

TITLE 16: BOARD OF PHARMACY
FINAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: Nicotine Replacement Products.

Title 16 Sections Affected: Adopt 16 California Code of Regulations (“CCR”) Section 1746.2.

Updated Information

The Initial Statement of Reasons is included in this rulemaking file. The information contained therein accurately reflects the position of the Board of Pharmacy (“Board”) regarding the adoption of the above section, and is updated to include the following information. The Board’s notice indicated that the Board did not intend to hold a hearing on the matter, unless requested. No request for a hearing was received by the Board during the 45-day comment period.

Information Supplementing the Initial Statement of Reasons

Under the heading “Factual Basis/Rationale” (on page 2), the notification requirements of the protocol set out in this regulation are clarified. The notification paragraph at 16 CCR 1746.2(b)(6) was placed within the regulation to insure compliance with California Business and Professions Code (B&P) section 4052.9(a)(2), and increase patient safety. A patient’s primary care provider needs to be fully informed of all prescription medications the patient is receiving. The regulation requirement that pharmacists must notify health care providers, where possible, best achieves the goal of keeping a patient’s primary care provider informed of the patients medical history. Given that some patients will not have a regular primary care provider, yet would still benefit from nicotine cessation products, 16 CCR Section 1746.2(b)(6) reiterates the steps required in B&P section 4052.9(a)(2). Under the regulation, pharmacists providing patients who cannot provide contact information for, or do not have, a primary care provider can still be furnished nicotine cessation products. In those cases, the patient must be given a written record of the prescription drug and/or device, and advised to consult with an appropriate health care provider of their choice. As was mentioned in the Initial Statement of Reasons, the Board worked closely with the Medical Board in drafting the notification requirement within the regulation, and decided this would best serve both patients and their primary care physicians.

Under the heading “Factual Basis/Rationale” (on page 2), the documentation requirements of the regulation were only briefly discussed. 16 CCR Section 1746.2(b)(7) of the regulation reiterates established pharmacy practice, as set out in B&P section 4081, which requires pharmacists to maintain documentation of the sale of all dangerous drugs and/or dangerous devices (defined in B&P section 4022 as any medication or device that requires a prescription to obtain). Since pharmacists will be dispensing nicotine replacement products without a doctor’s prescription, the regulation reiterates the B&P section 4081 record-keeping requirements to clarify that the previous record-keeping requirements for nicotine replacement products still apply. The existing requirements cover not only the length of time to retain records (three (3) years), but also the means (entry into electronic or paper records as presently allowed under B&P section 4105 and 16 CCR Section 1707.1(a)(1)).

Under the heading “Factual Basis/Rationale” (on page 2), the training requirements of the protocol were briefly discussed. The Board reviewed materials on training programs from UC San Francisco’s Rxforchange program, the Accreditation Council for Pharmacy Education, and America’s Pharmacist , (the official magazine of the National Community Pharmacists Association) and decided that two (2) hours of an approved continuing education training program should be sufficient to prepare pharmacists to furnish nicotine replacement products. Board-approved continuing education programs, required in the regulation, are programs accredited by the accreditation agencies listed in 16 CCR Section 1732.05(a)(1) and (2). Given the increasing number of individuals obtaining health insurance, and the documented health benefits of stopping smoking, the demand for nicotine replacement products is likely to grow. Given this, it is foreseeable that the market will respond to increased demand with new nicotine cessation products and variations on existing products. The Board decided ongoing continuing education focused on smoking cessation therapy from an approved provider should be obtained at least once every two (2) years so that pharmacists are kept informed of newly developed products and smoking cessation therapies.

The “Factual Basis/Rationale” section in the Initial Statement of Reasons inadvertently did not mention the patient privacy requirements set out in the protocol at 16 CCR 1746.2(b)(9). 16 CCR Section 1764 clearly sets out that pharmacists are not to discuss or disclose information about patient prescriptions with anyone other than the prescriber and the patient, along with certain other enumerated persons. The Board decided it was prudent to emphasize that pharmacists furnishing nicotine replacement products are acting under the pharmacy or facility’s policies and procedures that ensure patient confidentiality and privacy.

Local Mandate

A mandate is not imposed on local agencies or school districts.

Small Business Impact

This regulation will not have a significant adverse economic impact on businesses. This determination was based on the absence of substantive comments and the lack of any requests for a hearing regarding this rulemaking proposal.

The anticipated benefits of this regulatory proposal are:

This proposal would benefit public health and safety by reducing smoking-related illnesses and deaths. Having pharmacists furnish nicotine replacement products and smoking cessation therapy will reduce the cost and increase the convenience of obtaining those products.

Consideration of Alternatives

No reasonable alternative which was considered or that has otherwise been identified and brought to the attention of the Board would be more effective in carrying out the purpose for which it was proposed or would be as effective and less burdensome to affected private persons than the adopted regulation or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Objections or Recommendations/Responses to Comments

During 45-day public comment period from May 8, 2015 to June 22, 2015, the Board received four comments. The comments were provided to the Board in the Meeting Materials for the July 29, 2015, Board meeting, and were reviewed and considered by the Board. Comments were received from the California Pharmacists Association, the National Association of Chain Drug Stores, and the California Department of Public Health, all of which were in support of the proposed regulatory language for the nicotine replacement products rulemaking.

The Board received a comment through Robert Stein from Sally Huston, MS, PhD, Associate Professor, Clinical and Administrative Sciences, Keck Graduate Institute School of Pharmacy. Dr. Huston's comment contained two parts. Dr. Huston first suggested that additional language be added to 16 CCR Section 1746.2(b)(4)(B)(v) to describe what should be dispensed upon ascertaining if the patient has any history of allergic rhinitis. This recommendation was rejected as the Board concluded that the language, as written, would not be confusing to a pharmacist and that the pharmacist can use his or her professional judgment in determining what should be dispensed based on the patients' medical history.

Dr. Huston's second suggestion was that additional language be inserted into 16 CCR Section 1746.2(b)(4)(B) to narrow down the alternative languages which screening questions must be translated into by adding a phrase that the alternative translations should be in the "languages used in the local geographic area of the pharmacy." This recommendation was rejected by the Board. Again, the pharmacist can use their professional judgment on the appropriate language for the patient. Should a patient from outside the local geographical area enter a pharmacy, the pharmacist, using their professional judgment, needs to ensure that the patient has the necessary information prior to dispensing. Adding the recommended language will not resolve the issue.

The Board considered all of the comments and voted to adopt the nicotine replacement products regulation text as it was noticed.