California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Regulation Update

ACTION

Regulation Adoption to add 16 CCR §1727.1

Staff published a 45-day notice on August 16, 2005, to exclude the posting of pharmacist intern addresses on the Internet. The notice period ended on October 10, 2005. There were no changes or comments made to this language. Additionally, no hearing was requested. A copy of the Notice, Initial Statement of Reasons, and proposed language are in Attachment A.

The board needs to vote on whether to adopt this regulation. If adopted, the rulemaking package will be submitted for administrative review in October 2005; the regulation should be in place by early 2006.

ACTION

Regulation Adoption to repeal 16 CCR §1717(e) and to add 16 CCR 16, §1713

Staff published a 45-day notice on August 16, 2005, to establish requirements for the placement and use of secure prescription drop-off boxes and secure automated delivery devices. The notice period ended on October 10, 2005. The board held a regulation hearing at 1:30 today to accept additional public comment. A copy of the Notice, Initial Statement of Reasons, proposed language, and written public comment received by the board by October 10, 2005 are in Attachments A & B in the Regulation Hearing section of the board packet.

The board needs to vote on whether to adopt this regulation. If adopted, the rulemaking package will be submitted for administrative review in November 2005; the regulation should be in place by early 2006. If modifications to the language is made by the board, a 15-day comment period is required.

NO ACTION

Regulations Awaiting Notice

The Board has approved initiation of a rulemaking to repeal of 1717(e), Notice of Electronic Prescription File. The repeal of 1717(e) is currently awaiting notice. It will be released for the 45-day comment period before the January 2006, board meeting. (Attachment B)

Attachment A

TITLE 16. Board of Pharmacy

NOTICE IS HEREBY GIVEN that the Board of Pharmacy is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments relevant to the action proposed in writing. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the Board of Pharmacy at its office not later than 5:00 p.m. on October 10, 2005.

The board does not intend to hold a hearing in this matter. If any interested party wishes that a hearing be held, he or she must make the request in writing to the board. The request must be received in the board office not later than 5 p.m. on September 25, 2005.

The Board of Pharmacy, upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Pursuant to the authority vested by sections 4005 and 4100 of the Business and Professions Code, the Board of Pharmacy is considering changes to Division 17 of Title 16 of the California Code of Regulations as follows:

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Section 4005 of the Business and Professions Code grants the Board of Pharmacy authority to adopt regulations relating to the practice of pharmacy.

Section 1704 of the California Code of Regulations requires that each person holding a license to practice or engage in any activity in the State of California under any and all laws administered by the Board to file a proper and current residence address with the Board and to notify the board within 30 days of any and all changes of residence address.

The board proposes the adoption of section 1727.1 in Title 16 of the California Code of Regulations. This section concerns the posting of intern addresses on the World Wide Web or the Internet.

The purpose of the regulation is to specify that the board will not post pharmacy intern addresses on the World Wide Web or the Internet.

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None.

Nondiscretionary Costs/Savings to Local Agencies: None.

Local Mandate: None.

Cost to Any Local Agency or School District for Which Government Code Section 17561 Requires Reimbursement: None.

Business Impact: The Board of Pharmacy has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

Impact on Jobs/New Businesses: The Board of Pharmacy has determined that this regulatory proposal will not have a significant impact on the creation of jobs or new businesses or the elimination of jobs or existing businesses or the expansion of businesses in the State of California.

Cost Impact on Representative Private Person or Business: The Board of Pharmacy is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Effect on Housing Costs: None.

EFFECT ON SMALL BUSINESS

The Board of Pharmacy has made an initial determination that the proposed regulatory action would not have a significant adverse economic impact directly affecting small business. The Board of Pharmacy has made this determination because the proposed regulation does not affect business; the proposed regulation affects the internal operations of the board.

CONSIDERATION OF ALTERNATIVES

The Board of Pharmacy must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its attention would either be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposal described in this Notice.

Any interested person may present written statements relevant to the above determinations to the Board of Pharmacy at the above-mentioned address.

INITIAL STATEMENT OF REASONS AND INFORMATION

The Board of Pharmacy has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations and of the initial statement of reasons, and all of the information upon which the proposal is based, may be obtained upon request from the Board of Pharmacy at 400 R Street, Suite 4070, Sacramento, California 95814, or from the Board of Pharmacy Web site (www.pharmacy.ca.gov).

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file which is available for public inspection by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the web site listed below.

CONTACT PERSON

Any inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name:	Jan E. Perez
Address:	400 R Street, Suite 4070 Sacramento, CA 95814
Telephone No.:	(916) 445-5014 x 4016
Fax No.:	(916) 327-6308
E-Mail Address:	jan_perez@dca.ca.gov

The backup contact person is:

Name:	Virginia Herold
Address:	400 R Street, Suite 4070 Sacramento, CA 95814

Telephone No.: (916) 445-5014 x4005
Fax No.: (916) 327-6308
E-Mail Address: virginia_herold@dca.ca.gov

Website Access: Materials regarding this proposal can be found at www.pharmacy.ca.gov.

Board of Pharmacy

Initial Statement of Reasons

Subject Matter of Proposed Regulation: Intern Pharmacist Address

Sections Affected: Add 1727.1

Specific Purpose of the Proposed Changes:

The Board of Pharmacy proposes adding Section 1727.1 to the California Code of Regulations to exclude the posting of pharmacy intern (student) addresses on the internet.

Factual Basis/Rationale

The names, addresses, and board license numbers of board-licensed pharmacists, pharmacist interns, pharmacy technicians and exemptees are a mater of public record. In the past this information was made available to any one who made a written request to the board to verify license information including address of record. Since December 1, 2003, the board has posted this information in a searchable database on its web site. Given that the information is readily available to any one, the board advises licensees to use an address other than their home address, such as a work address or post office box.

While using an alternative address, such as a work address, is fairly easy for a pharmacist or pharmacy technician to provide, it is less practical for a pharmacy intern, who often works in several locations and for multiple employers as the intern completes his or her education and training. Consequently, pharmacy interns have requested the board remove intern addresses from the searchable database on the board's website and only make their addresses available to the public through a written request for such information.

Underlying Data

None.

Business Impact

This regulation will not have a significant adverse economic impact on businesses. This initial determination is based on the absence of testimony indicating adverse economic impact regarding this rulemaking proposal at the informational hearings held by the board.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

No reasonable alternative to the regulation would be either more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed regulation.

Board of Pharmacy
Specific Language

Adopt Section 1727.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1727.1 Intern Pharmacist Address.

The Board shall not make an intern pharmacist's address publicly available on "Internet," as defined by Business and Professions Code section 17538.

Note: Authority cited: Section 4005 and 4100, Business and Professions Code. Reference: Section 4005 and 4100 Business and Professions Code.

Attachment B

Notice of Electronic Prescription Files

Board of Pharmacy
Specific Language

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.~~