

ECP Collaborative Agreement Protocol

As a licensed health care provider authorized to prescribe medications in the State of Washington, I authorize _____, R.Ph., to prescribe emergency contraceptive pills (ECPs) according to the protocol that follows. The protocol provides written guidelines for initiating drug therapy in accordance with the laws (RCW 18.64.011) and regulations (WAC 246-863-100) of the State of Washington.

Purpose: Provide access to emergency medication within required time frame and to ensure the patient receives adequate information to successfully complete therapy.

Procedure: When the patient requests ECPs, the pharmacist will assess the need for treatment and/or referral for contraceptive care. The pharmacist will determine the following:

- The date of the patient's last menstrual period to rule out established pregnancy.
- That the elapsed time since unprotected intercourse is less than 72 hours (or 120 hours).
- Whether the patient has been a victim of sexual assault.
- The age of the patient.

Referrals: If ECP services are not available at the pharmacy, the patient will be referred to another ECP provider. The pharmacist should refer the patient to see a physician or family planning clinic provider if established pregnancy cannot be ruled out or if the elapsed time since unprotected intercourse is greater than 72 hours (or as agreed upon by collaborators).

If there is a concern that the patient may have contracted a sexually transmitted disease through unprotected sex, and/or if the patient indicates that she has been sexually assaulted, the pharmacist will initiate appropriate referral while providing ECPs. When the patient is a minor and sexual assault or abuse is suspected, the pharmacist will report or cause a report to be made to Child Protective Services.

While ECPs can be used repeatedly without serious health risks, patients who request ECPs repeatedly will be referred to a physician or family planning clinic provider for use of a regular contraceptive method.

Prophylactic Provision: The pharmacist may also prescribe and dispense a course of ECPs to a patient in advance of the need for emergency contraception. In addition the pharmacist will counsel the patient on available options for regular contraceptive methods or offer to refer for additional contraceptive services.

ECP Product Selection: The pharmacist will only dispense medication from a list of products approved for emergency contraception and agreed upon as part of this agreement. The pharmacist should seek to provide the most effective ECP product to patients. The list will contain ECPs and adjunctive medications for nausea and vomiting associated with ECPs. The list will be maintained at the pharmacy and shared by all participants in the agreement. Along with the medication, patients will be provided with information concerning dosing, potential adverse effects, and follow-up contraceptive care.

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

On a quarterly basis, the authorizing prescriber and the pharmacist will perform a quality assurance review of the prescribing decisions according to mutually acceptable criteria.

The pharmacist(s) who participate in the protocol must have completed training covering the procedures listed above, the management of the sensitive communications often encountered in emergency contraception, service to minors, and a crisis plan if the pharmacy operations are disrupted by individuals opposing emergency contraception. Further, the pharmacists agree to participate in the Emergency Contraception Hotline and provide data without patient identifiers to the Emergency Contraception Project.

The prescriptive authority is granted for a period of two years from the date of approval unless rescinded in writing earlier by either the authorizing prescriber or the pharmacist.

AUTHORIZING PRESCRIBER SIGNATURE

LICENSE NUMBER

AUTHORIZING PHARMACIST SIGNATURE

LICENSE NUMBER

DATE

SAMPLE List of Emergency Contraceptive Pill Formulations and Doses

| Formulation | Common Brand Names | Tablets per Dose | Doses Required | Timing of Administration |
|--------------------------|--|------------------|----------------|---|
| NG 0.50 mg + †EE 50 mcg | Ovral* (white tabs) | 2 | 2 | First dose within 72 hours of unprotected intercourse. Second dose 12 hours later. (Anti-emetic taken 1 hour prior to each dose) |
| LNG 0.15 mg + EE 30 mcg | Nordette* (light orange tabs) Levlen* (light orange tabs) Levora (white tabs) | 4 | 2 | Same |
| LNG 0.125 mg + EE 30 mcg | Tri-Levlen* (yellow tablets) Triphasil* (yellow tablets) | 4 | 2 | |
| NG 0.30 mg + EE 30 mc | Lo/Ovral* (white tabs) | 4 | 2 | |

Dedicated Combination Product

| | | | | |
|-----------------------|----------------|---|---|------|
| LNG 0.25mg + EE 50mcg | Preven® | 2 | 2 | Same |
|-----------------------|----------------|---|---|------|

Dedicated Levonorgestrel-only Product

| | | | | |
|-------------|----------------|---|---|-----------------------------------|
| LNG 0.75 mg | Plan B® | 1 | 2 | Same (No anti-emetic required) |
|-------------|----------------|---|---|-----------------------------------|

• NG = norgestrel †EE = ethinyl estradiol §LNG = levonorgestrel

* Regimen recommended for ECP use by FDA Advisory Panel, 1996 November 1997

Revise: EC Protocol 3-01