



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

To: Board Members

Subject: Agenda Item V: DISCUSSION AND POSSIBLE ACTION: To Initiate a Rulemaking to Add Title 16 California Code of Regulations Section 1746.1 Regarding Requirements for Pharmacists who Furnish Self-Administered Hormonal Contraceptives

At the January Board Meeting, the board approved the proposed protocol for self-administered hormonal contraception. The board also moved to regulation hearing the approved protocol if the Medical Board of California approved the protocol during its meeting on January 30.

The Medical Board did approve the protocol, but with a small change during its January 30 meeting. Following this memorandum is a copy of the Medical Board approved protocol with the Medical Board-suggested change indicated in underscore.

Meanwhile, the American Congress of Obstetricians and Gynecologists, who under provisions in SB 493 is a group with whom the board is required to consult in developing the protocol, appeared at the Medical Board meeting to request changes in the protocol. The Medical Board did not incorporate ACOG's recommendations into the protocol when it modified and approved the protocol. (Staff notes that since early summer 2014, board staff have been communicating with ACOG's representatives so they could participate in the development of the protocol. The first time the board learned of ACOG's concerns with the proposed protocol was during the Medical Board's meeting.)

At the February meeting of the SB 493 Implementation Committee, the agenda was crafted so that an ACOG representative could provide its comments to the committee. A representative of ACOG did attend and provided verbal comments about the protocol. The committee discussed each recommendation and decided to take no action to incorporate the changes. The changes involved whether:

1. On Depo-injection: ACOG recommended removal of this form of self-administered birth control because pharmacists may not know how to advise patients how to self-administer medications, and patients may be fearful of self-administration of as well.
2. ACOG recommended removal from the protocol (on page 1) the requirement that the pharmacist obtain the patient's blood pressure, and instead suggested asking the patient what her blood pressure is. The requirement as specified in the regulation is provided below:
 - "Measure and record the patient's seated blood pressure if combined hormonal contraceptives are requested or recommended.

The committee declined to accept either modification. A draft excerpt of the SB 493 Implementation Committee Meeting minutes as well as the Medical Board's approved version of the protocol are provided in **Attachment 1**.

At this meeting: the board needs to:

1. Evaluate whether to accept the committee's recommendation to decline to incorporate ACOG's recommended changes.

If the board decides to incorporate the changes, the protocol will be returned to the Medical Board for its review and approval at their next meeting (May 7 & 8).

2. If the board does not incorporate ACOG's comments into the protocol, the board needs to vote on whether to approve the protocol as amended by the Medical Board.

If so, as part of the motion, or via a second motion, the board needs to direct staff to initiate the rulemaking process to adopt section 1746.1.

Attachment 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:

- Oral;
- Transdermal;
- Vaginal;
- Depot Injection.

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

- Ask the patient to use and complete the self-screening tool;
- Review the self-screening answers and clarify responses if needed;
- Measure and record the patient's seated blood pressure if combined hormonal contraceptives are requested or recommended.
- 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.
- When a self-administered hormonal contraceptive is furnished, the patient shall be provided with appropriate counseling and information on the product furnished, including:
 - Dosage;
 - Effectiveness;
 - Potential side effects;
 - Safety;
 - The importance of receiving recommended preventative health screenings;
 - 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.

(6) Fact Sheet: 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.

Pharmacists should provide the patient with a copy of a current consumer-friendly comprehensive birth control guide such as that created by the FDA, and a copy of an administration-specific factsheet; examples of appropriate guides and 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 also 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?	/ /	
2	Have you ever taken birth control pills, or used a birth control patch, ring, or shot/injection? (If no, go to question 3)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	Did you ever experience a bad reaction to using hormonal birth control?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	Are you currently using birth control pills, or a birth control patch, ring, or shot/injection?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
3	Have you ever been told by a medical professional not to take hormones?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
4	Do you smoke cigarettes?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
5	Do you think you might be pregnant now?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
6	Have you given birth within the past 6 weeks?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
7	Are you currently breastfeeding an infant who is less than 1 month of age?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
8	Do you have diabetes?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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 <input type="checkbox"/>	No <input type="checkbox"/>
10	Do you have high blood pressure, hypertension, or high cholesterol?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
11	Have you ever had a heart attack or stroke, or been told you had any heart disease?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
12	Have you ever had a blood clot in your leg or in your lung?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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 <input type="checkbox"/>	No <input type="checkbox"/>
14	Have you had bariatric surgery or stomach reduction surgery?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
15	Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
16	Do you have or have you ever had breast cancer?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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 <input type="checkbox"/>	No <input type="checkbox"/>
18	Do you have lupus, rheumatoid arthritis, or any blood disorders?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
19	Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	If yes, list them here:		
20	Do you have any other medical problems or take regular medication?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	If yes, list them here:		

Note: Authority cited: Section 4052.3, Business and Professions Code. Reference: Section 4052(a)(10), Business and Professions Code.

Protocol Sources

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 resources serves as the basis for which self-administered hormonal contraception medications from which a pharmacist may select.

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 endorsed by the American College of Obstetricians and Gynecologists (ACOG).

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.

CPhA/CSHP, "Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraceptives."

This draft protocol was consulted in development of the Board's recommended protocol.

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.

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.

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.

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.

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.

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.

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.

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.

Sharon T. Cameron, et al., "Pilot Study of Home Self-Administration of Subcutaneous Depot 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.

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.

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 aroused anxiety and decreased adherence in some patients.

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 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.



**February 25, 2015 SB 493 Committee Meeting
Meeting Minutes Excerpt**

b. UPDATE ON THE STATUS OF THE DRAFT PROTOCOLS:

1. For Pharmacists Who Furnish Self-Administered Hormonal Contraceptives

President Weisser reported that at the January Board Meeting, the board approved the proposed protocol for hormonal contraception. The board also moved to regulation hearing the approved protocol if the Medical Board of California approved the protocol during its meeting on January 30.

The Medical Board approved the protocol with a small change. The approved protocol with the Medical Board-suggested change indicated immediately follows these minutes.

President Weisser stated that, the American Congress of Obstetricians and Gynecologists, who under SB 493 the board is required to consult in developing the protocol, appeared at the Medical Board meeting to request changes in the protocol. The Medical Board did not incorporate ACOG's recommendations into the protocol when it modified and approved the protocol.

President Weisser noted that if additional changes are made to the protocol, the Board of Pharmacy and the Medical Board will both need to approve the modification.

Liz McCaman commented that one of ACOG's concerns was the inclusion of depo-injections in the protocol. Ms. McCaman explained that the board decided to include it based on information from the CDC, USMEC and multiple studies showing its safety and effectiveness.

Ms. Veale asked if depo-injections were included in the protocol approved by the Medical Board. Ms. McCaman confirmed that the Medical Board approved the protocol with depo-injections included.

Mr. Law commented that he was pleased that the Medical Board approved the protocol with only a minimal change.

Ms. Veale asked why the committee was reviewing the protocol again if the Medical Board had already approved it. Ms. Herold responded that ACOG wanted the opportunity to address their concerns with the protocol as approved. President Weisser again stated that if any modifications were made at today's committee meeting the protocol would have to be approved again by the full board and the Medical Board.

Dr. Laura Sirott, practicing obstetrician and Vice Chairman for California, ACOG, commented that per their national policy ACOG is in support of over-the-counter access of oral contraceptives. Dr. Sirott noted that they define oral contraceptives as the pill, patch or ring and excludes the depo-injection.

Dr. Sirott stated that ACOG understands the desire to increase accessibility to the depo-injection; however they are concerned with patients self-administering an intramuscular injection as they are deep and painful. Dr. Sirott encouraged the committee to limit the protocol to subcutaneous injections with adequate training provided to the patient.

Dr. Sirott asked the committee to consider changing the language to say "offer to measure blood pressure." ACOG is of the opinion that most patients will know their blood pressure or could measure it themselves using the blood pressure stations available in most pharmacies. Dr. Sirott explained that ACOG is concerned that having the pharmacist take the patient's blood pressure could be a barrier to access.

Dr. Gutierrez asked if in a doctor's office contraceptives would be prescribed without taking the patient's blood pressure. Dr. Sirott responded that she would not prescribe contraceptives without first taking blood pressure as it is the standard of care.

Dr. Sirott asked the committee to consider changing the term "primary care provider" be changed to "primary healthcare provider" because the federal definition of primary care provider does not include OBGYNs. Liz McCaman responded that the governing statute uses the term "primary care provider" so the committee could not change the term.

Dr. Sirott expressed ACOG's opinion that the self-screening tool is overly complicated and could be simplified.

Dr. Kathy Hill-Besinque stated that pharmacists already dispense intramuscular injections to patients and the self-administered depo injections are already used worldwide. She added that the protocol specifically states that the patient must be trained by the pharmacist.

Dr. Hill-Besinque commented that most pharmacists would not feel comfortable dispensing hormonal contraceptives without first taking the patient's blood pressure. Dr. Hill-Besinque stated that a pharmacist should be following the same standard of care as a doctor or other health care professional.

Dr. Hill-Besinque noted that the language allows the questionnaire to be modified as long as it contains the same content.

Mr. Law asked how students are being trained for injections. Dr. Hill-Besinque responded that they receive extensive injection training and would be qualified to train the patient.

A member of the public commented that limiting the protocol to subcutaneous injections would limit patient access.

Dr. Sirott comments that ACOG's primary goal is to increase access to contraception.

Ms. McCaman stated that the author of one of the studies used as a reference for the creation of the protocol indicated that verifying normal blood pressure is essential to good, clinical decision making. Dr. Gutierrez added that the board would be holding the pharmacist responsible for their clinical decisions.

The committee did not take any action to modify the protocol based on ACOG's concerns. President Weisser thanked Dr. Sirott for attending the meeting and providing comments.

Ms. Herold noted that ACOG would have another opportunity to voice their concerns during regulation process during the 45-day comment period.