

Board of Pharmacy

Final Statement of Reasons

Subject Matter of Proposed Regulation: Emergency Contraception

Title 16 Sections Affected: Amend 16 Cal. Code Reg. § 1746

Updated Information

The Initial Statement of Reasons is included in this rulemaking file. The information contained therein accurately reflects the board's position regarding the adoption of the above sections, but is updated to include the following information. The following additional description is intended to provide additional clarification of the information contained in the Initial Statement of Reasons and documents identified therein.

Article 3 of Division 2 of Chapter 9 of the Business and Professions Code (starting at Section 4050) specifies the scope of practice and exemptions of a pharmacist. Existing law at Article 3, Section 4052(a)(8) of the Business and Professions Code authorizes a pharmacist to furnish emergency contraception (EC) drug therapy as authorized by Section 4052.3 of the Business and Professions Code. The provisions of Section 4052.3(a)(2) require that standardized procedures or protocols be developed and approved by the Board of Pharmacy and the Medical Board of California, in consultation with the American College of Obstetricians and Gynecologists, the California Pharmacist Association and other appropriate entities. Following the enactment of SB 490 (2003), the California State Board of Pharmacy (Board) and the Medical Board of California (MBC) worked with Dr. Kathleen Hill-Besinque, a women's health specialist pharmacist working with the California Pharmacist Association, as well as representatives from the American College of Obstetricians and Gynecologists. That effort resulted in the promulgation of Title 16 Section 1746 (operative 12/2/04) that specified the "statewide protocol" that was envisioned by the enacting legislation.

As required by Section 4052.3(a)(2), the MBC and the Board again sought the consultation and expert opinion of the American College of Obstetricians and Gynecologists and the California Pharmacist Association to update the statewide protocol specified at Title 16 Section 1746 to reflect changes in the availability of emergency contraception and the manufacturing of these drugs.

In 2001, SB 1169 (c. 900 Stats 2001) created the authority for a pharmacist to initiate emergency contraception drug therapy in accordance with standardized procedures or protocols developed by the pharmacist and an authorized prescriber acting within their scope of practice. That legislation stated that emergency contraception therapy is a drug regimen that reduces the chance of pregnancy significantly if administered within a specified number of hours of unprotected sex. In short, having an emergency contraception protocol allows a pharmacist to dispense emergency contraception drug therapy to an individual without having a patient-specific prescription document from a prescriber, so long as it is dispensed in

accordance with the protocol. This authority is currently found at Section 4052.3(a)(1) of the Business and Professions Code.

In 2004, SB 490 (c. 651 stats 2003) added a second process by which pharmacists could provide emergency contraception therapy that was standardized and approved by the MBC and the Board, and that did not require the pharmacist to develop a protocol in conjunction with an authorized prescriber – thus, the “statewide protocol” was developed. This regulation, effective December 2, 2004, is found at Title 16 Section 1746. In promulgating this regulation, and as required by statute, the MBC and the Board relied on the expert opinion of the women’s health specialist pharmacist from the California Pharmacist Association, as well as the expertise of representatives of the American College of Obstetricians and Gynecologists to determine which FDA-approved drugs should be identified in the statewide protocol. As a result, the statewide protocol was developed in conformance with the statutory provisions of the underlying legislation (SB 1169, 2001) and promulgated into regulations.

The medications specified in the statewide protocol are all prescription (Rx) medications approved by the U.S. Food and Drug Administration (FDA). In California, Business and Professions Code Section 4022 defines a “dangerous drug” as one that bears the legend: “Caution: federal law prohibits dispensing without prescription,” “Rx only” or words of similar import. The names of the drugs listed in the Table of Dedicated Emergency Contraception, and Oral Contraceptive Pills are all consistent with the “proprietary” names that bear FDA approval. While the FDA has numerous approved drugs, the boards relied on the expert opinions of the women’s health specialist pharmacist from the California Pharmacist Association and representatives of the American College of Obstetricians and Gynecologists to determine which FDA-approved drugs should be identified in the statewide protocol.

When the regulation was developed in 2004, and again when the protocol was being revised, the board worked with Dr. Kathleen Besinque, a women’s health specialist pharmacist representing the California Pharmacists Association, and Dr. Shannon Smith-Crowley representing the American Congress of Obstetricians and Gynecologists. At the meeting of the MBC held July 2011, Drs. Besinque and Crowley attended and presented information in support of updating the medications listed in the statewide protocol. The MBC supported the changes with no public comment on the matter. In September 2011, the Board of Pharmacy received the same information and supported the proposed changes, again with no public comment. Dr. Besinque also appeared at the Board of Pharmacy public meeting in October 2011 to answer any questions the board or public might have and the board voted in favor of draft regulatory text to modify the statewide protocol as previously considered by the MBC– again with no public comment on the matter. As reflected in the various board meeting materials and minutes, the Board and the MBC have publicly discussed the revision of the statewide EC protocol with little or no public interaction or comment. The matter has been publicly agendized at three separate meetings of the MBC (July 2011, July and September 2012), and at five separate meetings of the Board (July and October 2011, May, July and October 2012).

The board stated the necessity to update the protocol to reflect emergency and oral contraceptives that are now available, so that individuals can request and receive emergency contraceptive products that are currently approved by the FDA and that are approved for

furnishing through a statewide protocol. By doing this, the board eliminates confusion for pharmacists and patients, and allows for access to appropriate medications as envisioned in the underlying statutes. The changes also ensure that the drugs listed in the statewide protocol are not inconsistent with those approved by the FDA.

For example, in 2004, the drug “Preven” (manufactured by Gynetics) was one of the dedicated emergency contraceptives listed in the protocol. Today, the FDA identifies “Preven” as a discontinued drug product. Because it is discontinued, it no longer bears the symbol “Rx” and is not approved for furnishing by a pharmacy as a prescription drug – thus, it needs to be removed from the regulation to ensure the board’s regulated public has clear understanding of its authorities in this area. Not making this change would create confusion and would create inconsistency with federal laws.

Likewise, in 2004, the statewide protocol listed “Nordette” (approved by the FDA in 1982, and in 2004 manufactured by Wyeth) as an oral contraceptive pill approved for emergency contraception. Today, Nordette is still available, but the product is now owned by the manufacturer “Teva.” In the newly-adopted protocol, Nordette is still listed, but no manufacturer name is listed. (The newly-adopted protocol does not list any manufacturer names.) This ensures an FDA approved drug – and one that is approved in the statewide protocol – can be dispensed irrespective of what manufacturer distributes the drug, and further removes any inconsistency with federal laws.

More currently – and during this rulemaking process – the FDA issued a news release that it had approved a new 5-day emergency contraceptive, *ella*. Upon this approval, the board sought the expert opinion of the women’s health specialist pharmacist from the California Pharmacist Association and the representatives of the American College of Obstetricians and Gynecologists as to whether or not *ella* should be included in the statewide protocol and, based on their expert opinions, chose to modify the protocol to include *ella* (which resulted in the issuance of modified text). This action was taken at the Board’s public meeting held July 17, 2012.

Finally, as ‘generic’ drug products are approved by the FDA, the adopted language will allow a pharmacist to furnish a generic equivalent product of a drug specified in the protocol.

As reflected in the Notice, the board did not schedule a regulation hearing on the matter. Likewise, the board did not receive a request for a hearing.

The Board of Pharmacy considered the comments received during the 45-day public comment period at its Board Meeting held May 1, 2012. At that meeting the women’s health specialist for the California Pharmacists Association, Dr. Kathleen Hill-Besinque, was available to answer any questions the board had. At the recommendation of Dr. Besinque, the board rejected the one comment received during the 45-day public comment period, citing that the protocol – as proposed – was consistent with medical guidelines for the use of emergency contraception.

Following the May 1, 2012 meeting, and on the recommendation of Dr. Besinque, board staff presented modifications to the Table of Dedicated Emergency Contraception (at

Section 1746(b)(11)) to provide clarity on the administration of the two-tablet regimes. The board considered and approved modified language at its Board Meeting held July 17, 2012. No public comment was received on the matter.

The Medical Board of California considered and approved the modifications provided by the Board of Pharmacy at its quarterly board meeting held July 20, 2012, and approved additional modifications (the re-phrasing of text at § 1745(b)(3)). There was no public comment received on the matter.

Thereafter, on September 19, 2012, the Executive Committee of the MBC confirmed that the language considered and approved by the MBC at its July quarterly meeting was, in fact, the modified language that was appended to the Executive Committee's meeting materials. Again, there was no public comment received on the matter.

At the Board of Pharmacy meeting held October 25, 2012, the board approved the modified language that was approved by the MBC (on July 20, 2012). Thereafter, staff issued the modified language for a 15-day public comment period – during which time the board did not receive any comments. At the direction of the board (in its motion October 25, 2012), the Executive Officer adopted the regulation language as reflected in the modified text notice, and staff completed the rulemaking record.

Local Mandate:

None.

Business Impact:

This regulation will not have a significant adverse economic impact on businesses. This determination was based on the absence of comments or testimony indicating adverse economic impact regarding this rulemaking proposal.

The anticipated benefits of this regulatory proposal will be to provide pharmacists with an updated protocol – one which incorporates emergency contraceptives that have been approved since the protocol was last updated – for the purpose of dispensing emergency contraception.

Specific Technologies or Equipment:

This regulation does not mandate the use of specific technologies or equipment.

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 the regulation was proposed, 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.

Summary of Comments Received During the 45-Day Comment Period:

The board received one comment during the 45-day public comment period:

Comment from Amanda Davis, Pharm.D.

Dr. Davis stated her comments were specific to paragraph (3) of subdivision (b) of Section 1746. This paragraph specifies the procedure a pharmacist must follow when a patient requests emergency contraception pursuant to the statewide protocol. Dr. Davis bases her comments on the information available for *ellaOne* (also referred to as UPA) – which is an emergency contraception drug product approved in Europe (approved by the European Medicines Agency). *ellaOne* is not an FDA approved drug product and, as such, it cannot be included in the statewide emergency contraception protocol. Until such time that the FDA approves *ellaOne* as an approved drug for the United States drug market, the information on which Dr. Davis bases her comments are not relevant to those FDA approved drug products contained in the statewide emergency protocol.

First, Dr. Davis states that “with the advent of ulipristal acetate on the market as an alternative emergency contraceptive, it is important to differentiate between the two types of emergency contraception when counseling patients.” She states that while used for the same purpose, they have different properties. As a result, she suggested that the board strike the phrase “EC use will not interfere with an established or implanted pregnancy” and replace it with the phrase “Progesterone-based emergency contraception will not interfere with an established pregnancy” or a similar phrase that would exclude ulipristal. Dr. Davis states that, considering the current scientific evidence regarding ulipristal, it would be incorrect to tell a patient, implicitly or explicitly, that the medication cannot disrupt an established pregnancy. Dr. Davis makes reference to and attributes outcomes to animal studies and human studies. Dr. Davis quotes a report published by the European Medicines Agencies for *ellaOne* (the trade name for *ella* in Europe), “Ulipristal acetate prevents progesterone from occupying its receptor, thus the gene transcription normally turned on by progesterone is blocked, and the proteins necessary to begin and maintain pregnancy are not synthesized”. She concluded her statement that this is something that might also be applied to the EC fact sheet for patients. (Note: the board’s regulation at paragraph (4) of subdivision (b) requires a pharmacist to provide a fact sheet which is required by Business and Professions Code Section 4052.3(e), and review any questions the patient may have regarding EC.)

Response – At the board meeting held May 1, 2012, the board members asked the women’s health specialist pharmacist from the California Pharmacist Association, Dr. Besinque, if Dr. Davis’ comment warranted modification of the statewide protocol, specifically, if it was important for a pharmacist to communicate to a patient (when providing EC), that there are differences between the two types of emergency contraception, and if it is necessary to strike the language, and insert the suggested language offered by Dr. Davis. Dr. Besinque stated that the statewide protocol, as proposed, is consistent with US medical guidelines for the use of Emergency Contraception and that it is not necessary to amend the protocol to require a pharmacist to tell a patient the differences between the types of emergency contraceptives. Dr. Besinque noted that the existing protocol (at paragraph 2 of subdivision (b)) requires a pharmacist to ensure that the patient receives **adequate information to**

successfully complete therapy. After considering the expert opinion of Dr. Besinque, the board rejected the comment.

Comment

Dr. Davis also suggested that in paragraph (3) of subdivision (b), the board strike the proposed added text “If more than 72 hours have elapsed since unprotected intercourse, the use of ella (ulipristal) may be more effective than levonorgestrel. Other options for EC include consultation with your physician regarding the insertion of an IUD.” Dr. Davis suggested replacing this paragraph with the following language: “If more than 72 hours have elapsed since unprotected intercourse, consult with your physician to discuss other options for EC.”

First, Dr. Davis suggests that recommending the use of ulipristal “more than 72 hours” after intercourse would only be accurate if less than 120 hours has elapsed since the event. She states that the proposed phrasing does not specify this and may provide confusing or inaccurate information to a patient.

Response – The board considered this comment, and noted that paragraph (3) of subdivision (b) (in the second paragraph) does require a pharmacist to communicate that “treatment may be initiated up to five days (120 hours) after unprotected intercourse.” Further, paragraph (3) of subdivision (b) (in the fourth paragraph) requires the pharmacist to communicate information related to ella if more than 72 hours has elapsed since unprotected intercourse. Dr. Besinque noted that the information in the protocol is not confusing or inaccurate when read in its entirety. Staff reflected on the Legislative declaration provided in Business and Professions Code Section 4050, noting that the practice of pharmacy is a dynamic patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug therapy, and communication for clinical and consultative purposes. The statewide EC protocol specifies the *minimum* information that a pharmacist must communicate to the patient when providing EC. Likewise, prior to furnishing EC, a pharmacist that participates in the statewide protocol must have completed a specified amount of continuing education specific to emergency contraception. Based on the expert opinion of Dr. Besinque, and in considering the information that must be communicated to the patient pursuant to the protocol (in its entirety), the board rejected this comment.

However, in response to Dr. Davis’ comment, the MBC at its July Board Meeting modified the subparagraph slightly – not completely as Dr. Davis recommended – but to indicate that a patient should consult with their health care provider regarding other options for EC and to follow up after the use of EC. This modified language was subsequently approved by the Board of Pharmacy at its October 25, 2012 meeting, and then the modified language was issued for a 15-day public comment period.

Comment

Dr. Davis provided additional comments to support her statements (comment) above. When read in their entirety, Dr. Davis' comments suggest that she does not support the providing of EC to a patient if more than 72 hours has elapsed since unprotected intercourse, and that if that time period has elapsed, the **only** alternative is to refer the patient to their physician. She provided additional statements in support of this comment.

Response - The existing statewide protocol established in 2004 specifies that EC treatment may be initiated up to five days (120 hours) of unprotected intercourse – and the board did not propose modifications to the protocol to reduce that timeframe. Thus, Dr. Davis' comments that suggest if more than 72 hours has elapsed since unprotected intercourse the **ONLY** option is to refer the patient to a physician, is outside the scope of the board's proposal.

In addition, modifications made to the board's proposal (see 15-day modified text), does require a pharmacist to communicate the following statements to a patient, when the patient requests emergency contraception: "For other options for EC, consult with your health care provider." "Please follow up with your health care provider after the use of EC." With the exception of the modifications made to the proposal in the 15-day modified text to communicate that a patient consult with their health care provider, and to follow up with their health care provider following the use of EC, the board – based on the expert opinion of Dr. Besinque determined that the comments related to not providing EC after 72 hours was not within the scope of the proposal. The board rejected comments that were outside of the scope of the regulation. Likewise, with the exception of the modified language issued for a 15-day comment period, and based on the expert opinions of Dr. Besinque and Dr. Smith-Crowley, the MBC rejected the comments at its quarterly Board Meeting held July 20, 2012.