Expanding Access to Emergency Contraceptive Pills:
Promoting Pharmacist/Prescriber Collaborative Agreements

Training Manual

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Foreword

The *Emergency Contraceptive Pills (ECP) Training Manual* contains information on the therapeutic, patient care, regulatory, public relations, and reimbursement issues that affect access to emergency contraception. These materials initially were developed for the Emergency Contraception Collaborative Agreement Pilot Project in Washington State, where the Washington State Board of Pharmacy and several collaborating organizations first developed an ECP therapy management agreement between a pharmacist and independent prescriber.

These materials were used to train the pharmacists interested in ECPs and in establishing a collaborative agreement for prescribing them. While pharmacists are academically prepared to undertake a program of this nature, the challenges inherent to the increased distribution of emergency contraception (such as physician and public awareness) required that a standardized approach be implemented.

At the time these materials were initially developed, the Food and Drug Administration (FDA) had not approved the use of combination oral contraceptives for emergency contraception. The first emergency contraceptive product (Preven Emergency Contraceptive Kit) has since received approval for marketing in the United States. In addition, approval of a levonorgestrel-only product is expected in 1999. Evaluations of levonorgestrel-only therapy have demonstrated a decreased incidence of nausea and vomiting; antiemetic agents therefore may be required less often.

Because regulations governing pharmacist prescriptive practice vary from state to state, and because new emergency contraception products are emerging, the materials contained in the *ECP Training Manual* are intended to serve only as a model for organizations interested in implementing pharmacist/prescriber collaborative agreements. Readers should be reminded that the protocol contained in this manual must be adapted to the unique clinical practices of each prescriber.
Project Summary
Expanding Access to Emergency Contraceptive Pills: Promoting Pharmacist/Prescriber Collaborative Agreements

Project Summary

Introduction and Background
While efforts are underway across the country to improve women’s awareness of emergency contraceptive pills (ECPs) as a backup contraceptive method and to improve access to services, the most common ECP service delivery model (going to or calling a physician for a prescription) can present unnecessary barriers to women seeking treatment. Given that the treatment must be used within 72 hours of unprotected intercourse, establishing prescription and dispensing mechanisms that are convenient to women is crucial to their ability to use the therapy effectively.

Regulations governing pharmacist prescriptive practice may present opportunities for increasing access to ECPs in some states. Under a collaborative drug therapy management agreement between a pharmacist and an independent prescriber in Washington State, a pharmacist can prescribe ECPs directly to women who request them, either in response to an immediate need or in advance of need. The Washington State Board of Pharmacy has systems in place to facilitate this type of prescriptive practice.

Project Goal and Objectives
Funded by the David and Lucile Packard Foundation, the two-year (7/97–6/99) Washington State project sought to improve women’s access to ECPs by promoting collaborative drug therapy management agreements between pharmacists and independent prescribers.

The project provided an excellent opportunity to evaluate this approach and is of great interest to other states with similar prescriptive practices. Specific objectives included:

• informing retail pharmacists in the region about ECPs and collaborative agreement opportunities;
• delivering and evaluating tools and training to facilitate pharmacist/prescriber collaborative agreements;
• developing systems to link trained pharmacists with prescribers and facilitating the establishment of collaborative agreements for ECPs;
• conducting a 3- to 6-month promotional public awareness media campaign to reach women aged 18 to 34 with information about ECP availability through pharmacies;
• evaluating the impact of the project on women’s access to and use of ECPs;
• disseminating the results of the project to facilitate replication in other states where regulations allow.

Implementation Highlights
Pharmacists participating in this project received training in all aspects of providing ECPs, including therapeutic and dispensing information, patient care issues (screening, counseling, referral, etc.), administrative issues (filing a protocol, packaging, liability, etc.), public relations, and other relevant issues. Once trained, pharmacists sought “sponsorship” of independent prescribers to file a collaborative drug therapy agreement with the Washington State Board of
Pharmacy. Names of participating pharmacists with ECP prescriptive authority and pharmacies were posted on the national emergency contraception Hotline (1-888-NOT-2-LATE) and Web site (http://opr.princeton.edu/ec/).

In addition, ECP availability through pharmacist providers was publicized via such channels as radio and print advertisements, with the aim of increasing awareness of ECPs and linking patients to the Hotline and Web site. Both the Hotline and Web site provided callers with information on emergency contraception and listed five health clinics and five pharmacies where callers could receive ECPs. A press event was conducted to launch the project at the inception of the awareness campaign.

Project Evaluation and Results Dissemination

The project impact on improving women’s access to ECPs and reducing the number of unintended pregnancies was evaluated. Data measures that were collected included:

- number of ECP prescriptions dispensed under collaborative agreements;
- acceptability to women, pharmacists, and prescribers of accessing ECPs through pharmacist prescriptive practice;
- number of callers exposed to a pharmacist referral message through the Hotline and Web site;
- number of collaborative agreements for ECPs registered with the State Board of Pharmacy;
- number of pharmacists participating in in-service training;
- number of prescribers on roster of pharmacist sponsors;
- number of announcements and other promotional items placed.

Project collaborators disseminated periodic updates on the project’s progress through informal mechanisms. On completion of the project and evaluation, a final report will be disseminated to all project participants and through professional journals.
The Washington State Experience:
Emergency Contraception Collaborative Agreement Pilot Project

Fact Sheet

Pharmacy Participation/Prescriptions Filled
- More than 7,211 prescriptions for emergency contraceptive pills (ECPs) were written and filled by pharmacists in the first 10 months of service.
- There are currently more than 130 pharmacies in the state participating in the Project.
- More than 800 pharmacists have completed the required training to prescribe ECPs.

Response to 1-888-NOT-2-LATE Hotline
- Calls from Washington State to the Emergency Contraception Hotline (1-888-NOT-2-LATE) had increased to an average of 1,160 per month two months after the Project’s launch in late February 1998. Prior to the Project’s launch, calls from Washington State averaged about 110 per month.

Preliminary Evaluation Results
- Many women go to the pharmacy on weekends or after normal business hours for their ECP prescriptions, and they value this accessibility.
- Women receiving the service are satisfied with the quality of care they have received.
- A high percentage of survey respondents said they understood the written and verbal information given them by the pharmacist, they had sufficient opportunity to ask questions, and they felt they were treated with respect.
- A survey of collaborating licensed prescribers and participating pharmacists indicated a high level of satisfaction: 92.3% of prescribers and 84.0% of pharmacists were satisfied with the program.

Cost-Impact Model
- Washington State cost estimates and the number of women served in the project showed that emergency contraception obtained from a pharmacist prevented unintended pregnancies and was cost saving.
- In modeling the private payer cost impact, the cost savings were without exception overwhelmingly positive. When the base case assumptions were used—that is, an ECP effectiveness rate of 74% and a probability of conception for any given act of intercourse of 7.2%—the cost impact was positive for all the private and public payer models.
1. Therapeutic and Dispensing Information
Additional Materials included here:

- ACOG Practice Patterns
- AHFS Drug Information
2. Patient Care Issues
Pharmacist Information Sheet

Service to Minors
Regulations vary from state to state. In Washington, state laws authorize minors (no age limit) to consent to contraceptive and family planning services (Initiative 120, RCW 9.02.100); hence no parental consent and/or notification are required for contraceptive services. Every individual has the fundamental right to choose and refuse birth control. Even without such laws, minors may be protected to obtain confidential contraceptive services under the constitutional right to privacy.

Legal Issues
In Washington State, it is legal to prescribe contraceptives to minors. Because ECPs are considered the accepted standard of treatment to prevent an unintended pregnancy after unprotected intercourse, refusal to provide services and/or refer patients to another provider may leave a pharmacist open to liability.

Confidentiality
A breach in confidentiality may arise when an insurance company bills the parent or spouse for contraceptive services provided or the woman uses the family's medical coupon. Pharmacists should be careful to inform women of this possibility.

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 patient's name, address, and age;
- certainty that the patient does not want to become pregnant;
- the date of the patient's last menstrual period to rule out an established pregnancy;
- the time that has elapsed since unprotected intercourse occurred (less than 72 hours);
- whether the patient has been a victim of sexual assault.

The pharmacist will refer the patient to a physician or family planning clinic provider if established pregnancy cannot be ruled out or if the elapsed time is greater than 72 hours.

The pharmacist will need to make the appropriate referrals to Child Protective Services if there is evidence of sexual abuse/assault or rape against a minor.
Emergency Contraception Discussion Topics

The following cases illustrate some of the issues that pharmacists may encounter when prescribing emergency contraception. While a few of these situations have clear-cut answers, most simply raise the issues that must be considered in order to reach an appropriate solution. After each description, an “answer” has been provided and lists several discussion topics and key issues. Additional commentary also has been included in order to facilitate productive discussions.

A high-school student and her mother come to the pharmacy counter and ask to speak with you in private. You learn that the student has had unprotected intercourse in an attempt to become pregnant. Her mother asks if you can make sure that her daughter doesn't become pregnant...

Discussion:
• Who is the patient? Would she be willing to take the ECPs even if given to her?
• Do you, as the pharmacist, have the skills and time needed to resolve this family’s internal conflict?
• Can you—or should you—separate the student and her mother in order to speak privately with the student/patient? Would this lead to further conflict with the patient’s mother?
• Should the patient be referred immediately to a clinic that you know has counselors on hand?

Most pharmacists in our discussion sessions have agreed that they would refer this patient to a clinic. Pharmacists who develop strong relationships with local providers find that these referrals receive priority attention and the patients are seen as same-day “walk-ins” with minimal loss to follow-up.

Mrs. Jones calls you to ask about the prescription bottle she found in her teenage daughter’s dresser drawer...

Discussion:
• Check your state’s regulations concerning age limitations and the provision of contraceptive care to minors without parental consent.
• This scenario has occurred on several occasions. It can create a difficult situation in terms of patient confidentiality, legal liability, and angry parents.
• If minors in your state may receive contraceptive care without parental consent, you cannot divulge any confidential information (e.g., what the medication is for, who the prescriber was, or any other details of the prescription) to parents without the patient’s consent.
• A recommendation that the parent discuss the situation with their daughter might be warranted.
Our experience has generally shown that the parent’s anger initially has been directed toward the unknown prescriber, then directed at the pharmacy for not being forthcoming with information, and finally directed at the daughter. Try to redirect the parent’s questions to the daughter. You also may consider telling patients to dispose of their prescription containers when they are finished with them.

A woman has been to your pharmacy twice in the past six weeks for ECPs. She now is asking you to help her for the third time…

Discussion:

• If the patient has needed ECPs due to contraceptive failure, inquire about the nature of the failure and, if appropriate, educate her about proper contraceptive use.
• Does your documentation indicate that ongoing contraception advice was provided to this patient in the past? If not, make sure that a thorough discussion of more appropriate ongoing contraception occurs.
• Try to determine what barriers to ongoing contraception exist for this patient.
• If appropriate, provide a thorough STD discussion.
• Emphasize that ECPs are for emergency use only, and that they are not recommended for routine use because they are less effective than other contraceptive methods. If she continues to use ECPs over time, she is likely to experience a failure with them.
• Make sure that your attitude toward this patient is one of partnership and assistance rather than contempt or condescension.
• Make a referral for this patient (you may offer to make the appointment while she is in your pharmacy) and be sure to follow up on the referral.
• Try to determine if the patient has the intent and, in some cases, the ability to keep the referral appointment.
• Ask the patient if her need for ECPs is the result of abuse/sexual assault.

A few pharmacists have indicated that they would be “put off” by patients who “over-used” ECPs, and that they would consider “cutting off” patients who were excessive users. This seems to imply a pharmacist’s judgement of patient irresponsibility. Although not recommended, repeat ECP use is not known to pose health risks to users and is not a logical reason for denying women access to treatment. It is important for the pharmacist in this situation to meet this woman’s immediate need and avoid making a subjective decision to limit her access to this service. As indicated by the discussion points, these patients may have a greater need for education, compassionate care, and referral than other ECP users. Pharmacists should use each patient encounter as an opportunity to provide these services.

A woman’s boyfriend comes to the pharmacy because she is too embarrassed to come in herself. He has all the information about the woman that you need to provide ECPs… Do you go ahead and provide him with the medication?

Discussion:

• While you don’t want to limit access to emergency contraception services, have you established a pharmacist/patient relationship?
• Has the patient signed the advice and consent form?
• Can you verify that the patient didn’t come to you herself because she was battered?
• Do you know for certain that she doesn’t want to become pregnant?
• How do you determine whether the woman needs a referral for STDs, ongoing contraception, or other medical needs?

_The pharmacist in this scenario should not dispense ECPs to the boyfriend. In general, pharmacists have made their services available after-hours, on weekends, and, in some locations, even 24-hours a day. This accessibility has made it unnecessary to resort to alternatives to in-person care. Numerous “discoveries” have made by the face-to-face encounters pharmacists make with their ECP patients, and these have resulted in medical referrals and other important clinical decisions._
Patient Counseling Summary

- Make sure the patient does not want to become pregnant.
- Explain how to take ECPs correctly and conveniently. Recent research has shown that the earlier the regimen is initiated, the more effective it is. Women should be counseled to take the first dose as soon as is convenient, keeping in mind the timing of the second dose. For example, rather than encouraging her to take the first dose at 4:00 p.m. (with the second dose at 4:00 a.m.) it might be better to begin at 7:00 p.m.
- Emphasize that emergency contraception is for emergency use only and it is less effective than other means of birth control if used repeatedly.
- Explain that emergency contraception does not protect against or treat STDs. If she thinks she may have contracted an STD, she will need to see a physician immediately.
- Remind the patient to begin using ongoing contraception as soon as she resumes intercourse. She may be at high risk of pregnancy following ECP use if ovulation was delayed. If her regular contraception failed, counsel her on effective method use if necessary.
- Remind the patient that her period most likely will come on time but may come a few days earlier or later than normal.
- Remind the patient that ECP is not 100% effective and will not terminate an established pregnancy. If she does not get her period in 3 weeks, she may want to take a home pregnancy test or call for a referral for a follow-up with a nurse or a physician.

Explain to the patient that her packet includes a patient information sheet that has instructions on it as well as the pharmacy phone number so that she can call if she has any further questions. At the bottom of the patient information sheet is a questionnaire; please ask the patient to fill it out and drop it in the mailbox.
Other Counseling Issues

Several important issues related to counseling about emergency contraception are discussed below.

Stress
Patients seeking emergency contraception may be under stress after unprotected intercourse due to fear of becoming pregnant, embarrassment at failing to use contraception effectively, general embarrassment about sexual issues or lack of knowledge about emergency contraception, rape- and/or sexual abuse-related trauma, concern about AIDS and STDs, worry about missing the narrow window of opportunity for emergency contraception, or a combination of these factors.

To help reduce patient stress and anxiety, it is crucial that pharmacists be supportive and refrain from making judgmental comments or indicating disapproval through body language or facial expressions while discussing ECP treatment. Supportive pharmacist attitudes also will help improve compliance and set the stage for effective patient-pharmacist communication if follow-up is needed. Pharmacists who do not wish to provide ECP treatment for personal reasons should maintain objectivity and remain professional in manner when dealing with patients. In this case, patients should be referred to an alternate pharmacist, at the same pharmacy or at a referral pharmacy.

Referral for Ongoing Contraceptive Care
ECPs are meant for emergency protection and are not as effective as other birth control methods for regular ongoing contraception. Pharmacists should encourage patients to talk to a physician or nurse about using a regular contraceptive method to prevent pregnancy in the future. If the patient does not have a regular health care provider, the pharmacist can offer referrals to local providers.

Repeated Use of ECPs
Experience has shown that very few women request ECPs repeatedly, mainly because of the unpleasant side effects some women experience while using them. Although there are no known medical restrictions associated with repeated use of ECPs, this approach would be less effective in preventing pregnancy than typical use of any regular contraceptive method. If a patient presents repeatedly for ECPs, the pharmacist should provide treatment but inform her of the high cumulative failure rate with repeated use and provide referrals for ongoing care (see above).

HIV and STDs
Patients must understand that ECPs do not protect against STDs, including HIV/AIDS. Patients may be very concerned about possible infection, especially in cases of rape. Counseling on this topic is essential, and diagnosis and treatment referral should be provided when needed.
Alcohol/Drugs

In some cases, the patient may not remember whether penetrative sex took place or not. In such cases, it is best to assume that intercourse occurred and to prescribe ECPs accordingly if the patient requests them.

Presenting After 72 Hours/Multiple Acts of Unprotected Intercourse

Some women may present for ECPs later than 72 hours after unprotected intercourse or have unprotected intercourse more than once, with some acts of intercourse occurring more than 72 hours before seeking ECP treatment and some occurring within the 72-hour period. The pharmacist and patient should evaluate the decision to use ECPs in light of the following information, and the patient should be referred as needed:

- The effectiveness of ECPs taken 72 or more hours after sex has not been well documented. It is not likely that efficacy drops suddenly to zero, so treatment after 72 hours may be reasonable.
- Unprotected sex that occurred more than 72 hours before ECP treatment may have already resulted in pregnancy. If the woman is pregnant, ECPs will not disrupt or harm the pregnancy.
- With multiple acts of unprotected sex, ECP treatment can reduce risk of pregnancy resulting from unprotected sex acts that occurred within the 72-hour limit.
Confidentiality in the Pharmacy Setting

Because a physical exam, pregnancy test, and clinic or physician visit are not necessary to initiate ECP treatment, patients can obtain ECPs directly at pharmacies in states that have collaborative drug therapy agreements. It is important that all pharmacy staff on duty (including those who are authorized to provide ECPs, technician support, and telephone staff, who may be the patient’s first point of contact) be informed about the emergency contraceptive services available at their pharmacy.

Because of the open setting at most pharmacy counters, where other clients and customers waiting in line are visible and may be within hearing distance, patients may feel uncomfortable being screened, receiving instructions and counsel, and/or discussing ECP treatment in view and/or hearing distance of other clients and customers. Pharmacists must be aware of and sensitive to this and conduct the consultation in the appropriate professional manner to ensure proper confidentiality for the patient.

Suggestions for improving the level of patient privacy include:
- using a separate counseling room, where available;
- asking patients to move to a less crowded area of the pharmacy;
- using non-specific language to refer to sensitive terms (for instance, use “the incident” or “the situation” rather than saying “unprotected intercourse” or “sex”);
- using a written form to collect key information about the patient’s situation;
- suggesting the patient call in her prescription request, at which point she can receive screening and counseling by an authorized pharmacist prior to the pharmacy visit.
Patient Screening Checklist for ECPs

Patient name ________________________
Address ____________________________

1. Have you had unprotected sex during the last three days? Yes No
   Date(s): ________________ Time(s): ________________

2. When was the first day of your last menstrual period?
   Date: ________________
   Is this less than 4 weeks ago? Yes No

Pharmacist Checklist

The ECP package should include the following:

- Pills
- Antiemetic
- Package insert
- Patient information sheet with mail-in questionnaire
- Patient consent form
XYZ PHARMACY
Informed Consent for Emergency Contraception

Name ____________________________________________ Age __________________

Address ________________________________________ Phone (    ) ______________

First day of last menstrual period ___/__/__   Date of unprotected intercourse ___/__/__

(If more than one exposure, give date and time of initial exposure _____________ __________

Was this exposure the result of sexual assault? Yes_____ No _____

Before giving your consent, be sure that you understand both the pros and cons of Emergency Contraceptive Pills (ECPs). If you have any questions, we will be happy to discuss them with you. Do not sign your name at the end of this form until you have read and understood each statement and the pharmacist has answered your questions and can witness your signature. This information is confidential.

I understand that:

• ECPs contain hormones that act to prevent pregnancy. These pills are taken after having unprotected sex (sex without birth control or a birth control failure). They are to be used as an emergency treatment only and not as a routine method of contraception.

• ECPs work by preventing or delaying the release of an egg from the ovary, preventing fertilization, or causing changes in the lining of the uterus that may prevent implantation of a fertilized egg. I understand that if I am already pregnant, ECPs will not stop or interfere with the pregnancy.

• ECP treatment should be started within 3 days (72 hours) of unprotected sex.

• ECPs are not 100 percent effective.

• Reactions to the pills may include nausea and vomiting, fatigue, dizziness, breast tenderness, early or late menstrual period.

• I should see a physician if my period has not started within 3 weeks after treatment.

• I should use condoms, spermicides, or a diaphragm, or continue taking birth control pills to prevent pregnancy if I have sex before my next period. After that, I should continue to use a method of contraception.

• ECPs will not protect me from or treat sexually transmitted diseases, and I should seek diagnosis and treatment if I am concerned about this.

• I understand that it maybe useful to share this treatment information with my regular health care provider. Therefore, I request and authorize the release of this information to the following designated provider.

      Yes_____ No _____  Designated Provider’s Name ________________________________

Patient’s Signature __________________________________ Date __________________

Pharmacist’s Signature __________________________________ Date __________________

2 - 10
(For pharmacist use only: Referral made to ________________________________ (Rx number _____________)
FARMACIA XYZ
Información para participantes y
Consentimiento informado para usar anticoncepción de emergencia

Nombre ________________________________________________ Edad______________

Dirección ________________________________________________ Teléfono (     )_______

Fecha del primer día de su último periodo menstrual (mes/día/año)  _____-____-____
Fecha cuando tuvo relaciones sexuales sin usar protección (mes/día/año) _____-____-_____
(Si ha tenido más de una exposición, indicar la fecha y la hora de la primera exposición____________)

¿Fue esta exposición resultado de una violación? Sí____ No____

Antes de dar su consentimiento, esté segura que entiende los pros y los contras de las Pastillas de Anticoncepción de Emergencia (PAEs). Si tiene preguntas, con todo gusto se las responderemos. No firme su nombre al final de este formulario hasta que haya leído y entendido completamente cada punto y el farmacéutico le haya respondido a sus preguntas y puede ser testigo de su firma. Esta información es confidencial.

Entiendo que:
• las PAEs contienen hormonas que se actúan para prevenir el embarazo. Estas pastillas se toman después de haber tenido relaciones sexuales sin usar protección (sexo sin anticonceptivo o un fracaso de anticonceptivo). Se deben usar como tratamiento de emergencia únicamente y no como un método de anticonceptivo rutinario.
• las PAEs funcionan por medio de impidir o demorar la salida del huevo del ovario, así impidiendo la fertilización o causando cambios en el interior del útero que pueden prevenir la implantación de un huevo fertilizado. Entiendo que si ya estoy embarazada los PAEs no detendrán y no interfieren con el embarazo.
• se debe comenzar el medicamento dentro del periodo de 3 días (72 horas) después de haber tenido relaciones sexuales sin usar protección.
• las PAEs no son un 100 por ciento efectivas.
• algunas reacciones a las pastillas pueden incluir nausea y vómitos, cansancio, mareo, sensibilidad de los senos, periodos menstruales adelantados o atrasados.
• debo ver al médico si es que mi periodo no ha comenzado después de 3 semanas después del tratamiento.
• debo usar condones, espermicidas, diafragma, o continuar tomando pastillas anticonceptivas para prevenir embarazos si es que tengo relaciones sexuales antes de mi próximo periodo. Después, debo continuar usando un método regular de anticoncepción.
• las PAEs no me protegerán, ni son tratamiento para las enfermedades transmitidas sexualmente y que debo solicitar una prueba de diagnóstico y tratamiento, si es que estoy preocupada por esto.
• puede ser útil compartir con mi médico esta información sobre tratamiento.

Por lo tanto, autorizo dar esta información al proveedor indicado abajo.

Sí ____ No ____ Nombre del proveedor indicado________________________________________

Firma de la paciente ___________________________________ Fecha ______________________
Firma del farmacéutico _________________________________ Fecha _______________________
(Para uso del farmacéutico solamente: Se refiere a _________________________________________________ (Número de Rx ____)

2 - 13
Russian version of XYZ Pharmacy Included in Original Pharmacy Manual
Service to Minors

Consent
Regulations pertaining to service to minors vary from state to state. In Washington, state laws authorize minors (no age limit) to consent to contraceptive and family planning services (Initiative 120, RCW 9.02.100); hence no parental consent and/or notification are required for contraceptive services. Every individual has the fundamental right to choose and refuse birth control. Even without such laws, minors may be protected to obtain confidential contraceptive services under the constitutional right to privacy.

Confidentiality
Minors are assured the same confidentiality rights as others. A breach in confidentiality may arise when the insurance company bills the parent for contraceptive services provided or the minor uses the family’s medical coupon. Pharmacists should be careful to inform minors of this possibility.

Legal Issues
In Washington State, it is legal to prescribe contraceptives to minors. Because ECPs are considered the accepted standard of treatment to prevent an unintended pregnancy after unprotected intercourse, refusal to provide services and/or refer patients to another provider may leave a pharmacist open to liability.

In one known case prior to the FDA endorsement of ECP treatment, a California court ruled a religious-affiliated hospital liable for failing to provide a rape victim with information about and access to emergency contraception. The hospital had sought immunity from prosecution under the state Therapeutic Abortion Act, which provided that no health care facility with a religious affiliation could be liable for refusing to perform or permit an abortion. The court concluded that the immunity did not apply to emergency contraception, which is a “pregnancy prevention” treatment.

In case of suspected sexual assault/abuse of minors, health care providers are obligated to report or “cause a report to be made” to Child Protective Services, Department of Social and Health Services, and/or to local law-enforcement.

Dealing with Parents
Parents often do not have correct information about their child’s contraceptive use. Parents’ reactions to learning that their child has received contraceptive services vary and range from being upset to feeling displaced and sad. For instance, they may feel upset when discovering pills, condoms, or an ECP prescription in the child’s personal belongings because it indicates a level of sexual activity of which they were not aware. They may feel displaced and sad because the child was not talking with them first.

Often, the provider (e.g., pharmacists, nurses, physicians) becomes the primary target of the parents’ ill feelings and anger. In such cases, pharmacists must first be able to address the parents’ immediate concerns (e.g., ill feelings, sadness, fear, etc.) and provide correct information about contraceptives, and then address their questions. In talking with parents, pharmacists should keep the following objectives in mind:

- be direct, honest and professional;
- tell parents that you understand their concern;
- if appropriate, inform parents that minors can consent to contraceptive and family planning services under state laws and it is the pharmacist’s obligation to provide them.
3. Collaborative Agreements
Pharmacist Prescribing Protocol Checklist

For Review by Protocol Applicant

We are including this checklist for your convenience. These are the criteria we consider in acceptance of a prescriptive authority protocol. Prior to submitting your proposed protocol, please review the protocol for these criteria. Their presence will facilitate acceptance. Please enclose this checklist with your submission.

Date: ______________________________

Pharmacist Applicant: ____________________________________________________________

Practice Site, Address, and Phone Number: __________________________________________

Name of Protocol: _________________________________________________________________

Authorizing Prescriber: ____________________________________________________________

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Meets Criteria</th>
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<tbody>
<tr>
<td>1. Protocol contains statement delegating prescriptive authority</td>
<td></td>
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<tr>
<td>to pharmacist?</td>
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<tr>
<td>2. Authority is also delegated to other pharmacists under the supervision</td>
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<tr>
<td>of the named pharmacist?</td>
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<td>3. A time period for the protocol (not to exceed 2 years) is specified?</td>
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<td>4. Authority delegated is in the general scope of the authorizing</td>
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<tr>
<td>prescriber’s current practice?</td>
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<tr>
<td>5. Patients eligible to receive services under the agreement are specified</td>
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<tr>
<td>6. Delegated prescribing activities are specified (i.e., disease, drugs,</td>
<td></td>
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<td>categories)?</td>
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<tr>
<td>7. Type of pharmacist prescriptive authority delegated is specified in</td>
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<td>each case (e.g., continuation, modification, initiation)?</td>
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<tr>
<td>8. Protocol contains a plan, guideline, or protocol for making</td>
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<td>prescribing decisions?</td>
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<tr>
<td>9. Procedures for documenting prescribing decisions are specified?</td>
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<tr>
<td>10. A plan for periodic feedback/review of prescribing decisions</td>
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<td>(quality assurance) by the authorizing prescriber is specified?</td>
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<tr>
<td>11. All forms used are provided?</td>
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</table>
ECP Collaborative Agreement Protocol

As a licensed health care provider authorized to prescribe medications in the State of __________, I authorize ____________________, R.Ph., and other pharmacists employed at ________________ Pharmacy 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 and regulations of the State of __________.

**Purpose:** To provide access to emergency medication within the 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;
- whether the patient has been a victim of sexual assault;
- the age of the patient.

The pharmacist will refer the patient to see a physician or family planning clinic provider if established pregnancy cannot be ruled out or if the elapsed time is greater than 72 hours.

If there is a concern that the patient may have contracted a sexually transmitted disease through unprotected sex, and/or 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.

The pharmacist may also prescribe and dispense a course of ECPs to a patient who is at risk 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. 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.

The pharmacist will dispense only the number of ECPs required for one of the regimens listed in Table 1. Along with the medication, patients will be provided with information concerning dosing, potential adverse effects, and follow-up contraceptive care. For patients at risk for vomiting, the pharmacist may provide 50 mg of diphenhydramine or meclizine to be taken one hour before ECPs.

Each prescription authorized by the pharmacist will be documented in a patient profile as required by law. A quarterly report of ECP prescribing will be provided to the licensed health care provider(s) authorizing this agreement.

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. 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.

Date____________________

Signed:

Authorizing prescriber____________________________ License #_______________

Authorized pharmacist____________________________ License #_______________

**TABLE 1**

Brands of Emergency Contraceptive Pills Available in the United States

<table>
<thead>
<tr>
<th>Brand</th>
<th>Manufacturer</th>
<th>Pills per Dose*</th>
<th>Ethinyl Estradiol per Dose (µg)</th>
<th>Levonorgestrel per Dose (mg)**</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dedicated Product</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preven</td>
<td>Gynetics</td>
<td>2 blue pills</td>
<td>100</td>
<td>0.50</td>
</tr>
<tr>
<td><strong>Oral Contraceptive Pills</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ovral</td>
<td>Wyeth-Ayerst</td>
<td>2 white pills</td>
<td>100</td>
<td>0.50</td>
</tr>
<tr>
<td>Alesse</td>
<td>Wyeth-Ayerst</td>
<td>5 pink pills</td>
<td>100</td>
<td>0.50</td>
</tr>
<tr>
<td>Levlite</td>
<td>Berlex</td>
<td>5 pink pills</td>
<td>100</td>
<td>0.50</td>
</tr>
<tr>
<td>Nordette</td>
<td>Wyeth-Ayerst</td>
<td>4 light-orange pills</td>
<td>120</td>
<td>0.60</td>
</tr>
<tr>
<td>Levlen</td>
<td>Berlex</td>
<td>4 light-orange pills</td>
<td>120</td>
<td>0.60</td>
</tr>
<tr>
<td>Levora</td>
<td>Watson</td>
<td>4 white pills</td>
<td>120</td>
<td>0.60</td>
</tr>
<tr>
<td>Lo/Ovral</td>
<td>Wyeth-Ayerst</td>
<td>4 white pills</td>
<td>120</td>
<td>0.60</td>
</tr>
<tr>
<td>Triphasil</td>
<td>Wyeth-Ayerst</td>
<td>4 yellow pills</td>
<td>120</td>
<td>0.50</td>
</tr>
<tr>
<td>Tri-Levlen</td>
<td>Berlex</td>
<td>4 yellow pills</td>
<td>120</td>
<td>0.50</td>
</tr>
<tr>
<td>Trivora</td>
<td>Watson</td>
<td>4 pink pills</td>
<td>120</td>
<td>0.50</td>
</tr>
<tr>
<td>Ovrette</td>
<td>Wyeth-Ayerst</td>
<td>20 yellow pills</td>
<td>0</td>
<td>0.75</td>
</tr>
</tbody>
</table>

Adapted from *Journal of the American Medical Women’s Association* EC Supplement 1998, revised version of the table (page 213).

* The treatment schedule is one dose within 72 hours after unprotected intercourse, and a second dose 12 hours later.

** 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.
Antiemetic Options

These products work best if taken before the onset of symptoms. As shown in Tables 2 and 3, patients should be instructed to take a prophylactic dose at least one hour before the ECP dose, and then as needed.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>Timing of Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TABLE 2</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Non-Prescription Drugs</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Meclizine Hydrochloride</td>
<td>1–2 25-mg tablets</td>
<td>1 hour before first ECP dose; repeat if needed in 24 hours</td>
</tr>
<tr>
<td>(Dramamine II, Bonine)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diphenhydramine Hydrochloride</td>
<td>1–2 25-mg tablets</td>
<td>1 hour before first ECP dose; repeat if needed every 4–6 hours</td>
</tr>
<tr>
<td>(Benadryl)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dimenhydrinate (Dramamine)</td>
<td>1–2 50-mg tablets or</td>
<td>30 minutes to 1 hour before first ECP dose; repeat as needed every 4–6 hours</td>
</tr>
<tr>
<td>4–8 tablespoons of liquid</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cyclizine Hydrochloride</td>
<td>1 50-mg tablet</td>
<td>30 minutes before the first ECP dose; repeat as needed every 4–6 hours</td>
</tr>
<tr>
<td>(Marezine)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| **TABLE 3**                  |                           |                                              |
| **Prescription Drugs**       |                           |                                              |
| Meclizine Hydrochloride       | 1–2 25-mg tablets         | 1 hour before first ECP dose; repeat if needed in 24 hours |
| (Antivert)                    |                           |                                              |
| Trimethobenzamide Hydrochloride | 1 250-mg tablet or      | 1 hour before first ECP dose; repeat as needed every 4–6 hours |
| (Tigan)                       | 200-mg suppository        |                                              |
| Promethazine Hydrochloride    | 1 25-mg tablet or         | 30 minutes to 1 hour before first ECP dose; repeat as needed every 8–12 hours |
| (Phenergan)                   | suppository               |                                              |
Submitting a Pharmacist Prescriptive Authority Protocol to the State Board of Pharmacy

The Board of Pharmacy is very conscientious in meeting its responsibility under WAC 246-863-100, which specifies the requirements for pharmacist prescriptive authority protocols. Attention to the steps that follow will ensure acceptance of your protocol.

1. Complete the attached form “Pharmacist Prescribing Protocol Checklist” and submit it with your protocol and letter requesting acceptance.

2. Provide contact information, including fax number and e-mail address, if you have one, to facilitate resolution of any questions.

3. Obtain the signature of the authorizing prescriber (critical to acceptance by the Board).

4. With Emergency Contraception, the eligible patients are any patients that satisfy your screening questions and can receive treatment.

5. With Emergency Contraception, the pharmacist is initiating the therapy.

6. You can include the standard quality assurance procedures presented in the training or an alternative procedure.

7. Plan ahead. Your request must be received by ___________ for consideration at the next Board of Pharmacy meeting. Your protocol must be accepted by the Board before implementation.

8. Send the request to: [Insert address here.]
ECP Pharmacist Training
Quality Assurance Procedures

1. The participants in the protocol determine the data elements to be collected for care review.

   For routine care, those elements will usually be patient name, age, date of service, time since intercourse and last menstrual period, medication dispensed, and any pharmacist comments.

   For non-routine care, i.e., care in which the patient is referred, the pharmacist documents the facts that led to the referral. These could include sexually transmitted disease, need for contraceptive care, sexual assault, and delayed or repeated EC treatment, as examples.

2. On a quarterly basis, the authorized pharmacist will generate a report and provide it to the authorizing prescriber for review and comment.

3. The authorizing prescriber reviews the report, comments on the care provided, and provides the authorized pharmacist with a copy. Optimally, the authorizing prescriber and authorized pharmacist meet to review and discuss the care.

4. Both the authorizing prescriber and authorized pharmacist maintain the documentation for two years.
Liability Risk

What is the liability risk of a physician or other clinician with independent prescribing authority who enters into a collaborative drug therapy agreement with a pharmacist for prescribing emergency contraceptive pills?

In Washington State, pharmacists have had prescriptive authority since 1979. To date there have been no legal suits brought against pharmacists operating under prescribing protocols or their collaborating physicians/clinicians. Consequently, there is no case record to cite in response to this question. However, two Washington State malpractice attorneys and the risk manager of the largest physician medical malpractice insurer, who were contacted for an informal opinion, felt the liability risk was minimal for the following reasons:

- The prescribing protocol is sound and comprehensive.
- Emergency contraceptive pills have a good safety profile.
- In the absence of a direct therapeutic relationship with the emergency contraceptive pill user, a physician or other collaborating clinician may not be liable.

However, if the courts were to interpret liability on the part of the physician or other collaborating clinician, it would be covered under a standard malpractice insurance policy. Physicians and other clinicians interested in participating in this project, but concerned about liability issues, should be advised to contact their malpractice insurance carrier.
4. Public Relations
Emergency Contraception
Public Awareness Media Campaign

Providing emergency contraception directly from a pharmacist increases awareness of emergency contraception and accessibility for women seeking this form of preventative birth control. During the pilot project in Washington State, women were educated about this campaign through several media and educational avenues. Radio advertisements, public relations materials, and in-store collateral materials were created for this effort.

Advertising

One of the most effective media vehicles for a campaign of this nature is radio. With radio advertising women were educated about this campaign and informed of how to receive emergency contraception. A main focus of radio advertising was publicizing the emergency contraception Hotline, which gives callers information on emergency contraception and lists five health care providers and five pharmacies where callers can receive emergency contraception in their immediate area.

This advertisement was aired on approximately ten radio stations in the greater Seattle region for three to six months. Promotional opportunities with the selected radio stations were also pursued, including remote broadcasts, interactive forums between the audience and the station or a guest speaker, and other means of distributing information like brochures or wallet cards.

Public Relations

Public relations, also referred to as media relations, is simply the act of pursuing television, radio, and print media to write or air stories on the campaign. Because the message for this campaign is somewhat complex, a well-placed story can help to explain emergency contraception as well as inform women about the availability of emergency contraception at their pharmacies.

As part of the media relations effort, media kits were created and sent to members of the press in an effort to solicit stories. These kits included information on the campaign, background information, and pharmacist information.

In addition, a press event that provided local media with a photo opportunity and a forum to interview spokespeople for the campaign was held.
Collateral Materials

Another way to inform women about getting emergency contraception from their pharmacist is by distributing information at different points in the pharmacy. The Washington collaborators produced different “collateral” or retail materials that educated women in the pharmacy. Not all of these options were appropriate or viable for every pharmacy, so several options were developed to allow all pharmacies to participate in this manner.

- **Counter Wallet Cards:** These wallet cards listed the emergency contraception Hotline and Web site and gave women basic information about emergency contraception. They were placed on pharmacy counters and other appropriate areas in the pharmacy.

- **Poster:** An emergency contraception poster listing the Hotline was displayed anywhere in the pharmacy area (such as behind the pharmacy counter or on an informational bulletin board). Advertisements were also placed on public transportation vehicles in conjunction with the national public relations campaign.

- **Shelf Talker:** A shelf talker is a great way to inform women in relevant areas throughout the pharmacy. This informational piece is being considered as part of the sustained advertising program. Since half of all unintended pregnancies occur as a result of contraceptive failure, shelf talkers may be displayed in the condom or contraceptive aisles to serve as reminders for women that they can still prevent pregnancy if their contraception fails.
Talking to the Media

Talking to the media is a skill. It is not something most people are automatically comfortable with. The following information is meant to give you some groundrules to use when talking to the media. When executed correctly, both you and the reporter will walk away from an interview feeling good about the outcome and the resulting story.

1. **Inquire about the subject matter to be covered.** It is perfectly natural to ask a reporter about the general direction of a story and what topics will be covered. This does not mean asking for a list of questions that he or she is going to ask you. But by getting a sense of what the interview will cover, you will be more prepared and the reporter will get a better story.

2. **Decide whether or not you want to do the interview.** If you don’t like the direction a reporter has decided to take with a story, you have the right to decline the interview. This should only be done in extreme cases and as politely as possible. You never know when you may have to rely on that same reporter for a story.

3. **Have an agenda.** The reporter will have an agenda, and you should too. Make a list of two or three key points and focus on weaving those points into your interview.

4. **Don’t answer hypothetical questions.** Again, as politely as possible, simply say, “I’m sorry, but I don’t feel comfortable answering hypothetical questions.” Responding to this type of question can only get you into trouble, so don’t do it.

5. **Request time to answer each question.** Responding right away to a tough question can result in a less effective or potentially damaging answer. Take a few seconds to think about the question before answering, or ask the reporter to come back to the question later.

6. **You don’t have to answer every question.** If you don’t feel comfortable answering a question, don’t answer it. This doesn’t mean shy away from controversial questions. Rather, if you don’t know the answer to something, it is better to simply say, “I don’t know.”

7. **Don’t speak for someone else.** Quite often a reporter will ask you what the opposition thinks of you or what you are doing. Do not answer for another person or organization. Tell the reporter you cannot speak for that person.

8. **Correct the reporter’s misstatements.** Gently, but firmly correct a reporter’s misstatements. Phrases such as “you may have misunderstood what I meant” or “maybe I didn’t explain myself clearly” work well.

9. **Restate the question.** Restate the reporter’s question in your answer. This provides less room for quotes taken out of context and will help the reporter when putting the story together.
10. Don’t think of the reporter as your buddy, no matter how nice he or she is. Letting your guard down will cause you to say things you wouldn’t normally say. Even if the reporter is a friend, keep things on a professional level when you’re on camera.

11. NEVER go “off the record.” The phrase “anything you say can and will be used against you” comes to mind. Anything you say in an interview, whether the camera is rolling or not, can make it into a story. If a reporter asks you to go off the record and speak more candidly, refuse. Just because the camera isn’t rolling doesn’t mean that the reporter isn’t still recording sound.

12. Look around you. Make sure the area where the interview is taking place is free of clutter or things you would not want to appear on camera.

13. Wrap it up smoothly. Thank the reporter for their time and be courteous. You never know when you may want to approach them about a story in the future. You want the reporter to walk away with a positive image of you and your organization.

Talking Points
These are the key points about Emergency Contraceptive Pills (ECPs) that you should try to refer to during media interviews.

1. ECPs are regular birth control pills used in a different dosage to prevent pregnancy after sex. ECPs are contraceptives — they do not cause an abortion. They work to prevent pregnancy up to 72 hours after unprotected sex and will not work if a woman is already pregnant. If a woman is pregnant and takes ECPs, the pills will not harm the developing fetus.

2. Birth control pills are safe and effective, and they do not require a medical examination before being prescribed. In fact, the FDA made an almost unprecedented announcement in support of ECPs, calling the pills “safe and effective.” There are very few reasons that a woman could not take ECPs. All medical information needed to prescribe them can be gathered through a brief consultation with a trained pharmacist.

3. Women can easily access the closest pharmacies or health care providers (nationwide) that provide ECPs by calling the emergency contraception hotline at 1-888-NOT-2-LATE.
Frequently Asked Questions

The following information addresses some of the questions frequently asked by media about emergency contraception.

**Question:** Is there really that great of a need for emergency contraception?
**Answer:** Unfortunately, no form of contraception is 100 percent effective. In fact, it is estimated that 27,000 condoms break or slip every day in the United States, resulting in many unintended pregnancies. There are almost three million unintended pregnancies each year in the United States; half of these are the result of contraceptive failure. Emergency contraception has the potential to prevent millions of these unintended pregnancies and the abortions that may result from them.

**Question:** Just how many pharmacies are actually doing this?
**Answer:** (This answer will depend on your state’s participation. If you feel comfortable answering the question, we suggest the following). The response to this initiative has been tremendous. Many individual pharmacists and even whole pharmacy chains are participating, and independently dispensing emergency contraception.

**Question:** Isn’t increasing access to emergency contraception making it easier for people to be irresponsible?
**Answer:** A woman seeking ECPs is making a responsible decision to prevent an unintended pregnancy. Additionally, providing ECPs offers an opportunity to counsel a woman about ongoing contraception. Evidence to date shows that women are not relying on ECPs as their primary method of contraception. We make sure people know that ECPs are not as effective as other forms of contraception, and they cannot prevent sexually transmitted diseases. ECPs are simply a unique contraceptive method, and the only easily available method that can still prevent a pregnancy after unprotected sex.

**Question:** So, just how safe is emergency contraception?
**Answer:** There are no known serious side effects of emergency contraception. Some women using ECPs may experience temporary side effects, which include nausea, and sometimes vomiting, particularly with estrogen/progestin formulation ECPs. The FDA has published an article in the *Federal Register* calling emergency contraceptive pills safe and effective as “after the fact” birth control.

**Question:** Are you prescribing ECPs to teenagers without their parents’ consent?
**Answer:** (Before answering this question, you should know the laws in your state for prescribing contraception to minors. Here is the response we use.) In Washington State, any sexually active woman, no matter what age, has the right to seek contraceptive services. We respect this right.
Crisis Communications:
How to Handle Anti-Choice Opposition

The Washington State Emergency Contraception Collaborative Agreement Pilot Project experienced no significant opposition. Opposition from anti-choice organizations was muted and limited mainly to letter writing. Other organizations such as the Reproductive Health Technologies Project (RHTP) have also experienced very minimal opposition to both their Emergency Contraception Hotline (1-888-NOT-2-LATE) and their national and target-market awareness campaigns. All indicators point to the fact that there is no unified opposition to ECPs in this country. Even key anti-choice organizations have been quoted in newspapers such as the Wall Street Journal saying that they have no blanket opposition to ECPs.

In the event that you do encounter anti-choice opposition, the following steps will assist you in handling the situation effectively:

- If you receive a letter of complaint, respond in a timely manner. The response should be succinct and based on medical fact. Anti-choice groups will try to engage you in an emotional debate – don’t participate. Do not become drawn into multiple letter exchanges with a particular group. You will not be able to change their opinions or alter their resolve. A timely and factual response stating your position is sufficient. (Sample letter responses are provided in the “PR/Contingency Plans” section.)

- With regard to negative letters to the editor in the local paper, respond with a factual letter. You may wish to invite another medical professional, satisfied customer, or public health official to sign the letter as well. (A sample letter is provided in “PR/Contingency Plans” section.)

- Nationwide there has been no organized boycott of an ECP provider, and boycott threats in Washington State did not materialize. Although a few pharmacies received letters from people threatening to boycott the stores, their businesses were not impaired or subjected to any economic hardships. Regardless, it may be helpful to enlist the support of customers who are happy with the service. You may wish to ask these patrons to write supportive letters to individual or chain pharmacy management in regard to the new service.

- Having educational information and data on unintended pregnancy may be useful for dealing with this audience in a variety of situations. (Information on unintended pregnancy is provided in this section.)
Crisis Communications:
How to Handle Public Disturbances at the Pharmacy

The following recommendations were created to assist you in the unlikely event that you experience picketing or protesting at your pharmacy. To date, there have been no instances of picketing or on-site protesting at any of the participating Washington State pharmacies. While it is highly unlikely that you will encounter protests, the following information provides suggestions for dealing with any situation that could arise.

Because a public disturbance is often followed by media requests, we have also included suggestions for dealing with media in this situation. We recommend that you speak with media if possible – the opposition will be trying to get in front of the cameras, so it is important for the correct medical perspective to be covered as well.

- Establish a plan of action. It is always best to be prepared.

- Identify a pharmacy spokesperson, and have this person’s phone number available, as well as the phone numbers of any other key managers or personnel that you would need to alert. Let your employees know how you want them to handle a protest or media situation.

- If your pharmacy is part of a chain, find out who the media relations contact is at your corporate office. Call this person in the event of a protest, or if the media contacts you for an interview.

- If you are an independent pharmacy, decide whether or not you want to answer questions in a media situation. If you decide to talk to media, please see the talking points in this section. This information will provide you with frequently asked questions and the recommended answers.

- Decide how you want to handle picketing or protesting. It is best to avoid engaging in any verbal discussions or confrontations. Instead, ignore them and carry on business as usual. It is your legal right, however, to have protesters removed from your private property. If you decide to do so, please call your local police department.

- If you do experience protesting at your pharmacy, you may want to consider providing your customers with a flyer that describes the project and emergency contraception. The sample flyer in this section can be adapted as needed.
Emergency Contraception and Our Pharmacy:
Improving Access to an Important Contraceptive Option

Our pharmacy is one of many in the state providing Emergency Contraceptive Pills (ECPs) directly to women in need. Through this approach we hope to increase access to ECPs and help prevent unintended pregnancy. By working in collaboration with a licensed birth control pill prescriber, such as a physician or advanced registered nurse practitioner (ARNP), pharmacists can provide ordinary birth control pills directly to women for use as an emergency contraceptive.

Emergency contraception is a woman’s last chance to prevent pregnancy after unprotected sex.

- ECPs are ordinary birth control pills taken in a different dosage within 72 hours of unprotected sex.
- ECPs are at least 75 percent effective at preventing pregnancy after unprotected sex and will not work if a woman is already pregnant.
- ECPs are a safe and effective contraceptive — they are not, and cannot cause, an abortion.
- ECPs do not require a medical examination before being prescribed. A trained pharmacist can clinically screen potential ECP users.
- By using ECPs, a woman still has one last chance to prevent an unintended pregnancy before having to consider other options, such as abortion.

Unintended pregnancies affect all of us. It is estimated that emergency contraception could prevent half of the nearly three million unintended pregnancies reported in the United States each year. As demonstrated in a 1995 Institute of Medicine Study,¹ unintended pregnancy is a critical public health concern because of the magnitude and consequences of the problem:

- A woman with an unintended pregnancy is less likely to seek early prenatal care and is more likely to expose the fetus to toxic substances like cigarette smoke, alcohol, and prescription or other drugs.
- The child of an unintended conception is at greater risk of being born at low birthweight, dying in its first year of life, being abused, and not receiving sufficient resources for healthy development.
- The mother is at greater risk of depression and of physical abuse. Her relationship has three times the risk of dissolution.
- Both mother and father may suffer economic hardship and may fail to achieve their educational and career goals. Such consequences impede the formation and maintenance of healthy families.

We see this approach as a positive first step in solving one of the most prevalent public health issues facing our country and our communities — unintended pregnancy. Emergency contraception can prevent millions of unintended pregnancies and abortions each year in the United States. We are pleased to be a part of the solution to this public health problem, and to provide this service to our community. The project is a collaborative effort among local pharmacists, physicians, and health care organizations.

5. Insurance
Reimbursement Issues

Reimbursement issues vary widely from state to state. Pharmacist training therefore should address this topic in detail, including compensation for the pharmacist’s screening and counseling time as well as product cost.

Documents from the Emergency Contraception Collaborative Agreement Pilot Project in Washington State have been included in this manual to illustrate some of the issues that were addressed.
Medicaid Coverage Now Available in Washington State

The Medical Assistance Administration of the State of Washington has announced authorization of payment of emergency contraception services to pharmacies that have collaborative agreements for ECPs on file with the Board of Pharmacy. This move should make ECPs more available to women with public insurance.
Additional Materials included here:

- DSHS memo
- PRAMS/MAA emergency contraception information (dated October 29, 1998)
- MAA question-and-answer sheet
Appendices
Appendices

In addition to the materials included on the following pages, the original *ECP Training Manual* included several documents that were specific to Washington State, including:

- the names and contact information for over 40 authorized prescribers (physicians and ARNPs) who were willing to discuss the establishment of a collaborative agreement with trained pharmacists;
- Washington State reproductive health care referrals and resources;
- Puget Sound sexual abuse/assault and rape referrals and resources, including information for victims of rape and sexual abuse from the Child Protective Services.

Organizations implementing an emergency contraception program may wish to offer their participants comparable information for their own region, as this information proved useful to participants in the Washington project.
Appendix A

Washington Pharmacist article included here
Appendix B

*Federal Register* article included here
Appendix C

Emergency Contraception Hotline Registration Form

Your pharmacy will be listed on the national Emergency Contraception Web site (http://opr.princeton.edu/ec/) and on the Emergency Contraception Hotline (1-888-NOT-2-LATE) if you complete, sign, and return this form. Please note that the Web site and Hotline will normally list only the pharmacy name, city, state, telephone number, and whether your services are limited to qualified clients (e.g., HMO members). We ask for additional information on this form for our records, so please complete the entire form.

Name of pharmacy: _______________________________________________________

Administrative contact: ________________________ E-mail: __________________

Name(s) of staff with ECP prescriptive authority:  ______________________________
_______________________________________________________________________

Street address:  __________________________________________________________

City: _________________________ State: _______ ___ Zip: ______________

Telephone # (toll numbers only; no 800 numbers or extensions can be listed):
_______________________________________________________________________

Fax #: _________________________________________________________________

If, and only if, the pharmacy name and telephone number are insufficient to get a client to an appropriate person, indicate below what additional information would be required (e.g., name of pharmacist):

If your practice sees only qualified patients, please indicate by checking the appropriate box so that we can put this information on both the Web site and Hotline.

☐ College student health service  ☐ Indian health service
☐ Military health service  ☐ Health maintenance organization
☐ Pharmacy  ☐ Other ____________________________
Your signature indicates that you have authority to include your pharmacy in the directory of providers of emergency contraception and that your pharmacy has staff with authority to prescribe medication.

Signature: _________________________ Date: _______________________

For administrative purposes, if you are part of a larger pharmacy chain, medical group, or affiliate that has one central administrative office (for example, a Planned Parenthood clinic under an affiliate or a private practice with multiple offices), please provide the information below.

Administrative contact name: ____________________________________________

Name of group: _______________________________________________________

Mailing address: _______________________________________________________

Telephone: (____)_________ Fax: (____)______ E-mail: _________________

RETURN THE COMPLETED FORM TO:

[Insert address here.]

Please notify everyone on your staff (especially those who answer the telephone) that you will be listed in the directory.

Please notify us immediately if changes occur in the information provided above or if you would like to be removed from the directory. It is very important that our information is current. Periodically, we will send updates on emergency contraception issues and ask for feedback on the hotline and web site.

Thank you for your participation.
Appendix D

How to Use Emergency Contraceptive Pills

If you have had sex without birth control or your birth control method failed within the past 3 days, you can use emergency contraceptive pills (ECPs) to reduce your risk of pregnancy. If you had sex without birth control more than 3 days ago, you may be able to have an IUD inserted to prevent pregnancy (contact your health care provider as soon as possible).

Types of Pills

Any of the birth control pills listed below can be used as ECPs. Use only the type of pill your health care provider prescribed for you. Use only one type of pill.

<table>
<thead>
<tr>
<th>If you are taking:</th>
<th>Number of pills to swallow as soon as possible (first dose)</th>
<th>Number of pills to swallow 12 hours later (second dose)</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Dedicated Product</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preven</td>
<td>2 blue pills</td>
<td>2 blue pills</td>
</tr>
<tr>
<td><em>Oral Contraceptive Pills</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alesse</td>
<td>5 pink pills</td>
<td>5 pink pills</td>
</tr>
<tr>
<td>Lo/Ovral</td>
<td>4 white pills</td>
<td>4 white pills</td>
</tr>
<tr>
<td>Levlen</td>
<td>4 light-orange pills</td>
<td>4 light-orange pills</td>
</tr>
<tr>
<td>Levlite</td>
<td>5 pink pills</td>
<td>5 pink pills</td>
</tr>
<tr>
<td>Levora</td>
<td>4 white pills</td>
<td>4 white pills</td>
</tr>
<tr>
<td>Ovral</td>
<td>2 white pills</td>
<td>2 white pills</td>
</tr>
<tr>
<td>Ovrette</td>
<td>20 yellow pills</td>
<td>20 yellow pills</td>
</tr>
<tr>
<td>Nordette</td>
<td>4 light-orange pills</td>
<td>4 light-orange pills</td>
</tr>
<tr>
<td>Tri-Levlen</td>
<td>4 yellow pills</td>
<td>4 yellow pills</td>
</tr>
<tr>
<td>Triphasil</td>
<td>4 yellow pills</td>
<td>4 yellow pills</td>
</tr>
<tr>
<td>Trivora</td>
<td>4 pink pills</td>
<td>4 pink pills</td>
</tr>
</tbody>
</table>

Timing of Doses

- To reduce the chance of nausea, take an anti-nausea medication like Dramamine II or Benadryl 1 hour before you take the first dose of ECPs. Repeat according to labeled instructions.
- Take the first dose of ECPs as soon as convenient within 72 hours (3 days) after having unprotected sex. Try to time the first dose so that the timing of the second dose will be convenient.
- Take the second dose of ECPs 12 hours after taking the first dose.

Important: Do not take any extra ECPs. Taking more pills will not make the method work better and will increase the chance you will feel sick to your stomach.
What to Expect

- Some women who use ECPs feel sick to their stomach, and a few women vomit. Some women also feel dizzy or tired or have tender breasts. These side effects are not serious and usually stop in a day or so. If you vomit within 2 hours of taking the pills, call your provider for instructions.
- Your period may come on time or be a few days early or late.
- **Important:** ECPs are not 100 percent effective. If your period does not start **within 3 weeks** after taking ECPs, there is a chance that you may be pregnant. See your health care provider or do a home pregnancy test.

Preventing Pregnancy in the Future

- ECPs do not protect you against pregnancy **after** treatment. Use condoms, spermicides, or a diaphragm after using ECPs until your next period starts. You can switch to a different birth control method then.
- ECPs are meant for emergency protection. ECPs are not as effective as other forms of regular birth control. Talk to your health care provider about other regular birth control methods you can use to prevent pregnancy in the future. Protect yourself against AIDS and other sexually transmitted diseases as well as pregnancy—use condoms every time you have sex if you think you may be at risk.

Cómo Usar las Píldoras Anticonceptivas de Emergencia

Si usted ha tenido relaciones sexuales desprotegidas (esto es, relaciones en que no usó un método anticonceptivo) o si su método anticonceptivo falló en los últimos 3 días, usted puede usar las PAEs (píldoras anticonceptivas de emergencia) para reducir su riesgo de embarazo. Si usted tuvo relaciones sexuales desprotegidas hace más de tres días, puede conseguir que le inserten un DIU para prevenir el embarazo (Comuníquese inmediatamente con su proveedor de servicios de salud).

Tipos de Píldoras

Cualquiera de las píldoras a continuación pueden ser usadas como anticonceptivos de emergencia. Use sólo el tipo de píldora que su proveedor de servicios de salud le prescribió a usted. Use sólo un tipo de píldora.

<table>
<thead>
<tr>
<th>Si usted está tomando:</th>
<th>Cantidad de píldoras que deberá Tomar tan pronto como posible</th>
<th>Cantidad de píldoras que deberá tomar 12 horas más tarde</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Producto Dedicado</strong></td>
<td><strong>Tomar tan pronto como posible</strong></td>
<td><strong>Tomar 12 horas más tarde</strong></td>
</tr>
<tr>
<td>Preven</td>
<td>2 píldoras azules</td>
<td>2 píldoras azules</td>
</tr>
<tr>
<td><strong>Pastillas Anticonceptivas</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alesse</td>
<td>5 píldoras rosa</td>
<td>5 píldoras rosa</td>
</tr>
<tr>
<td>Lo/Ovral</td>
<td>4 píldoras blancas</td>
<td>4 píldoras blancas</td>
</tr>
<tr>
<td>Levlen</td>
<td>4 píldoras color naranja claro</td>
<td>4 píldoras color naranja claro</td>
</tr>
<tr>
<td>Levlile</td>
<td>5 píldoras rosa</td>
<td>5 píldoras rosa</td>
</tr>
<tr>
<td>Levora</td>
<td>4 píldoras blancas</td>
<td>4 píldoras blancas</td>
</tr>
<tr>
<td>Ovral</td>
<td>2 píldoras blancas</td>
<td>2 píldoras blancas</td>
</tr>
<tr>
<td>Ovrette</td>
<td>20 píldoras amarillas</td>
<td>20 píldoras amarillas</td>
</tr>
<tr>
<td>Nordette</td>
<td>4 píldoras color naranja claro</td>
<td>4 píldoras color naranja claro</td>
</tr>
<tr>
<td>Tri-Levlen</td>
<td>4 píldoras amarillas</td>
<td>4 píldoras amarillas</td>
</tr>
<tr>
<td>Triphasil</td>
<td>4 píldoras amarillas</td>
<td>4 píldoras amarillas</td>
</tr>
<tr>
<td>Trivora</td>
<td>4 píldoras rosa</td>
<td>4 píldoras rosa</td>
</tr>
</tbody>
</table>

Calendario de Administración

- Para reducir las posibilidades de náusea, tome un medicamento antináusea tal como Dramamine II o Benadryl 1 hora antes de tomar la primera dosis de las PAEs. Repita según las instrucciones de la etiqueta.
- Tome la primera dosis de PAEs apenas le sea conveniente pero no después de 72 horas (3 días) desde un acto sexual desprotegido. Trate de programar la primera dosis de manera que la hora de tomar la segunda dosis le resulte cómoda.
- Tome la segunda dosis de píldoras 12 horas después de tomar la primera dosis.

**Importante: No tome más PAEs.** El tomar más píldoras no reducirá su riesgo de embarazo sino que aumentará su riesgo de náusea.
Qué Esperar

- Algunas mujeres que toman las PAEs sienten náuseas y algunas mujeres vomitan. Asimismo, algunas mujeres se sienten mareadas o cansadas o sienten los senos muy sensibles. Estos efectos secundarios no son serios y por lo general pasan después de aproximadamente un día. Si usted vomita dentro de las 2 horas siguientes a la ingestión de las píldoras, pídale instrucciones a su proveedor de servicios de salud.
- Puede que su menstruación llegue a tiempo o se adelante o se atrasé por unos días.
- **Importante**: las PAEs no son cien porciento efectivas. Si no se da su menstruación dentro de las 3 semanas después de tomar las PAEs, comuníquese con su proveedor de servicios de salud o haga una prueba de embarazo.

Cómo Prevenir el Embarazo en el Futuro

- Las PAEs no le protegen a usted contra el embarazo después del tratamiento. Use condones, espermicidas o un diafragma para protegerse contra el embarazo durante el resto del ciclo. Al final del ciclo puede entonces cambiarse a otro método anticonceptivo.
- Las PAEs sólo raramente deben ser usadas como protección de emergencia, puesto que no son tan efectivas como otros métodos anticonceptivos. Pregúntele a su proveedor de servicios de salud sobre otros métodos anticonceptivos que usted pueda usar para evitar el embarazo en el futuro. Protéjase contra el SIDA y otras infecciones transmitidas sexualmente — use condones cada vez que tenga relaciones sexuales si piensa que corre cualquier riesgo.
