

BOARD OF PHARMACY

INITIAL STATEMENT OF REASONS

Hearing Date: No hearing is presently planned unless one is requested no later than 15 days before the close of the 45-day comment period.

Subject Matter of Proposed Regulations: Nicotine replacement products.

Section Affected: 16 CCR Section 1746.2.

Specific Purpose of Adoption: Business & Professions (“B&P”) Code section 4052.3 authorizes pharmacists to furnish nicotine replacement products under a protocol adopted by the Board of Pharmacy (“Board”) in collaboration with other entities. The Board seeks to adopt this collaboratively developed and approved protocol as 16 CCR Section 1746.2.

The problem to be addressed: These regulations address the problem to obtain nicotine replacement products; the public has been required to obtain a doctor’s prescription. B&P section 4052.9 instructed the Board to develop a protocol for pharmacists to follow that allows them to furnish nicotine replacement products without a doctor’s prescription; proposed 16 CCR Section 1746.2 is that protocol.

The anticipated benefits from this regulatory action: The anticipated benefits from this proposed regulation is that that the public will have easier access to nicotine replacement products, helping more people to quit smoking. Pharmacists will have a protocol to follow when dispensing nicotine replacement products without a doctor’s prescription.

Factual Basis/Rationale

This proposal seeks to adopt 16 CCR Section 1746.2, a protocol for pharmacists to furnish nicotine replacement products without a doctor’s prescription. This adoption is necessary to carry out the purpose of B&P section 4052.9. By following the proposed protocol, pharmacists will be able to furnish, if medically appropriate, nicotine replacement products without a doctor’s prescription.

In 2013, the Legislature enacted, and the Governor signed, Senate Bill 493 (Hernandez, Chapter 469, Statutes of 2013) which enabled pharmacists to serve as health care providers to the public in certain enumerated areas (including dispensing nicotine replacement products as described herein). The Board, following the instructions set out in B&P Code section 4052.3, worked with the Medical Board of California to develop the protocol set out in this rulemaking. This protocol was approved by the Board on January 27, 2015, and approved by the Medical Board on January 30, 2015. Under the protocol, pharmacists assess the patient’s current tobacco use and past quit attempts and ask six screening questions. The screening questions will be made available in alternative languages for patients whose primary language is not English. If risk factors for the use of certain types of nicotine replacement products are identified, pharmacists must either decline to furnish or furnish with caution and refer the patient to an appropriate health care provider. The pharmacist must review the use instructions for the

product with the patient, and shall recommend the patient seek additional assistance for behavior change, including but not limited to, the California Smokers' Helpline, web-based programs, apps, and local cessation programs.

The pharmacist shall answer any question the patient has about smoking cessation therapy and nicotine replacement products and, in consultation with the patient, will select any product from the list of therapies specified in the protocol in a table entitled, "Nicotine Replacement Therapy Medications for Smoking Cessation," and generic equivalent products may be furnished. The pharmacist must notify the patient's primary care provider of any nicotine cessation products furnished to the patient, or enter it into a record system shared with the primary care provider, and if those are not possible, provide the patient with a written record of the nicotine cessation product furnished. The pharmacist must maintain a record of having furnished a nicotine replacement product for smoking cessation for three years from the date of furnishing. The protocol requires that before a pharmacist may furnish prescription nicotine replacement products, they must complete two (2) hours of an approved continuing education training program, or the equivalent curriculum-based training program completed within the last two years in an accredited California school of pharmacy. Pharmacists who chose to furnish nicotine replacement products must obtain their approved training prior to attempting to furnish nicotine replacement products without a doctor's prescription.

Specific Benefits Anticipated: Smoking is one of the leading causes of death globally. Smoking leads to a dependence on nicotine and serious health problems. People who stop smoking greatly reduce their risk of smoking-related diseases and early death. Reducing the cost and easing access to nicotine replacement products for people for whom it is medically appropriate (determined by a pharmacist following the proposed protocol) is likely to benefit public health. When Californians quit smoking, there is a positive trickle-down effect on public health and safety due to the reduction of smoking-related diseases and deaths.

B&P Code section 4001.1 mandates that the protection of the public shall be the highest priority for the Board and that whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public comes first. Adopting the nicotine replacement products protocol provides protection to the public by setting out clear dispensing procedures and guidelines for pharmacists, while increasing public access to information and products that can help people quit smoking.

Underlying Data:

1. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held January 27-28, 2015.
2. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held October 28-29, 2014.
3. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held July 30-31, 2014.
4. Relevant Meeting Materials and Minutes from SB 493 Implementation Committee held February 25, 2015.

5. Relevant Meeting Materials and Minutes from SB 493 Implementation Committee held December 16, 2014.
6. Relevant Meeting Materials and Minutes from SB 493 Implementation Committee held November 5, 2014.
7. Relevant Meeting Materials and Minutes from SB 493 Implementation Committee held August 6, 2014.
8. Relevant Meeting Materials and Minutes from SB 493 Implementation Committee held June 4, 2014.
9. Centers for Disease Control and Prevention, "Quitting Smoking," *available at http://www.cdc.gov/tobacco/data_statistics/fact_sheets/cessation/quitting/index.htm.* (This resource describes the methods of quitting smoking and their effectiveness).
10. CPhA/CSHP, "Pharmacists Protocol for Dispensing Nicotine Replacement Products." (This draft protocol was consulted in development of the Board's recommended protocol).
11. Frank Vitale, "Brief Intervention Protocol for Assisting Patients with Tobacco Cessation," 64 AM. J. HEALTH-SYST PHARM. 2583 (2007). (This commentary provides important resources and specific dialogue for a pharmacists' procedure for assisting patients with tobacco cessation).
12. Nicole Van Hoey, "Opportunities for Smoking Cessation Services in Emerging Models of Care," America's Pharmacist (Oct. 2014). (This Continuing Education provided helpful referral resources, especially smartphone resources).
13. University of California, San Francisco, "Smoking Cessation Leadership Center," <http://smokingcessationleadership.ucsf.edu/>. (This site offers evidence-based resources for providers as well as continuing education opportunities in smoking cessation for CME and CEU credit).
14. University of California, San Francisco, "Rx for Change," <http://rxforchange.ucsf.edu/>. (This site offers evidence-based resources for providers and non-providers).
15. Accreditation Council for Pharmacy Education, "Basic Tobacco Intervention Workshop," P.L.A.N. Search Detail, *available at <https://www.acpe-accredit.org/pwtool/plan/DetailResultsPLAN.aspx?progtype=1&id=267501&cosp=289079&fromdate=10/27/2014>*. (This website shows ACPE-approved education involving smoking cessation).
16. Agency for Healthcare Research and Quality, "Treating Tobacco Use and Dependence: 2008—Clinical Practice Guideline," *available at <http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/tobacco/clinicians/index.html>*. (This site provides tobacco reference materials and guides for health care providers).
17. Economic Impact Analysis

Business Impact: The Board does not believe this regulation will have a significant adverse economic impact on businesses. Adopting this regulation simply provides pharmacists who chose to dispense nicotine replacement products without a doctor's prescription with a protocol to follow.

Economic Impact Assessment Results:

This regulatory proposal will have the following effects:

- It will not create or eliminate jobs in the State of California because pharmacists already dispense nicotine replacement products with a doctor's prescription; the proposed regulation simply sets out a protocol for dispensing nicotine replacement products without a prescription.
- It will not create new businesses or eliminate existing businesses within California because pharmacists already dispense nicotine replacement products with a doctor's prescription; the proposed regulation simply sets out a protocol for dispensing nicotine replacement products without a prescription.
- It would not affect the expansion of businesses currently operating in California because pharmacists already dispense nicotine replacement products with a doctor's prescription; the proposed regulation simply sets out a protocol for dispensing nicotine replacement products without a prescription.
- This regulatory proposal benefits the health and welfare of California residents because it increases public access to information on smoking cessation therapy and makes it easier to obtain nicotine replacement products, making it easier for people to stop smoking.
- This regulatory proposal will have no impact on worker safety because pharmacists have dispensed doctor-prescribed nicotine replacement products for decades, and the Board has not received any information about impacts on worker safety.
- This regulatory proposal will have no impact on the state's environment because pharmacists have dispensed doctor-prescribed nicotine replacement products for as long as such products have been available, and the Board has not received any information about environmental impacts.

Specific Technologies or Equipment: This regulation would not mandate the use of specific technologies or equipment.

Consideration of Alternatives: The Board of Pharmacy has determined that no reasonable alternative considered by the Board, or otherwise identified and brought to the Board's attention, would either be more effective in carrying out the purpose for which the actions are proposed, or would be as effective and less burdensome to affected private persons than the proposals described herein, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provisions of law. The Board found taking no action an unacceptable alternative in the face of the specific charge in the law that the Board enforce B&P section 4052.9(b) for its licensees. This proposed regulation implements B&P 4052.9.