

**Order of Adoption
Board of Pharmacy
California Code of Regulations**

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~~ 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. For other options for EC, consult with your health care provider.

Please follow up with your health care provider after the use of EC.

(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.

Dedicated Emergency Contraception

| <i>Brand</i> | <i>Manufacturer</i> | <i>Tablets per Dose</i> | <i>Ethinyl Estradiol per Dose (mg)</i> | <i>Levonorgestrel per Dose (mg)</i> |
|---------------------------------|---------------------|--|--|-------------------------------------|
| One-Dose Regimen | | | | |
| Plan-B | Duramed | 2 tablets | 0 | 1.5 |
| Two-Dose Regimens | | | | |
| Plan-B | Duramed | 1 tablet per dose | 0 | 0.75 |
| Preven | Duramed | 2 tablets per dose | 100 | 0.50 |
| Oral Contraceptive Pills | | | | |
| <i>Brand</i> | <i>Manufacturer</i> | <i>Tablets per Dose (two doses 12 hours apart)</i> | <i>Ethinyl Estradiol per Dose (mg)</i> | <i>Levonorgestrel per Dose (mg)</i> |
| 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 |

(11) Medications Used for Emergency Contraception

Dedicated Approved Products for Emergency Contraception

| <u>Brand</u> | <u>Dose</u> | <u>Ethinyl Estradiol per dose (mcg)</u> | |
|----------------------------|-----------------|---|---------------------------------|
| <u>One Tablet Regimens</u> | | | |
| <u>Plan B™ One-Step</u> | <u>1 tablet</u> | <u>0</u> | <u>1.5mg levonorgestrel</u> |
| <u>ella™</u> | <u>1 tablet</u> | <u>0</u> | <u>30mg ulipristal</u> |
| <u>Levonorgestrel</u> | <u>1 tablet</u> | <u>0</u> | <u>1.5mg levonorgestrel</u> |

| <u>Two Tablet Regimens</u> | | | |
|----------------------------|---|----------|--|
| <u>Next Choice™</u> | <u>2 tablets at once (1.5mg total dose) or 1 tablet (0.75mg) followed by 1 tablet (0.75mg) 12 hours later</u> | <u>0</u> | <u>Each tablet is 0.75 mg levonorgestrel</u> |
| <u>Levonorgestrel</u> | <u>2 tablets at once (1.5mg total dose) or 1 tablet (0.75mg) followed by 1 tablet (0.75mg) 12 hours later</u> | <u>0</u> | <u>Each tablet is 0.75 mg levonorgestrel</u> |

Oral Contraceptive Pills

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

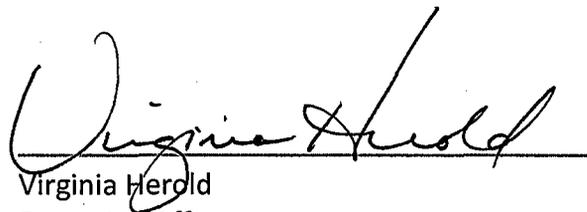
*The progestin in Ovral, Lo/Ovral, and Ovrette is norgestrel, which contains two isomers, only one of which (levonorgestrel) is bioactive; the amount of norgestrel in each dose is twice the amount of levonorgestrel.

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

| <i>Non-Prescription Drugs</i> | <i>Dose</i> | <i>Timing of Administration</i> |
|---|---|--|
| 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 <u>EC</u> 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.



Virginia Herold
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