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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

July 10, 2012

To: Members, Medical Board of California

From: Virginia Herold
Executive Officer
California State Board of Pharmacy

Subject: Emergency Contraception Protocol of the Medical Board of California with the California State Board of Pharmacy:
Proposed Amendments to Title 16, Section 1746 – Emergency Contraception Protocol

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Background

Business and Professions Code Section 4052.3 authorizes a pharmacist to initiate emergency contraception therapy in accordance with either (1) standardized procedures or protocols developed by the pharmacist and an authorized prescriber, as specified; or (2) standardized procedures or protocols developed and approved by both the Medical Board of California and the Board of Pharmacy, as specified.

The current state protocol was developed by the Medical Board in 2004 and was adopted by the Board of Pharmacy as a regulation later that same year. Title 16 CCR § 1746 became operative on December 2, 2004. Since that time, there have been changes in the availability of emergency contraception medicine, the manufacturers who produce the medication. The protocol also has a typographical error that requires correction (mcg instead of mg).

In October 2011, the board voted to initiate a proposed rulemaking to update the board's emergency contraception protocol at Title 16 Section 1746, to reflect the language and protocol approved by the Medical Board of California in July 2011. The board noticed the proposed regulation on January 6, 2012, and the 45-day public comment period concluded on February 20, 2012. The board received one comment during that period (**Attachment 1**). Both Shannon Smith Crowley, the Medical Board's technical expert and Kathleen Hill-Besinque, the California Pharmacists Association, technical expert, agreed there was no need to accept the written comment submitted.

Specifically, at the May 1, 2012 Board of Pharmacy Meeting, Dr. Besinque appeared before the board to answer questions related to the proposed protocol Thereafter, the board voted to reject the comments received during the 45-day public comment period.

Following the May 2012 Board Meeting, Dr. Besinque provided the board with suggested modifications to the Table of Dedicated Emergency Contraception (at Section 1746 (b)(11)) to provide clarity on the administration of the two-tablet regimes.

Attachment 2 contains a copy of the revised EC Protocol contained in section 1746, showing these modifications in the Table of Dedicated Emergency Contraception.

This version is being considered by the Board of Pharmacy at its next meeting on July 17-18, 2012.

At this Medical Board Meeting

The next step is for the Medical Board of California to consider the 45-day comment. If the Medical Board does not accept this comment, and if the Medical Board approves the final version of the protocol provided in **Attachment 2**, the Board of Pharmacy will finalize the rulemaking.

Following the adoption of a new emergency contraception protocol, the board will then need to update its patient information fact sheet. This fact sheet is required by Section 4052.3(e) of the Business and Professions Code and is provided to the patient by the pharmacist using the protocol to dispense emergency contraception. The Medical Board will have a chance to review the fact sheets as well.

Board of Pharmacy
Modified Language

To Amend § 1746 in Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1746. Emergency Contraception

(a) A pharmacist furnishing emergency contraception pursuant to Section ~~4052(a)(8)~~ 4052.3.(a)(2) of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Emergency Contraception (EC).

~~(1) Authority: Section 4052 of the California Business and Professions Code authorizes a pharmacist to furnish emergency contraception pursuant to the protocols specified in Business and Professions Code section 4052.3. Use of the following protocol satisfies that requirement.~~

(1) Authority: Section 4052.3(a)(2) of the California Business and Professions Code authorizes a pharmacist to furnish emergency contraception pursuant to a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol specified in this section satisfies that requirement.

(2) Purpose: To provide timely access to emergency contraceptive medication ~~within required limits~~ and ensure that the patient receives adequate information to successfully complete therapy.

(3) Procedure: When a patient requests emergency contraception, the pharmacist will ask and ~~state~~ communicate the following:

> Are you allergic to any medications?
>
> Timing is an essential element of the product's effectiveness. EC should be taken as soon as possible after unprotected intercourse. Treatment may be initiated up to five days (120 hours) ~~of~~ after unprotected intercourse. ~~EC effectiveness declines gradually over five days and EC use will not interfere with an established pregnancy.~~
>
> EC use will not interfere with an established or implanted pregnancy.
>
> 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 insertion of an IUD.

(4) The pharmacist shall provide ~~the~~ a fact sheet and review any questions the patient may have regarding EC. In addition, the pharmacist shall collect the information required for a patient medication record required by Section 1707.1 of Title 16 of the California Code of Regulations.

Fact Sheet: The pharmacist will provide the patient with a copy of the current EC fact sheet approved by the Board of Pharmacy as required by Business and Professions Code Section ~~4052(b)(3)~~ 4052.3(e).

(5) Referrals and Supplies: If emergency contraception services are not immediately available at the pharmacy or the pharmacist declines to furnish pursuant to conscience clause, the pharmacist will refer the patient to another emergency contraception provider. The pharmacist shall comply with all state mandatory reporting laws, including sexual abuse laws.

(6) The pharmacist may provide up to 12 non-spermicidal condoms to each Medi-Cal and Family PACT client who obtains emergency contraception.

(7) Advanced provision: The pharmacist may dispense emergency contraception medication for a patient in advance of the need for emergency contraception.

(8) EC Product Selection: The pharmacist will provide emergency contraception medication ~~compatible with product information~~ from the list of products specified in this protocol. This list must be kept current and maintained in the pharmacy. Along with emergency contraception products, the list will include adjunctive medications indicated for nausea and vomiting associated with taking EC containing estrogen. Patients will be provided information concerning dosing and potential adverse effects.

(9) Documentation: Each prescription authorized by a pharmacist will be documented in a patient medication record as required by law.

(10) Training: Prior to furnishing emergency contraception, pharmacists who participate in ~~the~~ this protocol must have completed a minimum of one hour of continuing education specific to emergency contraception.

~~(11) Brands and Doses of Oral Contraceptive Tablets Used for Emergency Contraception.~~

~~(11) Brands and Doses of Oral Contraceptive Tablets Used for Emergency Contraception.~~

~~Dedicated Emergency Contraception~~

~~Brand~~	~~Manufacturer~~	~~Tablets per Dose~~	~~Ethinyl Estradiol per Dose (mg)~~	~~Levonorgestrel per Dose (mg)**~~
		~~One Dose Regimen~~		
~~Plan B~~	~~Women's Capital Corporation~~	~~2 tablets~~	~~0~~	~~1.5~~
		~~Two Dose Regimens~~		
~~Plan B~~	~~Women's Capital Corporation~~	~~1 tablet per dose~~	~~0~~	~~0.75~~
~~Preven~~	~~Gynétics~~	~~2 tablets per dose~~	~~100~~	~~0.50~~
~~Oral Contraceptive Pills~~				
~~Brand~~	**~~Manufacturer~~**	**~~Tablets per Dose (two doses 12 hours apart*)~~**	**~~Ethinyl Estradiol per Dose (mg)~~**	**~~Levonorgestrel per Dose (mg)**~~**
~~Levora~~	~~Watson~~	~~4 white tablets~~	~~120~~	~~0.60~~
~~Ovral~~	~~Wyeth~~	~~2 white tablets~~	~~100~~	~~0.50~~
~~Ogestrel~~	~~Watson~~	~~2 white tablets~~	~~100~~	~~0.50~~
~~Nordette~~	~~Wyeth~~	~~4 light-orange tablets~~	~~120~~	~~0.60~~
~~Tri-Levlen~~	~~Berlex~~	~~4 yellow tablets~~	~~100~~	~~0.50~~
~~Alesse~~	~~Wyeth~~	~~5 pink tablets~~	~~100~~	~~0.50~~
~~Aviane~~	~~Duramed~~	~~5 orange tablets~~	~~100~~	~~0.50~~
~~Triphasil~~	~~Wyeth~~	~~4 yellow tablets~~	~~120~~	~~0.50~~
~~Levlen~~	~~Berlex~~	~~4 light-orange tablets~~	~~120~~	~~0.60~~
~~Trivora~~	~~Watson~~	~~4 pink tablets~~	~~120~~	~~0.50~~
~~Levlite~~	~~Berlex~~	~~5 pink tablets~~	~~100~~	~~0.50~~
~~Lo/Ovral~~	~~Wyeth~~	~~4 white tablets~~	~~120~~	~~0.60~~
~~Low-Ogestrel~~	~~Watson~~	~~4 white tablets~~	~~120~~	~~0.60~~
~~Ovrette~~	~~Wyeth~~	~~20 yellow tablets~~	~~0~~	~~0.75~~

~~* The progestin in Ovral, Lo/Ovral, and Ovrette is norgestrel, which contains two isomers, only one of which (levonorgestrel) is bioactive; the amount of norgestrel in eachdoes is twice the amount of levonorgestrel~~

(11) Medications Used for Emergency Contraception

Dedicated Approved Products for Emergency Contraception

Brand	Dose	Ethinyl Estradiol per dose (mcg)	
One Dose Regimen			
Plan B™ One-Step	1 tablet	0	1.5mg levonorgestrel
ella™	1 tablet	0	30mg ulipristal
Two Tablet ~~Dose~~ Regimens			
Next Choice™	2 tablets at once (1.5mg total dose) or 1 tablet (0.75mg) followed by 1 tablet (0.75mg) 12 hours later ~~1 tablet per dose~~	0	*Each tablet is 0.75 mg* ~~1.5mg~~ levonorgestrel
Levonorgestrel	2 tablets at once (1.5mg total dose) or 1 tablet (0.75mg) followed by 1 tablet (0.75mg) 12 hours later	*0*	*Each tablet is 0.75 mg levonorgestrel*

Oral Contraceptive Pills

Brand	Tablets per Dose (two doses 12 hours apart*)	Ethinyl Estradiol per dose (mcg)	Levonorgestrel per dose (mg)*
Alesse	5 pink tablets	100	0.50
Aviane	5 orange tablets	100	0.50
Levlen	4 light-orange tablets	120	0.60
Levlite	5 pink tablets	100	0.50
Levora	4 white tablets	120	0.60
Lo/Ovral	4 white tablets	120	0.50
Low-Ogestrel	4 white tablets	120	0.60
Nordette	4 light-orange tablets	120	0.60
Ogestrel	2 white tablets	100	0.50
Ovral	2 white tablets	100	0.50
Tri-Levlen	4 yellow tablets	100	0.50
Triphasil	4 yellow tablets	120	0.50
Trivora	4 pink tablets	120	0.50
Ovrette	20 yellow tablets	0	0.75

*The progestin in Ovral, Lo/Ovral, and Ovrette is norgestrel, which contains two isomers, only one of which (levonorgestrel) is bioactive; the amount of norgestrel in each dose is twice the amount of levonorgestrel.

In addition to the products specified in this paragraph, generic equivalent products may be furnished. Estrogen containing regimens are not preferred and should be used only when the other options are not available.

(12) Anti-nausea Treatment Options for use with Emergency Contraception

Anti-Nausea Treatment Options For Use With Emergency Contraception

Drug	Dose	Timing of Administration
Non-prescription Drugs		
Meclizine hydrochloride (Dramamine II, Bonine)	One or two 25 mg tablets	1 hour before first EC dose; Repeat if needed in 24 hours
Diphenhydramine hydrochloride (Benadryl)	One or two 25 mg tablets or capsules.	1 hour before first EC dose; repeat as needed every 4-6 hours
Dimenhydrinate (Dramamine)	One or two 50 mg tablets or 4-8 teaspoons liquid	30 minutes to 1 hour before first ~~ECP~~ EC dose; repeat as needed every 4-6 hours
Cyclizine hydrochloride (Marezine)	One 50 mg tablet	30 minutes before first EC dose; repeat as needed every 4-6 hours

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052 and 4052.3, Business and Professions Code. Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052 and 4052.3, Business and Professions Code.

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> EC use will not interfere with an established or implanted pregnancy.
>
> 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 insertion of an IUD.

(4) The pharmacist shall provide ~~the~~ a fact sheet and review any questions the patient may have regarding EC. In addition, the pharmacist shall collect the information required for a patient medication record required by Section 1707.1 of Title 16 of the California Code of Regulations.

Fact Sheet: The pharmacist will provide the patient with a copy of the current EC fact sheet approved by the Board of Pharmacy as required by Business and Professions Code Section ~~4052(b)(3)~~ 4052.3(e).

(5) Referrals and Supplies: If emergency contraception services are not immediately available at the pharmacy or the pharmacist declines to furnish pursuant to conscience clause, the pharmacist will refer the patient to another emergency contraception provider. The pharmacist shall comply with all state mandatory reporting laws, including sexual abuse laws.

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Plan B	Women's Capital Corporation	2 tablets	0	1.5
Two Dose Regimens				
Plan B	Women's Capital Corporation	1 tablet per dose	0	0.75
Preven	Gynétics	2 tablets per dose	100	0.50
Oral Contraceptive Pills				
Brand	**Manufacturer**	**Tablets per Dose (two doses 12 hours apart*)**	**Ethinyl Estradiol per Dose (mg)**	**Levonorgestrel per Dose (mg)****
Levora	Watson	4 white tablets	120	0.60
Ovral	Wyeth	2 white tablets	100	0.50
Ogestrel	Watson	2 white tablets	100	0.50
Nordette	Wyeth	4 light-orange tablets	120	0.60
Tri-Levlen	Berlex	4 yellow tablets	100	0.50
Alesse	Wyeth	5 pink tablets	100	0.50
Aviane	Duramed	5 orange tablets	100	0.50
Triphasil	Wyeth	4 yellow tablets	120	0.50
Levlen	Berlex	4 light-orange tablets	120	0.60
Trivora	Watson	4 pink tablets	120	0.50
Levlite	Berlex	5 pink tablets	100	0.50
Lo/Ovral	Wyeth	4 white tablets	120	0.60
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Next Choice™	2 tablets at once (1.5mg total dose) or 1 tablet (0.75mg) followed by 1 tablet (0.75mg) 12 hours later ~~1 tablet per dose~~	0	*Each tablet is 0.75 mg* ~~1.5mg~~ levonorgestrel
Levonorgestrel	2 tablets at once (1.5mg total dose) or 1 tablet (0.75mg) followed by 1 tablet (0.75mg) 12 hours later	*0*	*Each tablet is 0.75 mg levonorgestrel*

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Levlen	4 light-orange tablets	120	0.60
Levlite	5 pink tablets	100	0.50
Levora	4 white tablets	120	0.60
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Amanda Davis, Pharm.D.
10972 Campus Street
Loma Linda, CA 92354

February 16, 2012

California Board of Pharmacy
1625 North Market Boulevard, N219
Sacramento, CA 95834

To Carolyn Klein and the Board of Pharmacy:

I am writing in regards to the proposed amendment to § 1746 of Article 5 of Division 17 of Title 16 of the California Code of Regulations regarding emergency contraception, specifically, subdivision (b)(3). There are several erroneous, unclear, and problematic statements that I believe must be addressed before this amendment is to take effect.

First, 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. Although they are used for the same purpose, they have very different properties. Because of this, I suggest that you strike the phrase "EC use will not interfere with an established or implanted pregnancy." and replace it with, "Progesterone-based emergency contraception will not interfere with an established pregnancy," or any similar phrase that would exclude ulipristal. Considering the current scientific evidence regarding ulipristal, it would be incorrect tell a patient, implicitly or explicitly, that this medication cannot disrupt an established pregnancy. Such evidences can be found in animal studies on guinea pigs (1), rats (2), and macaque monkeys (3) where ulipristal acetate was found to be capable of inducing abortion. Human studies have found that the corpus luteum, which is necessary for maintaining pregnancy in early gestation, can undergo luteolysis after doses as low as 1 mg of ulipristal acetate are taken (4). Additionally, the official assessment report published by the European Medicines Agency for ellaOne (the trade name for ella in Europe) states that, "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" (5). It is for these reasons that I recommend that the statement be changed from a blanket statement concerning all emergency contraception to a more directed statement concerning only progesterone-based emergency contraceptives. This is something that might also be applied to the EC fact sheet for patients.

Second, I would like to suggest that you strike the point, "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 insertion of an IUD." and replacing it with the phrase, "If more than 72 hours have elapsed since unprotected intercourse, consult with your physician to discuss other options for EC." There are three reasons why the current phrasing is problematic:

1. Ulipristal is only approved for EC up to 120 hours post unprotected intercourse; therefore, 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. The proposed phrasing does not specify this and may provide confusing or inaccurate information to the patient.
2. If more than 72 hours have elapsed since unprotected intercourse, whether it be 5 days or 10 days, the ONLY other option a patient has is to consult with their doctor. We cannot provide ella at the pharmacy without a prescription, so it would be more beneficial to recommend that they see their physician immediately.
3. Since ulipristal has abortifacient properties and is likely able to cause a drug-induced abortion in the early stages of gestation, the recommendation of this particular product to patients is morally problematic. Like levonorgestrel, ulipristal is capable of preventing pregnancy, and if this was its only mechanism of action, then it might be appropriate to recommend this product in the pharmacy; however, given the abortifacient nature of this drug, we should be weary to casually recommend this medication to patients without even counseling them on its mechanism of action or even ascertaining their views on abortion. The pharmacy is no place to impose such a grave and life-altering decision on women. The California medical board and board of pharmacy should reconsider standing behind this drug when many of the pharmacists in this state do not stand behind it at all.

Thank you for taking the time to read through and consider my comments on this amendment. My hope and goal is for women to receive informed and accurate information from their pharmacists on emergency contraception and for pharmacists to feel confident in the medications that they are recommending to their patients.

Sincerely,

Amanda Davis, Pharm.D.

References

1. Poyser NL, Forcelledo ML. A comparison of the pregnancy-terminating potencies of three anti-progestins in guinea-pigs, and the effects of sulprostone. Prostaglandins Leukotrienes and Essential Fatty Acids (1994) 50; 245-247.

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3. Tarantal AF, Hendrickx AG, Matlin SA, et al. Effects of two anti-progestins on Early Pregnancy in the long-tailed macaque. Contraception. 1996;54:107-115.

4. Passaro MD, *et al.* Luteal phase dose-response relationships of the antiprogestin CDB-2914 in normally cycling women. *Human Reproduction*. 2003; 18(9): 1820-1827.

5. CHP Assessment Report for ellaOne. European Medicines Agency: *Evaluation of Medicines for Human Use.* Doc.Ref.: EMEA/261787/2009.