

TITLE 16: BOARD OF PHARMACY
FINAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: Self-Administered Hormonal Contraception.

Section Affected: Adopt Title 16 California Code of Regulations (CCR) section 1746.1.

Updated Information

The Initial Statement of Reasons, including the first and second amended versions, are included in this rulemaking file (unless otherwise specified, collectively referred to in the file as “Initial Statement of Reasons”). The information contained therein accurately reflects the position of the Board of Pharmacy (Board) regarding the adoption of the above section, and is updated to include the following information. The Board’s notice indicated that the Board did not intend to hold a hearing on the matter, unless requested. No request for a hearing was received by the Board during the 45-day comment period.

This regulation duplicates language found in Business and Professions Code (B&P) sections 4052 and 4052.3 which is cited as “authority” or “reference” for the proposed regulation and the duplication is necessary to permit better understanding of all requirements by those using the regulation and to satisfy the “clarity” standard of Government Code Section 11349.1(a)(3) in accordance with section 12, Title 1, CCR.

On December 30, 2015, the following documents were added to the rulemaking file:

1. 2010 United States Census, available at:
<http://www.census.gov/2010census/popmap/ipmtext.php?fl=06>
2. Jacqueline S. Gardner, et al., “Pharmacist prescribing of hormonal contraceptives: Results of the Direct Access study,” 48 J. AM. PHARM. ASSOC 212-221 (2008).
3. Sharon Cohen Landau, et al., “Birth control within reach: a national survey on women’s attitudes toward and interest in pharmacy access to hormonal contraception,” 74 Contraception 463-470 (2006)
4. Sharon Landau, et al., “Pharmacist interest in and attitudes toward direct pharmacy access to hormonal contraception in the United States,” 49 J. AM. PHARM. ASSOC 43-50 (2009).
5. K. Davis, M.A., Agency for Healthcare Research and Quality, Medical Expenditure Panel Survey, “Co-pays, Deductibles, and Coinsurance Percentages for Employer-Sponsored Health Insurance in the Private Sector, by Firm Size, 2012,” (2014) available at
http://meps.ahrq.gov/mepsweb/data_files/publications/st427/stat427.pdf

These documents were added as they were utilized by the Board in determining the business impact. Additionally, on December 30, 2015, the initial statement of reasons was revised to remove the economic impact analysis from the underlying data section as it was incorrectly listed. The initial statement of reasons was further revised to expand and define the estimated economic impact to businesses and patients utilizing pharmacies for self-administered hormonal contraception. The economic impact assessment was also revised to expand on the benefits to the health and welfare of California Residents.

On December 30, 2015, a 15-day public comment period began to allow the public the opportunity to review the documents added to the rulemaking file and to comment on the modifications made to the Initial Statement of Reasons.

On January 19, 2016, after having considered all comments in the record, the Board adopted the regulation text as noticed on May 8, 2015.

On March 9, 2016, the Initial Statement of Reasons was again revised to clarify the necessity of taking seated blood pressure when furnishing combined hormonal contraceptives. The initial statement of reasons was further revised to correctly identify the leaflet/factsheet that must be provided to patients and which factsheets may be provided. The original Initial Statement of Reasons mistakenly indicated that the pharmacist must provide all of the factsheets and this was not the Board's intent. Furthermore, clarifying information was added regarding notification of a patient's primary care provider, continuing education, record keeping, and patient privacy.

On March 9, 2016, a 15-day public comment period began to allow the public the opportunity to comment on the second modifications made to the Initial Statement of Reasons.

On March 28, 2016, after having considered all comments in the record, the Board, again, adopted the regulation text.

Non-substantive changes to correct grammar, punctuation, and numbering were also made. Additionally, subdivision (b)(6) was modified for clarity and arranged in the order in which the pharmacist would likely complete such tasks. The pharmacist should provide the comprehensive birth control guide first to the patient, next the pharmacist shall provide the patient with the product information leaflet, and finally, the pharmacist should provide the patient with the administration-specific factsheet.

All the documents relied upon for this rulemaking (including Board meeting attachments) were made available to the Board in connection with this rulemaking. Additionally, if any members of the public requested to view the documents relied upon, all of the documents in the rulemaking file would have been made available.

Local Mandate

A mandate is not imposed on local agencies or school districts.

Small Business Impact

This regulation will not have a significant adverse economic impact on businesses. This determination was based on the absence of substantive comments and the lack of any requests for a hearing regarding this rulemaking proposal.

The anticipated benefits of this regulatory proposal are:

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 prevent unintended 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.

Consideration of Alternatives

No reasonable alternative which was considered or that has otherwise been identified and brought to the attention of the Board would be more effective in carrying out the purpose for which it was proposed or would be as effective and less burdensome to affected private persons than the adopted regulation or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law. The Board considered removing the seated blood pressure requirements as an alternative; however, the Board determined that verifying blood pressure is essential to good, clinical decision making. 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. Additionally, as doctors take seated blood pressure prior to prescribing hormonal contraceptives as a standard of care, pharmacists should be held to that same standard of care.

Objections or Recommendations/Responses to Comments

45-Day Public Comment Period

During the 45-day public comment period from May 8, 2015 to June 22, 2015, the Board received several comments. The comments were provided to the Board in the meeting materials for the July 29, 2015 Board meeting, and were reviewed and considered by the Board. The Board again considered the comments at its September 30, 2015, Board meeting.

Written Comments from Brian Warren, California Pharmacists Association

Comment #1: Mr. Warren does not suggest any amendments to the regulation. Mr. Warren writes in support of the Board's draft protocol.

Mr. Warren and the California Pharmacists Association (CPhA) supports all elements contained in the Board's protocol, including the requirement to measure and record a patient's seated blood pressure prior to furnishing estrogen-progestin combination products.

Response to Comment #1: The Board appreciates the written comments on this rulemaking.

Written Comments from Mary Staples, National Association of Chain Drug Stores

Comment #2: Ms. Staples does not suggest any amendments to the regulation. Ms. Staples urges the Board to finalize the proposed rules on self-administered hormonal contraception.

Ms. Staples speaks to the public health benefit stemming from expanded patient access. Ms. Staples cites benefits to maternal health, safe pregnancies, and reduced unwanted pregnancies.

Response to Comment #2: The Board appreciates the written comments on this rulemaking and agrees that the proposed rules will improve public health in California.

Written Comments from Bonnie Zell, MD, MPH, FACOG, Icebreaker Health

Comment #3: Dr. Zell states that the seated blood pressure requirement will limit access to hormonal contraception. Dr. Zell requests modification of the protocol, specifically to strike the pharmacist's requirement to take seated blood pressure. Alternatively, she requests modification of the language such that it is up to the professional judgment of the pharmacist whether to require seated blood pressure or allow self-reported blood pressure. Dr. Zell states the blood pressure requirement is unnecessary and inconsistent with SB 493 (Hernandez), the statute that authorizes this rulemaking.

Response to Comment #3: This comment is rejected because the Board does not agree that requiring seated blood pressure for combination products will significantly impede contraceptive access. Measurement of seated blood pressure is unobtrusive, quick, and can easily be performed in a pharmacy. In addition to a blood pressure machine, seated blood pressure can be taken with an automated cuff or manual sphygmomanometer. If the patient is unwilling or unable to have her blood pressure measured, she can be furnished progestin-only products. The language of the protocol was specifically drafted to state that a pharmacist shall measure and record the patient's seated blood pressure only if combined hormonal contraceptives are requested or recommended. Significantly, the public is better protected by requiring a pharmacist to review the person's blood pressure before furnishing the drug. Certain hormonal contraceptives are not recommended for women with elevated blood pressure. Accurately identifying blood pressure will help prevent furnishing of a dangerous drug to a patient who may experience a negative side effect from the drug.

For the protection of patients, this protocol requires some face-to-face interaction with a pharmacist. The legislative history of SB 493 does not prohibit the taking of blood pressure.

Comment #4: Dr. Zell states that blood pressure can be adequately obtained and communicated to a healthcare provider through self-reporting tools.

Response to Comment #4: This comment is rejected because the Board does not agree that seated blood pressure can be adequately obtained for all patients through self-reporting tools. 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.

Data elements such as smoking history, family history, and recreational drug use are self-reported because the pharmacist cannot obtain the information via any other instrument. This is not the case with seated blood pressure, which a pharmacist can accurately measure on-site. 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. Accurate current blood pressure is required to safely determine whether to furnish and, if so, which drug to furnish.

Comment #5: Dr. Zell states that other comparable healthcare providers are not required to obtain a seated blood pressure before providing hormonal contraceptives.

Response to Comment #5: This comment is rejected. The Board agrees that other healthcare providers are not statutorily required to obtain a seated blood pressure before providing hormonal contraceptives. While perhaps not required by law, the Board received testimony from Dr. Kathy Besinque and an OB/GYN representative from the American College of Obstetricians Gynecologists that it is the standard of care for any physician to obtain seated blood pressure before providing hormonal contraceptives.

SB 493 requires that the regulatory self-screening tool be based on the United States Medical Eligibility Criteria for Contraceptive Use (USMEC), developed by the federal Centers for Disease Control and Prevention. The USMEC lists combined hormonal contraceptives as category 3, where the risks of taking the product outweigh the benefits, for anyone with elevated blood pressure. The pharmacist must have an accurate blood pressure reading to make an informed decision about which drug, if any, may be safely recommended to the particular patient.

Unlike for other healthcare providers, furnishing hormonal contraceptives is a new role for pharmacists. At this point, the Board believes requiring the pharmacist to take a seated blood pressure protects patients.

Comment #6: Dr. Zell states that other organizations do not recommend a seated blood pressure. Dr. Zell also states that these organizations call for hormonal contraception to be classified as over-the-counter.

Response to Comment #6: This comment is rejected because the Board credits those organizations and the practices of other healthcare providers who do take seated blood pressure prior to recommending a particular hormonal contraceptive. At this point in time, hormonal contraception is not in an over-the-counter classification. Any suggestions based on over-the-counter status are irrelevant and cannot be considered.

The Board of Pharmacy relied on multiple research studies, including studies by Dr. Daniel Grossman and Solmaz Shotorbani, Department of Pharmacy, University of Washington, on women's ability to correctly self-identify contraindications to oral contraceptives. Board staff personally consulted with both Dr. Grossman and Ms. Shotorbani during the editing process. Dr. Grossman's study only involved the contraceptive pill and did not include the patch, ring, or injection. Because of the expanded methods of administration, which will improve access for California women, the Board also consulted additional research on pilot projects of pharmacists dispensing hormonal contraception. Dr. Daniel Downing created the first pharmacist-initiated ongoing hormonal contraception services in the United States. Dr. Downing stated that his team felt the standard of practice with regard to verifying normal blood pressure when considering the initiation of estrogen-containing hormonal contraception was essential to good clinical decision-making.

Written Comments from Beth H. Parker, Planned Parenthood Affiliates of California

Comment #7: Ms. Parker requests modification of the protocol language to permit women to self-report blood pressure. Ms. Parker opines that self-reporting will ensure maximum access to contraception without compromising patient safety. Ms. Parker also argues that not all

pharmacies have blood pressure machines onsite. Ms. Parker also states that other organizations do not recommend a seated blood pressure and call for hormonal contraception to be classified as over-the-counter.

Ms. Parker states that blood pressure can be adequately obtained through self-reporting tools and points to the CDC Medical Eligibility Criteria as stating that obtaining a blood pressure reading and self-reporting to a provider is acceptable if a patient is not able to access an appointment for measuring blood pressure.

Response to Comment #7: The Board rejects this comment because it does not agree that seated blood pressure can be adequately obtained for all patients through self-reporting tools. Many patients with elevated blood pressure, especially those with reduced access to medical care, may not know of their condition or have the resources to continuously monitor their condition. Additionally, the protocol does not specify that seated blood pressure must be taken with a blood pressure machine. In addition to a blood pressure machine, seated blood pressure can be taken by the pharmacist with an automated cuff or manual sphygmomanometer. If the patient is unwilling or unable to have her blood pressure measured, she can be furnished progestin-only products. The language of the protocol was specifically drafted to state that a pharmacist shall measure and record the patient's seated blood pressure only if combined hormonal contraceptives are requested or recommended.

The proposed regulation does not change the status of self-administered hormonal contraception to over-the-counter classification. Any suggestions based on over-the-counter status are irrelevant and cannot be considered.

The Board of Pharmacy relied on multiple research studies, including studies by Dr. Daniel Grossman and Solmaz Shotorbani, Department of Pharmacy, University of Washington, on women's ability to correctly self-identify contraindications to oral contraceptives. Board staff personally consulted with both Dr. Grossman and Ms. Shotorbani during the editing process. Dr. Grossman's study only involved the contraceptive pill and did not include the patch, ring, or injection. Because of the expanded methods of administration, which will improve access for California women, the Board also consulted additional research on pilot projects of pharmacists dispensing hormonal contraception. Dr. Daniel Downing created the first pharmacist-initiated ongoing hormonal contraception services in the United States. Dr. Downing stated that his team felt the standard of practice with regard to verifying normal blood pressure when considering the initiation of estrogen-containing hormonal contraception was essential to good clinical decision-making.

Patient-reported data is appropriate in certain settings. Data elements such as smoking history, family history, and recreational drug use are self-reported because the pharmacist cannot obtain the information via any instrument. This is not the case with seated blood pressure, which a pharmacist can accurately measure on-site. Self-reporting may be problematic 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. Accurate current blood pressure is required to safely determine whether to furnish and, if so, which drug to furnish.

Furnishing hormonal contraceptives is a new role for pharmacists. As Ms. Parker points out, the CDC Medical Eligibility Criteria states that blood pressure is required for combined hormonal

contraceptive prescriptions. At this point, the Board believes requiring the pharmacist to take a seated blood pressure protects patients and is the proper standard of care.

Comment #8: Ms. Parker states that hormonal contraception is very safe and promotes women's health.

Response to Comment #8: The Board agrees with this comment; because hormonal contraception is extremely safe, the Legislature authorized the Board to draft this novel protocol.

Comment #9: Ms. Parker states that self-reporting of blood pressure will increase access to contraception for women.

Response to Comment #9: The Board rejects this comment because it does not agree that the ability to self-report blood pressure will affect a patient's access to contraception. Additionally, requiring seated blood pressure for combination products will not significantly impede contraceptive access. Measurement of seated blood pressure is unobtrusive, quick, and can easily be performed in a pharmacy. Section 4103 of the California Business and Professions Code allows, since before 1997, pharmacists to take blood pressure, and pharmacists are more than adequately trained to take this measurement in a manner that does not delay access. For additional explanation, see responses to Comment(s) number(s) 3, 4, 5, 6, and 7.

Comment #10: Ms. Parker states that access to contraception is crucial for women's economic opportunity and equality.

Response to Comment #10: This comment does not relate to the text of the regulation and no changes are made as a result.

Written Comments from Mitchell D. Crenin, MD, Catherine Cansino, MD, MPH, Melody Hou, MD, MPH, and Juliana Melo, MD, MSCS, Division of Family Planning, Department of Obstetrics & Gynecology, University of California, Davis

Comment #11: Drs. Cenin, Cansino, Hou, and Melo state that requiring any evaluation of blood pressure for women seeking progestin-only pills is beyond CDC recommendation.

Response to Comment #11: The Board agrees with this comment, but finds the comment consistent with the draft regulation. The language of the protocol was specifically drafted to only require a pharmacist to measure and record the patient's seated blood pressure when combined hormonal contraceptives are requested or recommended.

Comment #12: Drs. Cenin, Cansino, Hou, and Melo provided comment that the requirement for a pharmacist to take seated blood pressure is not necessary and should be removed from the protocol. They indicate that seated blood pressure exceeds what is required for appropriate evaluation. They state that blood pressure can be adequately obtained and communicated to a pharmacist through self-reporting tools, and blood pressure reporting can be "optional" if the pharmacist feels it is indicated based on other factors such as obesity.

Response to Comment #12: The Board rejects this comment because it does not agree that seated blood pressure can be adequately obtained for all patients through self-reporting tools. For additional explanation, see responses to Comment(s) number(s) 3, 4, 5, 6, 7, and 9.

Drs. Cenin, Cansino, Hou, and Melo also readily concede that in a medical office, blood pressure evaluation is standard of care for any visit, whether the woman is seeking combined oral contraceptives or getting a mole evaluated. The Board believes pharmacists are to be held to the same standard of care as other healthcare providers.

Comment #13: Drs. Cenin, Cansino, Hou, and Melo state the seated blood pressure requirement is beyond the recommendation of ACOG's over-the-counter initiative.

Response to Comment #13: See response to Comment numbers 6 and 7.

Comment #14: Drs. Cenin, Cansino, Hou, and Melo state that the ability to self-report venous thromboembolic (VTE) disease is just as important as blood pressure. If women can be trusted to report VTE, they should be trusted to report blood pressure.

Response to Comment #14: The Board rejects this comment because it does not agree that seated blood pressure can be adequately obtained for all patients through self-reporting tools. Additionally, VTE is a medical disease that is diagnosed by the healthcare provider. A patient diagnosed with VTE would be aware of that diagnosis. While a patient with high blood pressure may not be aware of the condition. For additional explanation, see responses to Comment(s) number(s) 3, 4, 5, 6, 7, and 9.

Comment #15: Drs. Cenin, Cansino, Hou, and Melo state that requiring seated blood pressure limits access and creates an unnecessary barrier.

Response to Comment #15: The Board rejects this comment because it does not agree that requiring seated blood pressure will limit access. Measurement of seated blood pressure is unobtrusive, quick, and can easily be performed in a pharmacy. Section 4103 of the California Business and Professions Code allows, since before 1997, pharmacists to take blood pressure, and pharmacists are more than adequately trained to take this measurement in a manner that does not delay access. For additional explanation, see responses to Comment(s) number(s) 3, 4, 5, 6, 7, and 9.

Comment #16: Drs. Cenin, Cansino, Hou, and Melo state that women should have the option for a blood pressure evaluation.

Response to Comment #16: The Board rejects this comment because it believes verifying blood pressure is essential to good, clinical decision making. Public protection is improved by requiring a pharmacist to measure and record the patient's seated blood pressure before furnishing combined hormonal contraception. For additional explanation, see responses to Comment(s) number(s) 3, 4, 5, 6, 7, and 9.

Drs. Cenin, Cansino, Hou, and Melo also readily concede that in a medical office, blood pressure evaluation is standard of care for any visit, whether the woman is seeking combined oral contraceptives or getting a mole evaluated. The Board believes pharmacists are to be held to the same standard of care as other healthcare providers

15-Day Public Comment Period

During the 15-day public comment period from December 30, 2015 to January 14, 2016, the Board received one comment. The comment was provided to the Board in the meeting

materials for the January 19, 2016, Board meeting, and were reviewed and considered by the Board.

Comment from starship1980s@aol.com, submitted via email

Comment #1: Commenter disagrees with the proposed regulation. Commenter states that pharmacists should not be allowed to dispense hormonal contraceptives without a prescription. Commenter states that a prescription should be required. Commenter further states it “will cause undue and unnecessary hardship on pharmacists as they are already loaded up with more than their share of work.” Additionally, the commenter requested a hearing regarding this issue.

Response to Comment #1: The Board rejects the comment. A pharmacist’s ability to dispense self-administered hormonal contraception is now authorized by statute; this regulation merely sets out the protocol pharmacists must follow in accordance with the statute. A regulation hearing was not scheduled based on the request as it was received outside the hearing request window as allowed by the Administrative Procedure Act. In addition, this matter was considered at numerous publicly noticed meetings of a committee and the full board over the last year or so.

At its January 19, 2016, meeting, the Board considered all of the comments and voted to adopt the self-administered hormonal contraception regulation text as it was noticed.

15-Day Public Comment Period

During the 15-day public comment period from March 9, 2016 to March 24, 2016, the Board received one comment. The comment was provided to the Board in the meeting materials for the March 28, 2016, Board meeting, and were reviewed and considered by the Board.

Comment from starship1980s@aol.com, submitted via email.

Comment #1: Commenter states “Pharmacists should not be allowed to administer or prescribe self administered hormonal contraceptives.”

Response to Comment #1: The Board rejects the comment. A pharmacist’s ability to dispense self-administered hormonal contraception is now authorized by statute; this regulation merely sets out the protocol pharmacists must follow in accordance with the statute.

At its March 28, 2016, meeting, the Board considered all of the comments and voted to adopt the self-administered hormonal contraception regulation text as it was noticed.