

## 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 of Pharmacy at its office not later than 5:00 p.m. on June 22, 2015.

The Board does not intend to conduct a regulation hearing on the matter, unless requested. Any interested person may submit a written request for a public hearing no later than 15 days prior to the close of the 45-day written comment period.

The Board, upon its own motion or at the request 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: Under the authority conferred by Business and Professions Code (“B&P”) sections 4005, 4052(a)(10) and 4052.9, in order to implement, interpret and make specific Business and Professions Code sections 4052(a)(10) and 4052.9, the Board is proposing to amend Article 5 of Division 17 of Title 16 of the California Code of Regulations (“CCR”), as follows:

### INFORMATIVE DIGEST/ POLICY STATEMENT OVERVIEW

The Board proposes to adopt Section 1746.2 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to set out a standard 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. This proposed rulemaking would increase access to nicotine replacement products which help people quit smoking. By following the proposed protocol, pharmacists may furnish, where medically appropriate, nicotine replacement products to the public.

Specific Benefits Anticipated: Having pharmacists furnish nicotine replacement products and smoking cessation therapy will reduce the cost and increase the convenience of obtaining those products. Californians quitting smoking will lead to a trickle-down effect on public health and safety by reducing smoking-related illnesses and deaths.

Consistency and Compatibility with Existing State Regulation: During the collaborative process of drafting the protocol set out in this regulation, the Board has conducted a search of similar regulations on this topic and has concluded that these regulations are neither inconsistent nor incompatible with existing state regulations.

**Mandate on Local Agencies or School Districts:** This regulatory action does not impose a mandate on local agencies or school districts.

**FISCAL IMPACT:**

- A. Cost or Savings to any state agency: NONE
- B. Cost to any local agency required to be reimbursed under Part 7 (commencing with Section 17500) of Division 4: NONE
- C. Cost to any school district required to be reimbursed under Part 7 (commencing with Section 17500) of Division 4: NONE
- D. Other nondiscretionary cost or savings imposed on local agencies: NONE
- E. Cost or savings in federal funds to the state: NONE

**Effect on Housing Costs:** NONE

**Business Impact:** The Board has made a determination that the proposed regulatory action will have no significant statewide adverse economic impact on directly affected businesses, including the ability of California businesses to compete with businesses in other states.

**Results of Economic Impact Assessment:** Pharmacists wishing to dispense nicotine replacement products must take two (2) hours of continuing education (CE) on the training of smoking cessation therapy and nicotine replacement therapy. However, pharmacists presently complete thirty (30) hours of CE each renewal cycle, and the two (2) hours of CE on nicotine replacement products can be applied to meet the existing CE requirement. Thus, while this regulatory proposal affects pharmacies, it will not have a significant statewide adverse economic impact directly affecting business, or businesses' ability to compete.

**Impact on Jobs/New Businesses:** The Board has determined that this regulatory proposal will not have any impact on the creation of jobs or elimination of jobs, or on the creation of new businesses or the elimination of existing businesses nor on the expansion of businesses in the State of California.

**Benefits of the Regulations:** This regulatory proposal benefits the health and welfare of California residents because having pharmacists dispense nicotine replacement products without a doctor's prescription will make obtaining such products easier and cheaper. Nicotine replacement products are used to help people stop smoking. When people stop smoking, there is a positive trickle-down effect on public health and safety due to the reduction of smoking-related diseases and deaths.

The Board has determined that this regulation has no impact on worker safety.

This regulatory proposal does not affect the state's environment because it simply allows pharmacists to continue dispensing nicotine cessation products pursuant to the protocol without a doctor's prescription. Pharmacists have been dispensing nicotine cessation products with a doctor's prescription for as long as such products have been available, and the Board has not received any information about measureable environmental effects.

**Cost Impacts:** The Board is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

**Business Report:** The proposed regulations do not require a new report to be made. Pharmacists have long been able to furnish nicotine cessation products to people who have a doctor's prescription. While there might be a slight increase in demand for nicotine cessation products once individuals can obtain these products without a doctor's prescription, the Board has concluded that this regulation will have a negligible effect on small businesses.

**Effect on Small Businesses:** The Board must determine that the proposed regulation would not affect small businesses. Pharmacists have long been able to furnish nicotine cessation products to individuals who have a doctor's prescription. While there might be a slight increase in demand for nicotine cessation products once individuals can obtain without a doctor's prescription, the Board has concluded that making this regulation permanent will have a negligible effect on small businesses.

**CONSIDERATION OF ALTERNATIVES:** The Board must determine 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 action is proposed; or would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policies or other provision of law.

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

**INITIAL STATEMENT OF REASONS AND INFORMATION:** The Board has prepared an initial statement of the reasons for the proposed actions and has available all the information upon which the proposals are based.

**TEXT OF PROPOSAL:** Copies of the exact language of the proposed regulation 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 person designated below as Contact Person, or by accessing the Board of Pharmacy's Web site at <http://www.pharmacy.ca.gov>.

**AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE:** All the information upon which the proposed regulation is based is contained in the rulemaking file which is available for public inspection by contacting the contact 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 Board of Pharmacy's Web site <http://www.pharmacy.ca.gov>.

**CONTACT PERSON:** Materials regarding this proposal can be found at [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov).  
Inquiries or comments concerning the proposed rulemaking actions may be addressed to:

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