

TITLE 16. BOARD OF PHARMACY

NOTICE IS HEREBY GIVEN that the Board of Pharmacy (“Board”) proposes 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 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 4052.3, in order to implement, interpret and make specific Business and Professions Code section 4052(a)(10) and §4052.3, the Board is proposing to add to Article 5 of Division 17 of Title 16 of the California Code of Regulations, as follows:

INFORMATIVE DIGEST/ POLICY STATEMENT OVERVIEW

The Board proposes to adopt Section 1746.1 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to set out a protocol pharmacists will follow to furnish self-administered hormonal contraception (“contraception”) without a doctor’s prescription. Under existing law, women were required to obtain a prescription from a doctor to obtain self-administered hormonal contraception. In 2014, the American Congress of Obstetricians and Gynecologists issued a statement supporting “making oral contraceptives available over-the-counter,” to “help more women get the contraceptives they need.” This proposed rulemaking would allow women to obtain self-administered hormonal contraception from a pharmacist where medically appropriate, as determined by the pharmacist following the protocol.

The practice of pharmacy is authorized, regulated and enforced in California by the Board. Because the federal government does not authorize or regulate practice in California, there are no existing federal regulations comparable to this rulemaking.

Specific Benefits Anticipated: Increasing women’s access to highly effective self-administered hormonal contraception is likely to contribute to public health and safety by reducing unwanted pregnancies.

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. B&P section 4052.3 (the statute this regulation is clarifying) also authorizes pharmacists to dispense emergency contraception drug therapy pursuant to a protocol set out in 16 CCR Section 1746, and that regulation is not inconsistent with the proposed rulemaking.

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 self-administered hormonal contraception must take one (1) hour of continuing education (CE) on self-administered hormonal contraception, application of the USMEC for Contraceptive Use and other CDC guidance on contraception. However, pharmacists presently complete thirty (30) hours of CE each renewal cycle, and the one (1) hour of CE on self-administered hormonal contraception 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 the regulatory proposal herein will not have any 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.

Benefits of the Regulations: This regulatory proposal benefits the health and welfare of California residents because having pharmacists dispense self-administered hormonal contraception will increase the availability of this highly effective form of contraception. Increasing women's access to effective contraception will contribute to public health and safety by preventing unplanned pregnancies.

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 self-administered hormonal contraceptives, only now, when done pursuant to the protocol, the pharmacist may do so without a doctor's prescription. Pharmacists have been dispensing self-administered hormonal contraception to women with doctor's prescriptions for years, 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 been dispensing self-administered hormonal contraception to women for years, and maintain those patient medication records for three (3) years. That standard record-keeping requirement remains unchanged, as the proposed regulation simply allows pharmacists to dispense self-administered hormonal contraception pursuant to the protocol without a doctor's prescription.

Effect on Small Businesses: The Board has determined that the proposed regulation would not affect small businesses. Pharmacists have long been able to furnish contraceptives to women who have a doctor's prescription. While there might be a slight increase in demand for self-administered hormonal contraception once women can obtain it without a doctor's prescription, the Board has concluded that this regulation 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 provisions 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 action and has available all the information upon which the proposed protocol is 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](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 www.pharmacy.ca.gov.

CONTACT PERSON: Materials regarding this proposal can be found at www.pharmacy.ca.gov. Inquiries or comments concerning the proposed rulemaking actions may be addressed to:

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The backup contact person is:

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