

TITLE 16. BOARD OF PHARMACY

NOTICE IS HEREBY GIVEN that the Board of Pharmacy (Board) 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 at its office not later than 5:00 p.m. on March 28, 2016.

Any person interested may present statements or arguments orally or in writing relevant to the action proposed at a hearing to be held April 13, 2016 at 10:00 a.m., at the University of Southern California – Orange County Center, 2300 Michelson Drive, Irvine, CA 92612

The Board, 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 section 4005 of the Business and Professions Code to implement, interpret, and make specific Title 21 Code of Federal Regulation sections 1304 and 1317, the Board is proposing to add and adopt Article 9.1, and Sections 1776, 1776.1, 1776.2, 1776.3, 1776.4, 1776.5, and 1776.6 of Division 17 of Title 16 of the California Code of Regulations as follows:

Informative Digest/Policy Statement Overview

The Board of Pharmacy (Board) proposes to add and adopt Article 9.1 and Sections 1776, 1776.1, 1776.2, 1776.3, 1776.4, 1776.5, and 1776.6 of Division 17 of Title 16 of the California Code of Regulations (CCR) for the purpose of adding to the Board's regulations specific requirements to allow pharmacies that wish to establish prescription drug take back services as part of the Board's efforts to combat prescription drug abuse within California for greater public safety.

Business and Professions Code (B&P) section 4001.1 specifies that protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. This section further states that whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

B&P section 4005 generally authorizes the Board to amend rules and regulations necessary for the protection of the public pertaining to the practice of pharmacy.

B&P section 4022 generally defines "dangerous drug" or "dangerous device" as any drug or device unsafe for self-use in humans or animals. California Health and Safety Code, Division 10, the California Uniform Controlled Substances Act, dealing with "controlled substances," a subset of dangerous and illicit drugs. There are five categories: Schedule 1 drugs are generally considered illicit and are rarely prescribed. Schedule II-V list controlled substances that are

prescribed to patients with specific controls on the prescribing and refilling of these substances because these substances are also more often abused than other medications. Controlled Substances in Schedules II-V are a subset of “dangerous drugs.”

B&P section 4037 generally defines “pharmacy” as any place licensed by the Board in which the practice of pharmacy is practiced.

B&P section 4110 generally defines the California licensing requirements to operate a pharmacy.

B&P section 4160 generally defines the California licensing requirements for wholesalers (distributors) and third-party logistics providers (reverse distributors).

Title 21, Code of Federal Regulations section 1304 and 1317 defines the Federal requirements for the disposal of controlled substances.

This proposal will allow pharmacies, hospitals/clinics with onsite pharmacies, distributors and reverse distributors licensed by the board and licensed skilled nursing facilities to offer drug take-back services. This proposal requires that licensees who elect to participate in drug take-back maintain specific records pursuant 16 CCR Section 1776 et seq and Title 21, CFR sections 1304 and 1317.

While licensees are not being mandated to provide drug take-back services, these regulations are necessary to provide regulatory oversight should the licensees elect to do so.

Anticipated Benefits of Proposal

This proposal will provide the public with options to dispose of unwanted, unused, or outdated prescription drugs. This will reduce the supply of controlled substances available for misuse and abuse without denying patient access for the medication. Approved entities that are licensed by the Board are permitted to engage in the collection of pharmaceutical drugs from ultimate users if they comply with the DEA and the Board’s regulations. Participation in a drug take-back service is voluntary.

Consistency and Compatibility with Existing State Regulations

During the process of developing these requirements, the Board has conducted a search of any similar regulations on this topic and has concluded that these regulations are neither inconsistent nor incompatible with existing state regulations.

Fiscal Impact Estimates

Fiscal Impact on Public Agencies Including Costs/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 Sections 17500
– 17630 Require Reimbursement: None

Business Impact:

The Board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. The Board has made an initial determination that the proposed regulatory action may affect approximately 1,000 business licensees consisting of pharmacies, hospitals/clinics with onsite pharmacies, distributors and reverse distributors licensed by the board.

As of June 30, 2015, the Board issued licenses to approximately 9,100 pharmacies, hospitals/clinics with onsite pharmacies, distributors and reverse distributors. The Board estimates that approximately 10% of business licensees will voluntarily participate in the drug take-back program. There are currently several drug take-back programs within California, two of those are programs in San Francisco County and Alameda County. Based on the number of licensees in those counties and the number of licensees participating in the county drug take-back programs, the Board determined that 8% of licensees are participating in those counties. Using this information, the Board made the estimate that a 10% participation rate is reasonable for determining the number of licensees that may voluntarily participate statewide.

In order to assess the cost impact that pharmacies, hospitals/clinics with onsite pharmacies, distributors and reverse distributors may incur to comply with the proposed regulations to participate in the drug take-back services, the Board contacted a few businesses that sell the equipment necessary to comply with the proposed regulation and the DEA's regulations.

If a licensee electing to participate in the drug take-back services selected the option to have a collection receptacle on site, it is estimated that the receptacle, the liners, and the shipment for destruction would cost between \$20.00 and \$200.00 a month depending on the frequency of the shipment of liners for the receptacle. There is no initial cost for the receptacle as it is included in the cost of the liners. This is an annual expense of between \$240.00 and \$2,400.00.

If a licensee electing to participate in the drug take-back services selected the mail-back option, the cost of the envelopes to provide to patients, which includes a pre-paid shipping label, will vary depending on the how much advertising is done to the public, how densely populated is the area around the store, how many other medication collection locations are there in the area, and where the envelopes are displayed in the store. The estimated cost of a box of 250 envelopes is \$1,050.00. A large pharmacy may require 1,000 envelopes a year, at a cost of \$4,200.00. While a small pharmacy may only require 250 envelopes a year.

In order to keep a pharmacy, hospital/clinic with onsite pharmacy open, a pharmacist is required to be present. According to the United States Bureau of Labor Statistics' May 2012 National Occupational Employment and Wage Estimates, the annual

average salary for a pharmacist in California is \$125,800. The estimated annual costs for this regulation range from \$240 to \$4,200. The estimated amount is less than 3% of the annual average pharmacist salary. The Board does not consider this to be a significant expense.

Cost Impact on Representative Private Person or Business:

The Board is not aware of any cost impacts that a representative private person would necessarily incur in reasonable compliance with the proposed action. The cost impacts that a representative business would necessarily incur in reasonable compliance with the proposed action and that are known to the Board are estimated to range from \$240 to \$4,200. The estimated amount is less than 1% to 3% of the annual average pharmacist salary and the Board does not consider this to be a significant expense

Effect on Housing Costs: None

Effect on Small Business:

While the Board does not have nor does it maintain data to define if any of its licensees (pharmacies) are a “small business” as defined in Government Code section 11342.610, the Board has made an initial determination that the proposed regulatory action would not have a significant adverse economic impact directly affecting small businesses. Again, the estimated annual costs for this regulation range from \$240 to \$4,200. The estimated amount is less than 1% to 3% of the annual average pharmacist salary.

Results of Economic Impact Assessment/Analysis:

Impact on Jobs/New Businesses:

The Board 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. For pharmacies that elect to provide drug take-back services, there may be a benefit of increased revenue by an increase in foot traffic within the business or an intangible benefit of improving public safety and good will in their community. A collector may also cease providing this service at any time. Therefore, the Board estimates that any cost in providing this voluntary service will be offset by the benefit and will have no economic impact.

Benefits of Regulation:

The Board has determined that this regulatory proposal will benefit the health and welfare of California residents, worker safety, and state's environment because the proposed regulation will reduce the amount of controlled substances available in California residences which will reduce the amount of drugs being misused and abused. According to the Substance Abuse and Mental Health Services Administration (SAMHSA), over 71 percent of opioids are obtained from family or friends, 5 percent of which were taken from a friend without asking. This will result in

improved health for Californians. If fewer people are misusing and abusing controlled substances, there may be a corresponding reduction in crimes seeking prescription medications. On-the-job accidents will decrease if fewer employees and/or co-workers are working under the influence of a controlled substance. Finally, providing drug take-back services will reduce the amount of controlled substances being disposed of by being flushed down the toilet or thrown out in the trash, where the drugs could contaminate lakes, rivers, streams, and soil.

Consideration of Alternatives

The Board 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, would be as effective and less burdensome to affected private persons than the proposal described in this Notice, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Any interested person may present statements or arguments in writing relevant to the above determinations at the address listed for the Contact Person.

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 any document incorporated by reference, 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 1625 N. Market Blvd., N219, Sacramento, California 95834, or from the Board of Pharmacy's website <http://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 website listed below.

Contact Person

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

Name: Lori Martinez
Address: 1625 N. Market Blvd., N219
Sacramento, CA 95834
Phone No.: (916) 574-7917
Fax No.: (916) 574-8618
E-Mail Address: Lori.Martinez@dca.ca.gov

The backup contact person is:

Name: Anne Sodergren
Address: 1625 N. Market Blvd., N219
Sacramento, CA 95834
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Website Access

Materials regarding this proposal can be found at the Board of Pharmacy's website:
www.pharmacy.ca.gov.