

**STATE OF CALIFORNIA
OFFICE OF ADMINISTRATIVE LAW**

In re:)	
)	
BOARD OF PHARMACY)	DECISION OF DISAPPROVAL OF REGULATORY ACTION
)	
)	(Gov. Code, sec. 11349.3)
REGULATORY ACTION:)	
Title 16,)	
California Code of Regulations)	
(CCR))	OAL File No. 04-0308-01 S
ADOPT: 1751.01, 1751.02,)	
)	
AMEND: 1751, 1751.2, 1751.3,)	
1751.4, 1751.5, 1751.6,)	
1751.7, 1751.9)	
)	
REPEAL: 1751.8)	
_____)	

DECISION SUMMARY

This action implements SB 293 (Chap. 827, Stats. 2001) by establishing required standards for compounding injectable sterile drug products.

On April 20, 2004, the Office of Administrative Law (“OAL”) disapproved the proposed adoption, amendment and repeal of the above-cited sections in Title 16, California Code of Regulations (“CCR”) for failing to follow the procedures required by the Administrative Procedure Act (“APA”).

DISCUSSION

Regulations adopted by the Board of Pharmacy (“Board”) must be adopted pursuant to the APA. See Business and Professions Code section 4005. Any regulatory act a state agency adopts through the exercise of quasi-legislative power delegated to the agency by statute is subject to the APA unless a statute expressly exempts or excludes the act from the requirements of the APA. (Gov. Code section 11346.) No exemption or exclusion applies to the regulatory action here under review. Thus, before the instant regulatory action may become effective, OAL must review it for compliance with both the procedural requirements of the APA and certain substantive standards.

A. PROCEDURE

The Department’s rulemaking file fails to comply with the requirements of Government Code section 11343(e) which states in pertinent part:

“Every state agency shall:

. . . .

(e) Transmit to the California Building Standards Commission for approval a certified copy of every regulation, or order of repeal of a regulation, that is a building standard, together with a citation of authority pursuant to which it or any part thereof was adopted, a copy of the notice of proposed action required by Section 11346.4, and any other records prescribed by the State Building Standards Law (Part 2.5 (commencing with Section 18901) of Division 13 of the Health and Safety Code).” [Emphasis added.]

“Building standard” is defined in Health and Safety Code section 18909 as:

“§ 18909. “Building standard”

(a) “Building standard” means any rule, regulation, order, or other requirement, including any amendment or repeal of that requirement, that specifically regulates, requires, or forbids the method of use, properties, performance, or types of materials used in the construction, alteration, improvement, repair, or rehabilitation of a building, structure, factory-built housing, or other improvement to real property, including fixtures therein, and as determined by the commission.

(b) Except as provided in subdivision (d), “building standard” includes architectural and design functions of a building or structure, including, but not limited to, number and location of doors, windows, and other openings, stress or loading characteristics of materials, and methods of fabrication, clearances, and other functions.

(c) “Building standard” includes a regulation or rule relating to the implementation or enforcement of a building standard not otherwise governed by statute, but does not include the adoption of procedural ordinances by a city or other public agency relating to civil, administrative, or criminal procedures and remedies available for enforcing code violations.

(d) “Building standard” does not include any safety regulations that any state agency is authorized to adopt relating to the operation of machinery and equipment used in manufacturing, processing, or fabricating, including, but not limited to, warehousing and food processing operations, but not including safety regulations relating to permanent appendages, accessories, apparatus,

appliances, and equipment attached to the building as a part thereof, as determined by the commission.

(e) “Building standard” does not include temporary scaffoldings and similar temporary safety devices and procedures, that are used in the erection, demolition, moving, or alteration of buildings.

(f) “Building standard” does not include any regulation relating to the internal management of a state agency.

(g) “Building standard” does not include any regulation, rule, order, or standard that pertains to mobilehomes, manufactured homes, commercial coaches, special purpose commercial coaches, or recreational vehicles.

(h) “Building standard” does not include any regulation, rule, or order or standard that pertains to a mobilehome park, recreational vehicle park, temporary recreational vehicle park, or travel trailer park, except that "building standard" includes the construction of permanent buildings and plumbing, electrical, and fuel gas equipment and installations within permanent buildings in mobilehome parks, recreational vehicle parks, temporary recreational vehicle parks, or travel trailer parks. For purposes of this subdivision, “permanent building” means any permanent structure constructed in the mobilehome park, recreational vehicle park, temporary recreational vehicle park, or travel trailer park that is a permanent facility under the control and ownership of the park operator.

(i) “Building standard" does not include any regulation, rule, order, or standard that pertains to mausoleums regulated under Part 5 (commencing with Section 9501) of Division 8.

(j) “Building standard” does not include any regulation adopted by the California Integrated Waste Management Board, the Department of Toxic Substances Control, the Occupational Safety and Health Standards Board, or the State Water Resources Control Board concerning the discharge of waste to land or the treatment, transfer, storage, resource recovery, disposal, or recycling of the waste.”

The proposed regulatory action includes amendments to sections which clearly involve a “building standard” as defined in Health and Safety Code section 18909. Proposed amendments to section 1751 include updating the Board’s existing Title 24 references to “Clean Room and Work Station Requirements” and Title 24 Mechanical Code ventilation requirements for designated areas used for preparation of sterile injectable products. Title 24 of the California Code of Regulations is reserved solely for printing of California Building Standards and is maintained by the California Building Standards Commission. In addition, the adoption of proposed section 1751.01 involves the addition of facility and equipment standards for sterile injectable compounding from non-sterile ingredients environments. Proposed section 1751.01 mandates the following for those “environments”:

“(a) On and after January 1, 2005 this subdivision shall apply to any pharmacy compounding sterile injectable products from one or more non-sterile ingredients.

The aseptic processing of such products shall occur in one of the following environments:

- (1) A class 100 laminar airflow hood within a class 10,000 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas.
- (2) A class 100 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas.
- (3) A barrier isolator that provides a class 100 environment for compounding.”

The references to a “class 100 laminar airflow hood,” a “class 10,000 cleanroom,” and a “class 100 cleanroom” also seem to fall within the definition of a “building standard” in Health and Safety Code section 18909(a). Neither the proposed amendments to section 1751 or the proposed adoption of additional potential building standards in section 1751.01 were submitted to the California Building Standards Commission for approval as required by Government Code section 11343. This is a procedural violation of APA requirements. In addition, Health and Safety Code section 18942.1 prohibits OAL from filing with the Secretary of State any “. . . building standard improperly transmitted to the Office of Administrative Law. . .” and instead directs OAL to “transmit the building standard to the commission and notify the adopting agency of this action.” OAL is complying with this mandate by copying this APA disapproval decision to the California Building Standards Commission.

CONCLUSION

For the reasons set forth above, OAL has disapproved the adoption, amendment, and repeal of the above-cited sections of Title 16 of the CCR. If you have any questions, please contact me at (916) 323-8916.

Date: April 27, 2004

GORDON R. YOUNG
Senior Staff Counsel

For:

EDWARD G. HEIDIG
Director

Original: Patricia Harris, Executive Officer

cc: Paul Riches

cc: Stan Nishimura, Executive Director, California Building Standards Commission