

Agenda Item C1

Regulation Update

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Memorandum

To: Legislation & Regulation Committee

Date: January 19, 2006

From: Jan E. Perez
Legislation and Regulation Coordinator

Subject: Regulation Update

NO ACTION

Board Approved – Pending Administrative Approval

On October 25, 2005 the board approved CCR 1727.1 to exclude the posting of pharmacist intern addresses on the Internet. This proposed regulation is currently undergoing administration review. It is anticipated that this regulation will be effective in late spring 2006.

Board Approved - Awaiting Notice

Repeal CCR 1717.2, Notice of Electronic Prescription Files. The purpose for repealing the regulation is to remove a barrier that prevents pharmacists, in certain situations, from having full knowledge of all the prescription drugs that a patient is taking. Removing this barrier will result in better patient care while protecting patient medical record privacy. Staff is in the process of drafting the Initial Statement of Reasons and Notice documents so action can be taken at the April 2006 board meeting.

Amend CCR 1760, Disciplinary Guidelines. This rulemaking would allow the board to use the 2006 revision of the Disciplinary Guidelines when deciding appropriate discipline action to take for violations of Pharmacy Law. Staff anticipates it will complete its final internal review of the guidelines by the end of January 2006. At that time the Guidelines will be ready for public notice and the formal start of the rulemaking process. The mater will be brought before the board at the board's April 2006 meeting.

Add CCR 1784, Self-Assessment of a Wholesaler by the Designated Representative-In-Charge. Staff has completed its internal review of the assessment form. It will be publicly noticed and brought to the board for action at the board's April 2006 meeting.

Attached is a copy of the specific language for each proposed regulation awaiting notice.

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Board of Pharmacy
Specific Language for Repeal of Section 1717.2

Repeal Section 1717.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~§1717.2. Notice of Electronic Prescription Files.~~

~~(a) Any pharmacy which establishes an electronic file for prescription records, which is shared with or accessible to other pharmacies, shall post in a place conspicuous to and readily readable by prescription drug consumers a notice in substantially the following form:~~

~~NOTICE TO CONSUMERS:~~

~~This pharmacy maintains its prescription information in an electronic file which is shared by or accessible to the following pharmacies:~~

~~By offering this service, your prescriptions may also be refilled at the above locations. If for any reason you do not want your prescriptions to be maintained in this way, please notify the pharmacist in charge.~~

~~(b) Whenever a consumer objects to his or her prescription records being made accessible to other pharmacies through use of electronic prescription files, it is the duty of the pharmacy to assure that the consumer's records are not shared with or made accessible to another pharmacy, except as provided in Section 1764. The pharmacist to whom the consumer communicated the objection shall ask the consumer to sign a form which reads substantially as follows:~~

~~I hereby notify (name of pharmacy) that my prescription drug records may not be made accessible to other pharmacies through a common or shared electronic file.~~

~~_____ (date) _____ (signature of patient)~~
~~_____ (acknowledgment of pharmacist)~~

~~The pharmacist shall date and co-sign the form, and shall deliver a copy thereof to the patient. The original shall be maintained by the pharmacy for three years from the date of the last filling or refilling of any prescription in the name of the consumer.~~

~~Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.~~

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Board of Pharmacy
Specific Language to Amend Section 1760

Amend Section 1760 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1760. Disciplinary Guidelines.

In reaching a decision on a disciplinary action under the Administrative Procedure Act (Government Code section 11400 et seq.) the board shall consider the disciplinary guidelines entitled "Disciplinary Guidelines" (Rev. 1/~~2004~~ 2006), which are hereby incorporated by reference.

Deviation from these guidelines and orders, including the standard terms of probation, is appropriate where the board, in its sole discretion, determines that the facts of the particular case warrant such a deviation--the presence of mitigating factors; the age of the case; evidentiary problems.

Authority cited: Section 4005, Business and Professions Code; and Section 11400.20, Government Code. Reference: Sections 4300 and 4301, Business and Professions Code; and Sections 11400.20 and 11425.50(e), Government Code.

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Board of Pharmacy
Specific Language to Add Section 1784

Add Section 1784 to Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1784. Self-Assessment of a Wholesaler by the Designated Representative-in-Charge.

(a) The designated representative-in-charge of each wholesaler as defined under section 4022.5 of the Business and Professions Code shall complete a self-assessment of the wholesaler's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the designated representative-in-charge shall complete a self-assessment within 30 days whenever:

(1) A new wholesaler permit has been issued, or

(2) There is a change in the designated representative-in-charge, and he or she becomes the new designated representative-in-charge of a wholesaler.

(c) The components of this assessment shall be on Form M- (created 1/06) entitled "Wholesaler Dangerous Drugs & Dangerous Devices Self- Assessment which is hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.

(d) Each self-assessment shall be kept on file in the pharmacy for three years after it is performed.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4201, and 4160 Business and Professions Code.

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