



MEDICAL BOARD OF CALIFORNIA
Executive Office



Agenda Item 19

Date: July 20, 2011

To: Members
Medical Board of California

Subject: Revised Protocol for Pharmacists Furnishing Emergency Contraception

The Medical Board originally adopted the protocol for pharmacists furnishing emergency contraception at its Quarterly Board Meeting on May 7, 2004. This protocol was required to be developed and approved by both the Medical Board and the Pharmacy Board per SB 490 (Alpert, Chapter 651, Statutes of 2003), which amended Business and Professions Code Section 4052 to add this requirement.

Attached is the revised protocol for pharmacists furnishing emergency contraception, which is being presented to the Board for your consideration and approval. The strikeout document is included so you may see the changes, and the final revised document without strikeouts is included for your review.

This revised protocol will be presented by Ms. Smith-Crowley, Ms. Besinque, and Ms. Herold.

Attachments

Pharmacists Protocol for Dispensing Emergency Contraception

~~Senate Bill 490 (Chapter 651, Statutes of 2003) permits pharmacists~~ Pharmacists may ~~to~~ furnish emergency contraception medications based on a statewide protocol adopted by the California State Board of Pharmacy and the Medical Board of California (section 4052.3(a)(2) of the California Business and Professions Code).

On the following page is the approved protocol. Pharmacists may use this protocol after they have completed one hour of continuing education credit in emergency contraception ~~(a requirement of the new law)~~.

~~Additionally p~~ Prior legislation (~~Senate Bill 1169, Chapter 900, Statutes of 2001~~) Pharmacists may also ~~permits pharmacists to~~ furnish emergency contraception medications to patients based on a protocol with a single licensed prescriber (section 4052.3 of the California Business and Professions Code). Existing protocols developed with a prescriber remain valid.

~~Last p~~ Pharmacists ~~also~~ may also furnish levonorgestrel emergency contraception ~~Plan B~~ without a prescription or a physician protocol to a man or woman aged 17 or older pursuant to FDA requirements.

~~The~~ This statewide protocol was prepared with the intent to keep it simple and to comply with the statutory requirements established by ~~California law, Senate Bill 490.~~

The statutory provisions for pharmacists furnishing emergency contraception are found in California Business and Professions Code section 4052.

Protocol for Pharmacists Furnishing Emergency Contraception (EC)

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 following protocol satisfies that requirement.

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

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 ~~(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~~her physician regarding insertion of an IUD.

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 by Section 1707.1 of Title 16 of the California Code of Regulations (reference attached).

Fact Sheet: The pharmacist will provide the patient with a copy of the current EC fact sheet approved by the Board of Pharmacy.

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.

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

Advanced Provision: The pharmacist may dispense emergency contraception medication for a patient in advance of the need for emergency contraception.

EC Product Selection: The pharmacist will provide emergency contraception medication ~~compatible with product information~~ from the list of products appended to 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.

Documentation: Each prescription authorized by a pharmacist will be documented in a patient profile as required by law.

Training: Prior to furnishing emergency contraception, pharmacists who participate in this protocol must have completed a minimum of one hour of continuing education ~~or curriculum-based instruction from an ACPE accredited School of Pharmacy~~ specific to emergency contraception.

Appendix 1: Brands and Doses of Oral Contraceptive Tablets- Medications Used for Emergency Contraception

Dedicated Approved Products for Emergency Contraception				
Brand	Manufacturer	Tablets per Dose	Ethinyl Estradiol per dose (mcg)	Levonorgestrel per dose (mg)
One Dose Regimen				
PlanB	Duramed	2 tablets per dose	0	1.5
PlanB-OneStep		1 tablet	0	1.5mg levonorgestrel
Ella		1 tablet	0	30mg ulipristal
Two Dose Regimen				
NextChoice		1 tablet per dose	0	1.5mg levonorgestrel
Plan-B	Duramed	1 tablet per dose	0	0.75
Preven**	Duramed	2 tablets per dose	100	0.50
Oral Contraceptive Pills				
Brand	Manufacturer	Tablets per Dose (two doses 12 hours apart*)	Ethinyl Estradiol per dose (mcg)	Levonorgestrel per dose (mg)
Levora	Watson	4 white tablets	120	0.6
Ovral	Wyeth	2 white tablets	100	0.5
Ogestrel	Watson	2 white tablets	100	0.5
Nordette	Wyeth	4 light-orange tablets	120	0.6
Tri-Levlen	Berlex	4 yellow tablets	100	0.5
Alesse	Wyeth	5 pink tablets	100	0.5
Aviane	Duramed	5 orange tablets	100	0.5
Triphasil	Wyeth	4 yellow tablets	120	0.5
Levlen	Berlex	4 light-orange tablets	120	0.6
Trivora	Watson	4 pink tablets	120	0.5
Levlite	Berlex	5 pink tablets	100	0.5
Lo/Ovral	Wyeth	4 white tablets	120	0.5
Low-Ogestrel	Watson	4 white tablets	120	0.6
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 each dose is twice the amount of levonorgestrel

** **--In addition to the products listed above, generic equivalent products may be furnished. Estrogen containing regimens are not preferred and should be used only when the other options are not available. Preven was discontinued as of May 2004

Appendix 2 --~~Sample list~~ List of Anti-Emetics 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 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

Appendix 3 – Title 16, Section 1707.1 of the California Code of Regulations

§1707.1. Duty to Maintain Medication Profiles (Patient Medication Records)

(a) A pharmacy shall maintain medication profiles on all patients who have prescriptions filled in that pharmacy except when the pharmacist has reasonable belief that the patient will not continue to obtain prescription medications from that pharmacy.

(1) A patient medication record shall be maintained in an automated data processing or manual record mode such that the following information is readily retrievable during the pharmacy's normal operating hours.

(A) The patient's full name and address, telephone number, date of birth (or age) and gender;

(B) For each prescription dispensed by the pharmacy:

1. The name, strength, dosage form, route of administration, if other than oral, quantity and directions for use of any drug dispensed;

2. The prescriber's name and where appropriate, license number, DEA registration number or other unique identifier;

3. The date on which a drug was dispensed or refilled;

4. The prescription number for each prescription; and

5. The information required by section 1717.

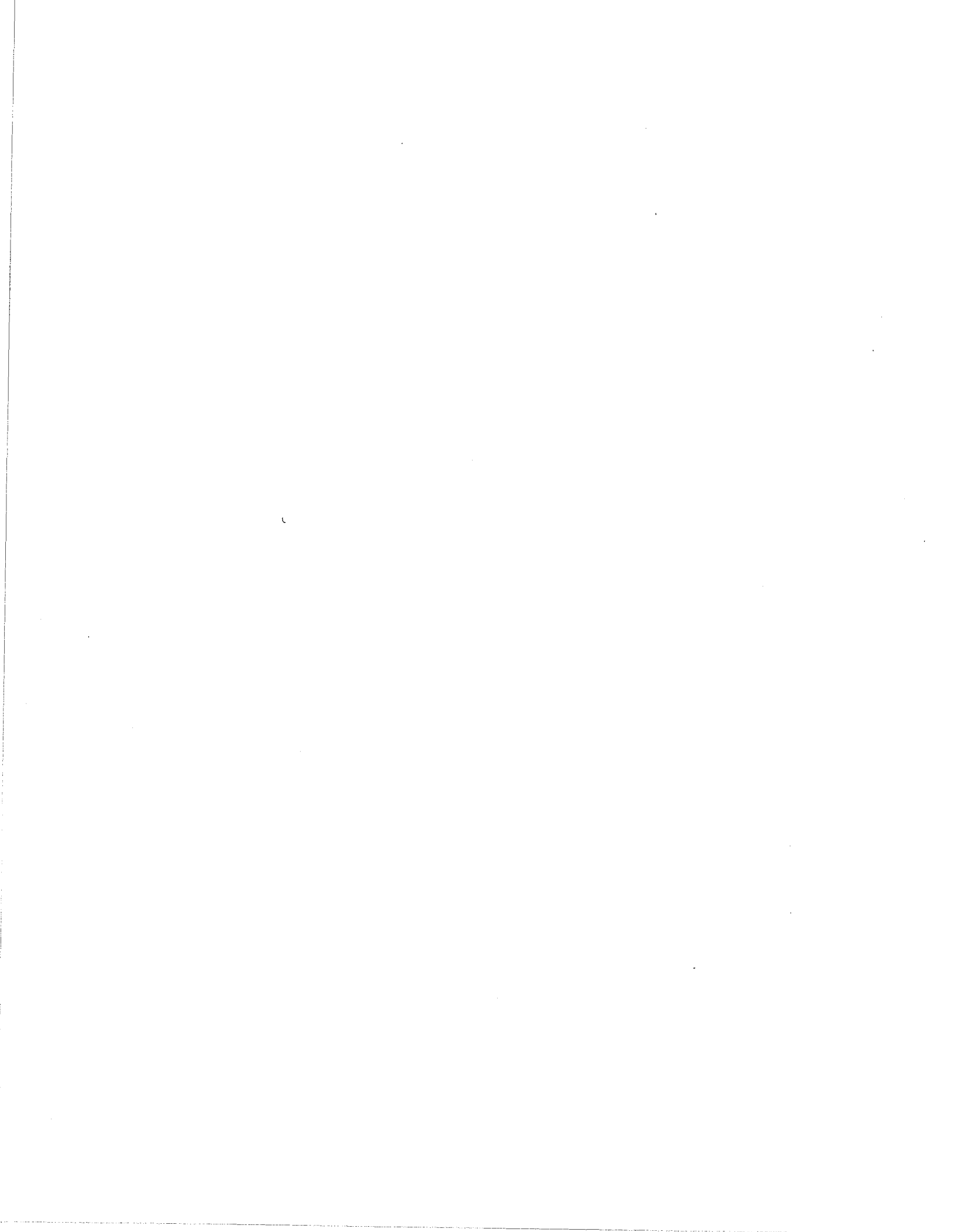
(C) Any of the following which may relate to drug therapy: patient allergies, idiosyncrasies, current medications and relevant prior medications including nonprescription medications and relevant devices, or medical conditions which are communicated by the patient or the patient's agent.

(D) Any other information which the pharmacist, in his or her professional judgment, deems appropriate.

(2) The patient medication record shall be maintained for at least one year from the date when the last prescription was filled.

Authority cited: Sections 4005, 4121 and 4122, of the Business and Professions Code.

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This statewide protocol was prepared with the intent to keep it simple and to comply with the statutory requirements established by California law.

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