California State Board of Pharmacy
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III. Proposed Regulations to Add Title 16 California Code of Regulations (CCR) section 1746.1, Related to Self-Administered Hormonal Contraception

In May 2015, the board initiated a formal rulemaking to add Section 1746.1 Title 16 California Code of Regulations related to Self-Administered Hormonal Contraception. On January 19, 2016, the Board adopted the final regulation text. On March 2, 2016, the Office of Administrative Law requested that additional information be added to the Initial Statement of Reasons. On March 9, 2016, a revised Initial Statement of Reasons was noticed for a 15-day comment period. The comment period closed on March 24, 2016.

One comment was received.

At this Meeting

The board will have the opportunity to discuss the comment received and determine whether to advance the rulemaking forward with the regulation text as adopted on January 19, 2016.

The Attachment immediately following this memo contains the Revised Initial Statement of Reasons, the comment received, and the adopted text.

Self-Administered Hormonal Contraception

Revised Initial Statement of Reasons

BOARD OF PHARMACY

SECOND REVISED INITIAL STATEMENT OF REASONS

Changes made in the first revised Initial Statement of Reasons are shown by ~~single strike-through~~ for deleted language and double underline for added language.

Changes made in this second revised Initial Statement of Reasons are shown by ~~double strike-through~~ for deleted language and dashed 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 (§ 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 if combined hormonal contraceptives are requested or recommended. At the February 2015 SB-493 committee meeting (minutes included with March Board meeting materials) the Board received competing testimony about the necessity of taking seated blood pressure. Testimony provided by the American Congress of Obstetricians and Gynecologists (ACOG) expressed their belief that most patients would know their blood pressure or could take it using blood pressure stations within the pharmacy; however, ACOG acknowledged that contraceptives would not be prescribed by a doctor without first taking blood pressure as it is a standard of care. Additionally, testimony was provided that pharmacists should be following the same standard of care as a doctor and that most would not be comfortable dispensing hormonal contraceptives without taking blood pressure. Verifying blood pressure is essential to good, clinical decision making and pharmacists will be held responsible for their clinical decisions. Public protection is improved by requiring a pharmacist to measure and record the patient's seated blood pressure before furnishing combined hormonal contraception because certain medications are not recommended for women with elevated blood pressure. Accurately identifying blood pressure will help prevent furnishing of a medication to a patient who may experience a negative side effect from the drug. Additionally, measuring blood pressure is an appropriate standard of care in that it is consistent with physician practice, where combined hormonal contraceptives would not be prescribed by the physician without first checking the patient's blood pressure. Many patients with hypertension, especially those with reduced access to medical care, may not know of their condition or have the resources to continuously monitor their condition. Self-reporting may also be problematic or inaccurate because of the time differential. When the patient measured her seated blood pressure last, possibly yesterday and possibly last year, it could have been normal. However, on the date of furnishing the patient's blood pressure may be elevated. Because of this and for the protection of patients, this protocol requires that a pharmacist first take the patient's seated blood pressure before furnishing combined hormonal contraception.

The pharmacist must also 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 to be consistent with federal law and B&P Code section 4052.3(c)~~,~~. A pharmacist should provide the patient with a current customer-friendly comprehensive birth control guide and a copy of an administration-specific factsheet. The Initial Statement Reasons mistakenly indicated that pharmacists must provide the patient with the customer-friendly comprehensive birth control guide and a copy of an administration-specific factsheet. This was not the Board's intent and is corrected in this revised Initial Statement of Reasons. While the Board recommends that these two documents be provided, § 1746.1(b)(6) does not require a pharmacist to provide them. As noted above, pursuant to §1746.1(b)(4)(B), the pharmacist is required to review the self-screening tool with the patient and clarify any responses; before the pharmacist recommends a medication

to the patient pursuant to §1746.1(b)(10), it may be helpful for the patient to review a comprehensive birth control guide, but that is not required because the other provisions of the regulation adequately protect the public. An administration-specific factsheet, which explains details about the specific route of administration chosen, may assist with that process, but that is not required because the other provisions of the regulation adequately protect the public, such as, the proper training in administration of § 1746.1(b)(4)(D) and the product specific information and counseling required in § 1746.1(b)(4)(E). The term "administration-specific" is a common and readily understood term in the industry that refers to the physical route by which the medication is administered to the patient; the possible routes of administration are also referred to in §1746.1(b)(3).

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. The notification paragraph at § 1746.1(b)(8) was placed within the regulation to ensure compliance with B&P Code section 4052.3(a)(1), and increase patient safety. A patient's primary care provider needs to be fully informed of all prescription medications the patient is receiving. The protocol 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 self-administered hormonal contraception, § 1746.1(b)(8) reiterates the steps required in B&P Code section 4052.3(a)(1). Under the protocol, pharmacists with patients who cannot provide contact information for, or do not have a primary care provider can still be furnished self-administered hormonal contraception. ~~When not possible~~ In those cases, the pharmacist must provide the patient with a written record of the drug or device furnished and advised to consult with an appropriate health care provider of their choice. 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 Board worked closely with the Medical Board in drafting the regulation and its notification requirement, and determined this would best serve both patients by ensuring that primary care providers were aware of all medication s the patient had been furnished; and that primary care providers can best provide follow up care to patients. The requirement also conforms to B&P Code section 4052.3(a)(1).

The protocol requires that a pharmacist complete ~~a provider training program~~ one (1) hour of continuing education from a Board-approved provider specific to self-administered hormonal contraception, application of the United States Medical Eligibility Criteria for Contraceptive Use (USMEC) 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.

The protocol reiterates established pharmacy practice, as set out in B&P Code section 4081, which requires pharmacists to maintain documentation of the sale of all dangerous drugs and/or dangerous devices (defined in B&P Code section 4022 as any medication or device that requires a prescription to obtain). Since pharmacists will be furnishing self-administered hormonal contraception without a doctor's prescription, the regulation reiterates the B&P Code section 4081

record-keeping requirements to clarify that the previous record-keeping requirements for self-administered hormonal contraception 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 Code section 4105 and 16 CCR section 1707.1(a)(1)).

Additionally, patient privacy requirements are set out in the protocol at § 1746.1(b)(13). Existing Board regulation (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 self-administered hormonal contraception are acting under the pharmacy or facility's policies and procedures that ensure patient confidentiality and privacy.

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 (Materials: Agenda Item V, including attachment 1 (regulation text and excerpts from the February 25, 2015, SB 493 Committee meeting minutes); Board Minutes pages 8-10). (This material was previously referenced in the Initial Statement of Reasons; however, this identifying information is added for clarity.)
2. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held January 27-28, 2015 (Materials: Agenda Item IX(f) SB 493 Implementation Committee, including attachment 3 (regulation text and protocol sources); Board Minutes pages 28-35). (This material was previously referenced in the Initial Statement of Reasons; however, this identifying information is added for clarity.)
3. Relevant Meeting ~~Materials and~~ Minutes from Board of Pharmacy Meeting held October 28-29~~-30~~, 2014~~,~~(page 19).
4. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held July 30-31, 2014 (Materials: Agenda Item XIII(4) SB 493 Implementation Committee, including attachment 4; Board Minutes pages 29-30). (This material was previously referenced in the Initial Statement of Reasons; however, this identifying information is added for clarity.)
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). (T*his 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.

Self-Administered Hormonal Contraception

15-day Comment

Martinez, Lori@DCA

From: starship1980s@aol.com
Sent: Wednesday, March 09, 2016 5:01 PM
To: Martinez, Lori@DCA
Subject: Title 16 CCR § 1746.1, related to Self-Administered Hormonal Contraceptio

Pharmacists should not be allowed to administer or prescribe self administered hormonal contraceptives

Self-Administered Hormonal Contraception

Adopted Text

BOARD OF PHARMACY
Department of Consumer Affairs

ORDER OF ADOPTION

Adopt §1746.1 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1746.1 Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraception.

(a) A pharmacist furnishing self-administered hormonal contraception pursuant to Section 4052.3 of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraception

(1) Authority: Section 4052.3(a)(1) of the California Business and Professions Code authorizes a pharmacist to furnish self-administered hormonal contraceptives in accordance with a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol in this section satisfies that requirement.

(2) Purpose: To provide timely access to self-administered hormonal contraception medication and to ensure that the patient receives adequate information to successfully comply with therapy.

(3) Definition of Self-Administered Hormonal Contraception: Hormonal contraception products with the following routes of administration are considered self-administered:

(A) Oral;
(B) Transdermal;
(C) Vaginal;
(D) Depot Injection.

(4) Procedure: When a patient requests self-administered hormonal contraception, the pharmacist shall complete the following steps:

(A) Ask the patient to use and complete the self-screening tool;
(B) Review the self-screening answers and clarify responses if needed;
(C) Measure and record the patient's seated blood pressure if combined hormonal contraceptives are requested or recommended;
(D) Before furnishing self-administered hormonal contraception, the pharmacist shall ensure that the patient is appropriately trained in

administration of the requested or recommended contraceptive medication.

(E) When a self-administered hormonal contraceptive is furnished, the patient shall be provided with appropriate counseling and information on the product furnished, including:

(1) Dosage;
(2) Effectiveness;
(3) Potential side effects;
(4) Safety;
(5) The importance of receiving recommended preventative health screenings;
(6) That self-administered hormonal contraception does not protect against sexually transmitted infections (STIs).

(5) Self-Screening Tool: The pharmacist shall provide the patient with a self-screening tool containing the list of questions specified in this protocol. The patient shall complete the self-screening tool, and the pharmacist shall use the answers to screen for all Category 3 and 4 conditions and characteristics for self-administered hormonal contraception from the current United States Medical Eligibility Criteria for Contraceptive Use (USMEC) developed by the federal Centers for Disease Control and Prevention (CDC). The patient shall complete the self-screening tool annually, or whenever the patient indicates a major health change.

A copy of the most recently completed self-screening tool shall be securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense.

This self-screening tool should be made available in alternate languages for patients whose primary language is not English.

Fact Sheets:

(A) The pharmacist should provide the patient with a copy of a current, consumer-friendly, comprehensive birth control guide such as that created by the FDA. Examples of appropriate guides are available on the Board of Pharmacy's website.

(B) The pharmacist shall provide the patient with the FDA-required patient product information leaflet included in all self-administered hormonal contraception products, as required by the Business and Professions Code Section 4052.3(c). The pharmacist shall answer any questions the patient may have regarding self-administered hormonal contraception.

(C) The pharmacist should provide the patient with a copy of an administration-specific factsheet. Examples of appropriate factsheets are available on the Board of Pharmacy's website.

(7) Follow-Up Care: Upon furnishing a self-administered hormonal contraceptive, or if it is determined that use of a self-administered hormonal contraceptive is not recommended, the pharmacist shall refer the patient for appropriate follow-up care to the patient's primary care provider or, if the patient does not have a primary care provider, to nearby clinics. A patient who is determined not to be an appropriate candidate for self-administered hormonal contraception shall be advised of the potential risk and referred to an appropriate health care provider for further evaluation.

(8) Notifications: The pharmacist shall notify the patient's primary care provider of any drug(s) or device(s) furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with a written record of the drug(s) or device(s) furnished and advise the patient to consult an appropriate health care professional of the patient's choice.

(9) Referrals and Supplies: If self-administered hormonal contraception services are not immediately available or the pharmacist declines to furnish pursuant to a conscience clause, the pharmacist shall refer the patient to another appropriate health care provider.

The pharmacist shall comply with all state mandatory reporting laws, including sexual abuse laws.

(10) Product Selection: The pharmacist, in consultation with the patient, may select any hormonal contraceptive listed in the current version of the USMEC for individuals identified as Category 1 or 2, based on the information reported in the self-screening tool and the blood pressure (if recorded by the pharmacist). The USMEC shall be kept current and maintained in the pharmacy or health care facility, and shall be available on the Board of Pharmacy's website.

Generic equivalent products may be furnished.

(11) Documentation: Each self-administered hormonal contraceptive furnished by a pharmacist pursuant to this protocol shall be documented in a patient medication record and securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense. A patient medication record shall be maintained in an automated data processing or manual record mode

such that the required information under title 16, sections 1717 and 1707.1 of the California Code of Regulations is readily retrievable during the pharmacy or facility's normal operating hours.

(12) Training: Prior to furnishing self-administered hormonal contraception, pharmacists who participate in this protocol must have completed a minimum of one hour of a board-approved continuing education program specific to self-administered hormonal contraception, application of the USMEC, and other CDC guidance on contraception. An equivalent, curriculum-based training program completed on or after the year 2014 in an accredited California school of pharmacy is also sufficient training to participate in this protocol.

(13) Patient Privacy: All pharmacists furnishing self-administered hormonal contraception in a pharmacy or health care facility shall operate under the pharmacy or facility's policies and procedures to ensure that patient confidentiality and privacy are maintained.

(14) Self-Screening Tool Questions

HORMONAL CONTRACEPTION SELF-SCREENING TOOL QUESTIONS

1	What was the first date of your last menstrual period?	/ /	
2a	Have you ever taken birth control pills, or used a birth control patch, ring, or shot/injection? (If no, go to question 3)	Yes ☐	No ☐
2b	Did you ever experience a bad reaction to using hormonal birth control?	Yes ☐	No ☐
2c	Are you currently using birth control pills, or a birth control patch, ring, or shot/injection?	Yes ☐	No ☐
3	Have you ever been told by a medical professional not to take hormones?	Yes ☐	No ☐
4	Do you smoke cigarettes?	Yes ☐	No ☐
5	Do you think you might be pregnant now?	Yes ☐	No ☐
6	Have you given birth within the past 6 weeks?	Yes ☐	No ☐
7	Are you currently breastfeeding an infant who is less than 1 month of age?	Yes ☐	No ☐
8	Do you have diabetes?	Yes ☐	No ☐
9	Do you get migraine headaches, or headaches so bad that you feel sick to your stomach, you lose the ability to see, it makes it hard to be in light, or it involves numbness?	Yes ☐	No ☐
10	Do you have high blood pressure, hypertension, or high cholesterol?	Yes ☐	No ☐
11	Have you ever had a heart attack or stroke, or been told you had any heart disease?	Yes ☐	No ☐
12	Have you ever had a blood clot in your leg or in your lung?	Yes ☐	No ☐
13	Have you ever been told by a medical professional that you are at a high risk of developing a blood clot in your leg or in your lung?	Yes ☐	No ☐
14	Have you had bariatric surgery or stomach reduction surgery?	Yes ☐	No ☐

15	Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?	Yes ☐	No ☐
16	Do you have or have you ever had breast cancer?	Yes ☐	No ☐
17	Do you have or have you ever had hepatitis, liver disease, liver cancer, or gall bladder disease, or do you have jaundice (yellow skin or eyes)?	Yes ☐	No ☐
18	Do you have lupus, rheumatoid arthritis, or any blood disorders?	Yes ☐	No ☐
19a	Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)?	Yes ☐	No ☐
19b	If yes, list them here:		
20a	Do you have any other medical problems or take regular medication?	Yes ☐	No ☐
20b	If yes, list them here:		

Authority: Sections 4005 and 4052.3, Business and Professions Code.
Reference: Sections 4052, 4052.3, and 4103, Business & Professions Code.