

BOARD OF PHARMACY

REVISED INITIAL STATEMENT OF REASONS

Changes made to the originally proposed language are shown by ~~single strike-through~~ for deleted language and double underline for added language.

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: Self-administered hormonal contraception.

Section Affected: 16 CCR Section 1746.1.

Specific Purpose of Adoption: Business & Professions (“B&P”) Code section 4052.3 authorizes pharmacists to dispense self-administered hormonal contraception under a protocol adopted by the Board of Pharmacy (“Board”) in collaboration with other entities. The Board seeks to adopt the collaboratively developed and approved protocol as 16 CCR Section 1746.1.

The problem to be addressed by these regulations is that women’s access to self-administered hormonal contraception has been limited in that it requires a doctor’s prescription. B&P section 4052.3 instructed the Board to develop a protocol for pharmacists to follow to dispense self-administered hormonal contraception without a doctor’s prescription; proposed 16 CCR Section 1746.1 is that protocol.

The anticipated benefits from this regulatory action are that women will have increased access to self-administered hormonal contraception, resulting in fewer unplanned pregnancies. Pharmacists will have a protocol to follow to dispense self-administered hormonal contraception.

Factual Basis/Rationale

This proposal seeks to adopt 16 CCR Section 1746.1, which is a protocol for pharmacists to follow when dispensing self-administered hormonal contraception. This adoption is necessary to carry out the purpose of B&P section 4052.3. By following the proposed protocol, pharmacists will be able to dispense, where medically appropriate, self-administered hormonal contraception 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 contraception as described herein). The Board, following the instructions set out in Business & Professions (“B&P”) Code section 4052.3, worked with the Medical Board of California and in consultation with the American Congress of Obstetricians and Gynecologists, the California Pharmacists Association and other appropriate entities to develop the proposed protocol. The protocol was approved as amended by the Medical Board on January 30, 2015, and the Board accepted those amendments and re-approved the protocol with the Medical Board’s amendments on March 9, 2015. Under the protocol, pharmacists provide patients with a self-screening tool (available in English and

alternative languages) to identify risk factors for the use of self-administered hormonal contraceptives, and pharmacists must keep a copy of that tool for at least three (3) years from the date of dispensing. If self-administered combined hormonal contraceptives are requested or appropriate to furnish, the pharmacist must measure and record the patient's seated blood pressure. The pharmacist must ensure the patient is appropriately trained in taking the requested or recommended contraceptive medicine, including dosage, effectiveness, potential side-effects, safety, the importance of receiving recommended preventative health screenings and is told self-administered hormonal contraceptives do not protect against sexually transmitted infections or diseases. Pharmacists must provide patients with the FDA-required patient product information leaflet included in all self-administered hormonal contraception products, a current customer-friendly comprehensive birth control guide and a copy of an administration-specific factsheet.

The patient must be referred to the patient's primary care provider, or if the patient doesn't have one, to nearby clinics, for appropriate follow-up care whether or not a self-administered hormonal contraception product is furnished. The pharmacist must notify the patient's primary care provider, when possible. When not possible, the pharmacist must provide the patient with a written record of the drug or device furnished. The pharmacist must maintain a record of having furnished self-administered hormonal contraception for three years from the date of dispensing. If self-administered hormonal contraceptive services aren't available or if the pharmacist declines to furnish them due to a conscience clause, the patient shall be referred to another appropriate health care provider. The protocol requires that a pharmacist complete a training program specific to self-administered hormonal contraception, application of the United States Medical Eligibility Criteria for Contraceptive Use developed by the federal Centers for Disease Control (CDC) and other CDC guidance on contraception prior to attempting to furnish self-administered hormonal contraception pursuant to the protocol.

Specific Benefits Anticipated: Self-administered hormonal contraceptives are among the most effective contraceptive medications and devices available to women. This regulation increases women's access to these effective forms of birth control by reducing both the time required and the overall cost of obtaining self-administered hormonal contraception. Unintended pregnancies are linked to many maternal and child health problems. Using effective birth control to increase the time between pregnancies improves both women's and children's health. Effective birth control use reduces unplanned pregnancies, which reduces the number of pregnancy terminations and maternal deaths. Increasing women's access to self-administered hormonal contraception contributes to public health and safety by reducing unwanted pregnancies.

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. This self-administered hormonal contraceptive protocol provides protection to the public by setting out clear dispensing procedures and guidelines for pharmacists, while increasing women's access to self-administered hormonal contraception.

Underlying Data:

1. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held March 9, 2015.
2. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held January 27-28, 2015.
3. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held October 29-30, 2014.
4. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held July 30-31, 2014.
5. Centers for Disease Control and Prevention, "United States Medical Eligibility Criteria for Contraceptive Use," (2010) *available at* <http://www.cdc.gov/reproductivehealth/unintendedpregnancy/USMEC.htm>. (*This resource served as the basis for self-administered hormonal contraception medications from which a pharmacist may select*).
6. Centers for Disease Control and Prevention, "U.S. Selected Practice Recommendations for Contraceptive Use, 2013," *available at* <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6205a1.htm>. (*This document from the CDC offers guidance on how to use contraceptive methods most effectively. It is adapted from a World Health Organization (WHO) publication, and was endorsed by the American College of Obstetricians and Gynecologists (ACOG)*).
7. S. Shotorbani, et al., "Agreement Between Women's and Providers' Assessment of Hormonal Contraceptive Risk Factors," 73 CONTRACEPTION 501, 501-506 (2006). (*This article provided a Medical History Questionnaire that was used in the development of the protocol's self-assessment tool. The article's research found 96% agreement between women's self-administered risk factor questionnaire and their providers' evaluation of their medical eligibility for hormonal contraceptive use.*)
8. CPhA/CSHP, "Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraceptives." (*This draft protocol was consulted in development of the Board's recommended protocol.*)
9. Food and Drug Administration Office of Women's Health, "HPV, HIV, Birth Control" (last updated June 24, 2014), *available at* <http://www.fda.gov/ForConsumers/ByAudience/ForWomen/WomensHealthTopics/ucm117971.htm> (*This site contains a consumer-friendly birth control guide recommended for patient education.*)
10. Office on Women's Health, U.S. Department of Health and Human Services, "Birth Control Methods" (last updated Nov. 21, 2011), *available at* <http://www.womenshealth.gov/publications/our-publications/fact-sheet/birth-control-methods.pdf>. (*This fact sheet was consulted in development of the Board's recommended fact sheet.*)
11. Division of Reproductive Health, Centers for Disease Control and Prevention, "Contraception" (last updated Oct. 14, 2014), <http://www.cdc.gov/reproductivehealth/unintendedpregnancy/contraception.htm>. (*This website, especially the chart, is recommended as a resource for pharmacists choosing to provide additional user-friendly information on various birth control methods.*)
12. The American College of Obstetricians and Gynecologists, "Birth Control - Especially

- for Teens,” FAQ112 (Dec. 2013), *available at* <http://www.acog.org/Patients/FAQs/Birth-Control-Especially-for-Teens>. (*This fact sheet was consulted in development of the Board’s recommended fact sheet.*)
13. J. McIntosh et al., “Changing Oral Contraceptives from Prescription to Over-the-Counter Status: An Opinion Statement of the Women’s Health Practice and Research Network of the American College of Clinical Pharmacy,” *Pharmacotherapy* Vol. 31, Number 4, 424-437 (2011). (*This opinion paper discusses pharmacist training on page 432. Both pharmacists and pharmacy students generally expressed interest in more education specifically on appropriate product selection.*)
 14. Fatim Lakha, et al., “The Acceptability of Self-Administration of Subcutaneous Depo-Provera,” *72 CONTRACEPTION* 14-18 (2005). (*This research finds that subcutaneous self-injectable hormonal contraception is beneficial for many women with appropriate training and reminder system.*)
 15. Nicole J. Monastersky Maderas & Sharon Cohen Landau, “Pharmacy and Clinic Partnerships To Expand Access to Injectable Contraception,” *47 J. AM. PHARM. ASSOC.* 527-531 (2007). (*This research finds that pharmacy reinjection of contraception is a viable option for many women, and is most successful when combined with primary care provider support and integration.*)
 16. Sujatha Prabhakaran & Ashley Sweet, “Self-Administration of Subcutaneous Depot Medroxyprogesterone Acetate for Contraception: Feasibility and Acceptability,” *85 CONTRACEPTION* 453-457 (2012). (*This research article finds that self-administration injections were easy and convenient for women with training from two Planned Parenthood health centers.*)
 17. Sharon T. Cameron, et al., “Pilot Study of Home Self-Administration of Subcutaneous Depo-Medroxyprogesterone Acetate for Contraception,” *85 CONTRACEPTION* 458-464 (2012). (*This research concludes that self-administration is feasible and has similar continuation and satisfaction rates to clinician-administration injections.*)
 18. Rebekah L. Williams, et al., “Self-Administration of Subcutaneous Depot Medroxyprogesterone Acetate by Adolescent Women,” *88 CONTRACEPTION* 401-407 (2013). (*This research concludes that many adolescents are interested in and capable of self-administration with brief education and minimal assistance.*)
 19. S. Vinker, et al., “The Effect of Drug Information Leaflets on Patient Behavior,” *ISR. MED. ASSOC. J.* 9(5) 383-4386 (May 2007). (*This research concludes that reading the leaflet did not greatly affect adherence but caused anxiety and decreased adherence in some patients.*)
 20. 21 C.F.R §§ 201 “Labeling,” *available at* <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=201> *These FDA regulations require manufacturers to include comprehensive patient leaflets in both prescription-only and OTC products.*
 21. 21 C.F.R. § 310.501 “Patient Package Inserts for Oral Contraceptives,” (Apr. 1, 2014), *available at* <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=310.501>. (*These FDA regulations are specific to leaflet requirements for oral contraceptives.*)
 22. 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 choose to dispense self-administered hormonal contraception without a doctor's prescription, with a protocol to follow.

The Board has made an initial determination that the proposed regulatory action would have no significant adverse economic impact directly affecting businesses or individuals because this proposal provides an additional outlet where women can receive hormonal contraception. According to the Centers for Disease Control and Prevention (CDC), approximately 61.7% of women, aged 15-44 use contraception in the United States. Of this, 16.0% use hormonal contraception.

According to the 2010 United States Census, California had a population of 37,253,956. Of that population, approximately 8,556,578 are women between the ages of 18 and 50 years old. Using the CDC estimate of approximately 61.7%, approximately 5,279,470 women in California use some method of contraception. Sixteen percent of that population, or 844,715, would be estimated to use hormonal contraception based on the CDC's study.

According to the research article, "Birth Control within reach: a national survey of women's attitudes toward and interest in pharmacy access to hormonal contraception," an estimated 68% of women using hormonal contraception would be willing to utilize a pharmacy for access if it was available. Using this figure, approximately 574,406 women in California would be willing to utilize a pharmacy to obtain hormonal contraception. During the study conducted in Washington State, the women who reported interest in utilizing a pharmacy for hormonal contraception also reported that they would want to have a gynecologic exam during the recommended three-year intervals.

As such, the Board does not believe that all these women will immediately begin utilizing a pharmacy to obtain hormonal contraception. The Board expects that patients will continue to see their primary care physician for other health related matters. The Board also expects that patients will continue to seek gynecologic exams every three years, as recommended by the American Congress of Obstetricians and Gynecologists, and will continue to receive the hormonal contraception prescription as part of that exam.

Additionally, the Board believes that the use of pharmacies will be slow to begin and utilization by women may take several years. In order to provide hormonal contraception, pharmacists wishing to participate will be required to complete a one hour continuing education program and pharmacies also have to develop and implement the procedures for each location and ensure compliance with the standardized protocol.

The cost of the hormonal contraception itself will likely remain the same irrespective of how the patient receives the prescription. The cost to the patient may vary based upon whether they receive the prescription from their doctor versus from a pharmacy. During the study conducted in Washington State, pharmacists were paid a fee of \$25.00 for screening and prescribing services and according to the Agency of Healthcare Research and Quality, in 2012 the average co-payment for a doctor's visit was approximately \$24.00.

Assuming that 10% of women elect to utilize a pharmacy for hormonal contraception or approximately 57,500 women will utilize a pharmacy during the first year of implementation. At an estimated cost of \$25.00, the total expense in the first year of implementation would be \$1,437,500.

Economic Impact Assessment:

This regulatory proposal will have the following effects:

- It will not create or eliminate jobs in the State of California because pharmacists already dispense self-administered hormonal contraception with a doctor's prescription; the proposed regulation simply sets out a protocol for dispensing self-administered hormonal contraception without a doctor's prescription.
- It will not create new businesses or eliminate existing businesses within California because pharmacists already dispense self-administered hormonal contraception with a doctor's prescription; the proposed regulation simply sets out a protocol for dispensing self-administered hormonal contraception without a doctor's prescription.
- It would not affect the expansion of businesses currently operating in California because pharmacists already dispense self-administered hormonal contraception with a doctor's prescription; the proposed regulation simply sets out a protocol for dispensing self-administered hormonal contraception without a doctor's prescription.
- This regulatory proposal benefits the health and welfare of California residents because it increases women's access to safe and highly effective forms of contraception that will reduce unplanned pregnancies, resulting in positive impacts on women's and children's health. This regulatory proposal ensures that pharmacists, that so choose to provide hormonal contraception, have a standardized protocol to follow to furnish women with self-administered hormonal contraceptive products for the prevention of unintended pregnancy. By providing an additional option to obtain hormonal contraception, it will make it easier for members of the public to obtain self-administered hormonal contraceptive products which may reduce the number of unintended pregnancies, and the negative public health impacts of unintended pregnancies. When members of the public no longer need a doctor's prescription to purchase self-administered hormonal contraceptive products, there may be an increase in sales of self-administered hormonal contraceptive products.
- This regulatory proposal will have no impact on worker safety because pharmacists have dispensed doctor-prescribed self-administered hormonal contraceptives 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 self-administered hormonal contraceptives for decades, 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 4052.3(a) for its licensees.~~ This proposed regulation implements B&P section 4052(a)(10), B&P section 4052.3(a) and B&P section 4052.3(c). The only alternative would be to not implement the standardized procedures and protocols. This is not reasonable as the Board would not be in compliance with current law, which requires the development of the procedures and protocols. This determination was made during the development and regulatory process and with consultation with experts in the field.