.

- b. Subsection (i)(2) of section 72319 of title 22 as proposed to be amended by this rulemaking would have added the word "psychologist" as follows:

Physical restraints for behavior control shall only be used on the signed order of a physician, **psychologist**, or other person lawfully authorized to prescribe care....  
(Emphasis added).

Section 1180.4(e) of the Health and Safety Code provides:

- (1) A facility described in subdivision (a) of Section 1180.2 or subdivision (a) of Section 1180.3 may not use prone mechanical restraint on a person at risk for positional asphyxiation as a result of one of the following risk factors that are known to the provider:
  - (A) Obesity.
  - (B) Pregnancy.
  - (C) Agitated delirium or excited delirium syndromes.
  - (D) Cocaine, methamphetamine, or alcohol intoxication.
  - (E) Exposure to pepper spray.
  - (F) Preexisting heart disease, including, but not limited to, an enlarged heart or other cardiovascular disorders.
  - (G) Respiratory conditions, including emphysema, bronchitis, or asthma.
- (2) **Paragraph (1) shall not apply when written authorization has been provided by a physician**, made to accommodate a person's stated preference for the prone position or because the physician judges other clinical risks to take precedence. The written authorization may not be a standing order, and shall be evaluated on a case-by-case basis by the physician. (Emphasis added.)

As proposed by this rulemaking, section 72319(i)(2) authorizes physical restraint for behavior control on the signed order of a psychologist without specifying any limitation. This would conflict with Health and Safety Code section 1180.4(e) with respect to prone mechanical restraint for those persons at risk of positional asphyxiation as a result of the risk factors specified in the statute. Pursuant to Health and Safety Code section 1180.4(e)(2), written authorization from a physician is required in those instances. Even if one were to argue that there is no violation of the "consistency" standard of the APA since the more specific statute would take precedence over the more general regulation, the revision to the regulation would still be in violation of the "clarity" standard. A person reading section 72319(i)(2) of title 22 as proposed to be revised by this rulemaking would not understand from the regulation that a signed order from a psychologist will not authorize physical restraints for behavior control in all instances.

**2. THE REGULATIONS SUBMITTED TO OAL FOR FILING WITH THE SECRETARY OF STATE CONTAIN A CHANGE THAT WAS NOT MADE AVAILABLE TO THE PUBLIC**

Subdivision (c) of Government Code section 11346.8 requires that substantial changes to the original text be made available to the public for comment before the changes are adopted:

No state agency may adopt, amend, or repeal a regulation which has been changed from that which was originally made available to the public pursuant to section 11346.5, unless the change is (1) nonsubstantial or solely grammatical in nature, or (2) sufficiently related to the original text that the public was adequately placed on notice that the change could result from the originally proposed regulatory action. **If a sufficiently related change is made, the full text of resulting adoption, amendment, or repeal, with the change clearly indicated, shall be made available to the public for at least 15 days before the agency adopts, amends or repeals the resulting regulation.** Any written comments received regarding the change must be responded to in the final statement of reasons required by Section 11346.9. (Emphasis added.)

Section 44 of title 1 of the California Code of Regulations specifies how such sufficiently related changes are to be made available:

(a) At least 15 calendar days prior to the adoption of a change to a regulation required to be made available to the public by Government Code section 11346.8(c), the rulemaking agency shall mail a notice stating the period within which comments will be received together with a copy of the full text of the regulation as originally proposed, with the proposed change clearly indicated, to the following:

- (1) all persons who testified at the public hearing; and
  - (2) all persons who submitted written comments at the public hearing; and
  - (3) all persons whose comments were received by the agency during the public comment period; and
  - (4) all persons who requested notification from the agency of the availability of such changes.
- (b) The rulemaking record shall contain a statement confirming that the agency complied with the requirements of this section and stating the date upon which the notice and text were mailed and the beginning and ending dates for this public availability period.

The text of the regulations submitted to OAL for filing with the Secretary of State in this rulemaking contained a change from the texts that were made available to the public during the initial 45 day and subsequent 15 day comment periods.

Existing section 70577(d)(2) of title 22 provides in part:

Medical examinations shall be performed as often as indicated by the medical needs of the patient as determined by the patient's attending psychiatrist....

The text made available to the public during the initial 45 day comment period provided:

Medical examinations shall be performed as often as indicated by the medical needs of the patient as determined by the patient's attending psychiatrist or psychologist....

Following the receipt of public comment on this change, the text made available during the additional 15 day comment period provided:

Medical examinations shall be performed as often as indicated by the medical needs of the patient as determined by the patient's attending licensed healthcare practitioner acting within the scope of his or her licensure....

Following the receipt of public comment on this 15 day change, the final text submitted to OAL in this rulemaking for review and filing with the Secretary of State provides simply:

Medical examinations shall be performed as often as indicated by the medical needs of the patient....

This final version of section 70577(d)(2) submitted to OAL eliminates the language specifying who makes the determination of how often medical examinations are to be performed based on the medical needs of the patient. This change has substance and must be made available for comment pursuant to Government Code section 11346.8(c) and section 44 of title 1 of the California Code of Regulations.

### CONCLUSION

For the reasons set forth above, OAL has disapproved this regulatory action. Please also note that there are some minor discrepancies in the text submitted to OAL in this rulemaking for filing with the Secretary of State from the existing text in the California Code of Regulations in (1) the authority and reference citations for section 70055, (2) the authority citations for section 70707, (3) the reference citations for section 71053, and (4) the word "contact" should be underlined in section 79637(e)(6). The rulemaking file should also include a copy of the brief notice extending the deadline for the 15 day comment period. If you have any questions, please contact me at (916) 323-6808.

Date: October 14, 2009

**CRAIG TARPENNING**

---

CRAIG S. TARPENNING  
Senior Staff Counsel

for: SUSAN LAPSLEY  
Director

Original: Mark Horton  
cc: Barbara Gallaway