



**CENTER FOR
REPRODUCTIVE
RIGHTS**

*Emergency
Contraception (EC)*
*An Affirmative Agenda
to Improve Access*



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Emergency Contraception (EC)

A Safe and Effective Way to Prevent Unplanned Pregnancy

It is estimated that over three million American women have unplanned pregnancies each year, and over half of these end in abortion. Emergency contraception (EC), sometimes called the “morning-after pill,” is an effective method of preventing unwanted pregnancy.¹

EC IS SAFE AND EFFECTIVE TO USE

EC prevents pregnancy via a course of hormonal contraceptive pills, taken in one- or two-dose regimens. EC is most effective if the first dose is taken within 24 hours after unprotected sex; however, it can be effective up to 5 days after intercourse. If the regimen is started within 24 hours, EC can be 95% effective.

EC comes in two formulations:

- **Combined Emergency Contraceptive Pills** – ordinary oral contraceptive pills containing estrogen and progestin hormones
- **Progestin-only Emergency Contraceptive Pills or “minipills”** – regular oral contraceptive pills, taken in higher doses and containing progestin only. These have been used as EC for 30 years.

Today there are two pre-packaged, specially-designed EC kits on the market, Preven and Plan B.

EC is well tolerated by most women, including those who have had trouble using oral contraceptives regularly. Reported side effects are generally mild, including headache, nausea and stomach discomfort, and vary with the brand used.

Because EC can be used at all stages of a woman’s menstrual cycle, its mode of action varies. After intercourse, EC may prevent pregnancy by preventing ovulation, blocking fertilization or preventing implantation of a

Some extreme anti-choice groups oppose EC by equating it with abortion, which they also oppose. These groups are out of step with the mainstream medical community, and their views find almost no support in laws and policies at the state and federal level.

fertilized egg.

EC IS NOT ABORTION

According to both medical science and legal convention, pregnancy begins only after implantation of a fertilized egg in the uterus. EC therefore acts to prevent a pregnancy. Studies show that EC has no effect on established pregnancies.

Some extreme anti-choice groups oppose EC by equating it with abortion, which they also oppose. These groups are out of step with the mainstream medical community, and their views find almost no support in laws and policies at the state and federal level. The attacks against EC are unwarranted and must therefore be seen as part of an agenda to ban all contraceptives.

EC IS SUPPORTED BY THE FDA AND MEDICAL ASSOCIATIONS

The Food and Drug Administration (FDA) has deemed the use of EC safe and effective in the prevention of pregnancy. The Center for Reproductive Rights petitioned the FDA in 1994 on behalf of medical associations to improve access to EC. In response to the petition and other advocacy efforts, in 1997, the FDA announced that six brands of oral contraceptive pills were safe and effective for use as EC. This announcement put the

FDA's explicit "stamp of approval" on agency reviewed EC regimens. Since then, two products of oral contraceptive pills packaged, sold, and marketed specifically for use as EC have been approved by the FDA: Preven in 1998 and Plan B in 1999.

Increasing Access to EC

ACCESS TO EC WILL IMPROVE NATIONWIDE IF THE FDA APPROVES A CHANGE OF STATUS AND MAKES EC AVAILABLE OVER-THE-COUNTER.

On February 14, 2001, the Center for Reproductive Rights petitioned the FDA on behalf of more than 60 medical, public health, and other organizations, to change the status of

Many women, and even some health care professionals, remain unaware of the availability of EC. Detailed information, including nearby clinics that offer EC, can be obtained from the Emergency Contraception Hotline at 1-888-NOT-2-LATE or via the web at www.not-2-late.com.

EC from prescription to over-the-counter, based on the fact that EC is safe and effective for use without a prescription. In 2003, Plan B (an EC manufacturer) also petitioned the FDA for over-the-counter

status for EC. Both the American Medical Association and the American College of Obstetricians and Gynecologists approve of a change to over-the-counter status, recognizing that over-the-counter availability may be the only way for some women to obtain EC in time to prevent a pregnancy. EC is now available either over-the-counter or directly from a pharmacist in many countries, including Canada, France, Portugal, Great Britain and Finland, and increasing availability is part of a world-wide trend.

PARTNERSHIPS BETWEEN HEALTHCARE PROVIDERS

Some states authorize pharmacists to prescribe medications pursuant to collaborative agreements with physicians or other healthcare professionals, clinics or HMOs. Pharmacists in these states may be able to develop collaborative agreements that will allow them to provide EC to patients without an individual prescription. For example, in the state of Washington, women are able to obtain EC from a pharmacist, avoiding a potentially costly and time-consuming visit to a physician's office or hospital. From 1998 until June 2001 Washington pharmacists prescribed and filled nearly 35,600 prescriptions

If made available over-the-counter, EC has enormous potential to alleviate the public health problem of unplanned and unwanted pregnancies.

for EC. The project prevented an estimated 2000 pregnancies, of which about half would have ended in abortion. Through legislative and regulatory efforts, other states are beginning to establish similar programs to improve access to EC.

OBSTACLES TO WOMEN'S ACCESS TO EC

Despite the recognized value of EC, EC is not always made available to women.

Refusal clauses (or so-called "conscience clauses") are provisions in state and federal legislation that permit doctors, other medical personnel, and sometimes pharmacists, to refuse to perform any procedure or dispense medication that conflicts with the provider's religious or moral beliefs. Advocates are exploring ways to reduce the scope of refusal clauses in order to protect access to EC and other reproductive health services, and to ensure that such provisions are not added to new laws.

Additionally, Catholic healthcare systems and other hospital networks also try to avoid providing EC in their hospitals, even to sexual assault survivors who seek treatment in their emergency rooms. As Catholic healthcare providers increasingly merge with their secular counterparts, the restrictions on access to the fullest range of reproductive health services become more and more troubling. Reproductive rights advocates in the states are working to pass legislation to ensure that all hospital emergency rooms that treat women after a sexual assault inform them about EC as part of this care and provide EC upon request.

A final obstacle to women's access to EC is a lack of awareness about EC. For example, one study found that only 68% of women are aware that they can prevent pregnancy after intercourse, and only 6% have ever used EC². In order to increase awareness about EC, the U.S. Congress and state legislators are considering bills that would increase public awareness about EC and encourage healthcare providers to inform their patients about EC.

1 See e.g. Stanley K. Henshaw, *Unintended Pregnancy in the United States*, 30 *Family Planning Perspectives* 24-29, 46 (January/February 1998); see also Rachel K. Jones, Jacqueline E. Darroch and Stanley K. Henshaw, *Contraceptive Use Among U.S. Women Having Abortions in 2000-2001*, 34 *Perspectives on Sexual and Reproductive Health* (November/December 2002) (estimating that EC is responsible for up to 43% of the 11% decline in abortion rates between 1994 & 2000).

2 See Kaiser Family Foundation/SELF magazine, *National Survey of Women on their Sexual Health* (June 2003); see generally Kate Zernike, *Use of Morning-After Pill Rising and It May Go Over the Counter*, *New York Times*, May 19, 2003, at A1.



State Trends in Emergency Contraception Legislation

It has been over four years since the Food and Drug Administration (FDA) approved a specific regime for emergency contraception (EC). It has been over two years since the Center for Reproductive Rights (formerly the Center for Reproductive Law and Policy) petitioned the FDA to make EC available over the counter (OTC). Yet EC is still not available OTC, and many women are still unaware of EC or are unable to obtain EC in a timely manner. Increasingly, states have become aware of the potential for EC to decrease the number of unplanned pregnancies and abortions, and are taking action to increase access to EC.

Pharmacy Access

Until the FDA makes EC available OTC, a doctor's prescription is required to obtain EC. This is problematic since EC must be taken within a short time period after intercourse (preferably 24 - 72 hours, but up to 120 hours) to be effective in preventing pregnancy. Many women have difficulty accessing their doctors within this short time frame – especially in rural areas or over weekends.

In 1998, Washington became the first state to allow women to obtain EC through a pharmacist directly. Washington's pilot project set up collaborative drug therapy agreements between doctors and pharmacies based on prescriptive protocols. Under the agreements, pharmacists were able to dispense EC to women who met screening criteria outlined in the protocols. From February 1998 until June 2001, Washington pharmacists filled nearly 35,600 prescriptions for EC, preventing an estimated 2000 pregnancies, of which about half would have ended in abortion.

Washington's program has become a model for other states. In the past few years, Alaska, California, Hawaii and New Mexico have begun allowing pharmacists to dispense EC directly to women without an individual doctor's prescription. Other states have been considering similar legislation to provide direct pharmacy access to EC¹.

Increased access to EC is supported around the world: women in Albania, Belgium, Canada, Denmark, Finland, France, Israel, Morocco, Norway, Portugal, South Africa, Sweden, the United Kingdom and other countries can get EC without a prescription.

EC in Emergency Rooms

Despite EC's proven ability to prevent unwanted pregnancy, many hospital emergency rooms (ERs) do not inform women about EC nor make EC available to them. Sexual assault advocates have been particularly concerned about the failure of ERs to make EC a standard practice of care for women who have been sexually assaulted. In 2001, Illinois became the first state to legislate on this issue, enacting a law requiring hospitals to provide rape survivors with medically accurate information about EC. Since then, Washington, California, New Mexico and New York have passed laws requiring hospital ERs to provide rape survivors with information about EC and to dispense EC upon request. Other states and the U.S. Congress are considering similar legislation.²

Given EC's efficacy in preventing pregnancy, EC should be a standard of care for all women in ERs who want to prevent unwanted pregnancy.

EC Education

Polling data consistently shows that many women in the United States are unaware of EC. For example, in a study released in November 2000 by the Kaiser Family Foundation, one-fourth of the women aged 18-44 surveyed said they had never heard of EC, and nearly two-thirds said they didn't realize it was available in the United States³. A more recent study shows that 68% of American women know there is *something* they can do within days of unprotected intercourse to prevent pregnancy, but are often confused as to the exact details.⁴ The same study shows that only 6% of American women have ever used EC.⁵

Given the lack of awareness about EC, several states are contemplating the passage of legislation that would raise awareness about EC through the creation of public education campaigns.⁶ Similar EC education bills have also been introduced in Congress.⁷ These bills are a crucial step towards increasing awareness and access to EC.

Short timeline of emergency contraception

Late 1970s – Doctors first begin to use doses of several regular birth control pills as EC

1997 – FDA approves six common types of birth control pills to be safe and effective for use as EC

1998 – Preven, the first specific emergency contraception regime, is approved by the FDA

1999 – Plan B is approved for sale by the FDA

2001 – The Center for Reproductive Rights petitions the FDA to make EC available OTC

2003 – Plan B petitions the FDA to make EC available OTC

1. Bills relating to pharmacy access were introduced in several state legislatures in 2003, including Maryland, Maine, New York, Oregon, Texas and West Virginia.
2. Bills requiring hospitals to provide sexual assault victims with medically accurate information about EC and/or to provide EC upon request were introduced in several legislatures in 2003, including Arkansas, Arizona, Colorado, Hawaii, Massachusetts, Minnesota, New Jersey, and Wisconsin. The U.S. House of Representatives also introduced a federal version, entitled the “Compassionate Assistance for Rape Emergencies Act,” H.R. 2527, 108th Congress (2003).
3. See e.g., Leslie Lawrence, *Special Report: The Last Chance Contraceptive*, Kaiser Family Foundation: Daily Reproductive Health Report (Jan 2002), at http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=2&DR_ID=8923 (discussing 2000 study). A 1997 study by the Kaiser Family Foundation showed that 66% of women surveyed had heard of EC but only 52% of the 66% knew that EC could prevent pregnancy after intercourse; 72% were unaware that EC was available in the U.S.; and only 11% actually knew the key facts about EC. See *Summary of Findings: Survey of Americans on Emergency Contraception* at http://www.kff.org/content/archive/1352/contraception_2.html.
4. Kaiser Family Foundation/SELF magazine, *National Survey of Women on their Sexual Health* (June 2003).
5. *Id.*
6. For example, in 2003, EC education bills were introduced in Kansas, Michigan, Missouri, New Mexico and West Virginia.
7. Emergency Contraception Education Act, H.R. 1812, 108th Congress (2003); S. 896, 108th Congress (2003).

July 2003



Emergency Contraception ("EC") Talking Points

There is a strong need for EC in the United States:

- In the U.S., there are over 3 million unintended pregnancies each year.
- Half of these pregnancies end in abortion (i.e., 1.5 million abortions).
- Use of EC could prevent an estimated 700,000 abortions each year.¹

EC is safe and effective:

- There are no serious side effects or medical consequences of taking EC.
- EC is 95% effective if taken within 24 hours of intercourse.²

EC is not an abortifacient:

- EC *prevents* pregnancy by blocking ovulation, fertilization or implantation.
- Unlike EC, medical abortion, or RU-486, *ends* an *existing* pregnancy.

Availability of EC will not reduce the use of birth control:

- Over 50% of women with unintended pregnancies were using birth control when they became pregnant.³
- Contraceptive use does not decline in women supplied with EC.⁴
- EC is more expensive, less effective and less widely available than birth control.
- Women who are sexually assaulted often do not have the option of using birth control.

EC must be made more widely available:

- A recent survey revealed that almost half of all university-based health clinics do not offer students access to EC.⁵
- Only five states currently have programs allowing pharmacists to dispense EC directly to women without requiring an individual doctor's prescription.⁶
- Only four states mandate that hospital emergency rooms (ERs) provide EC to victims of sexual assault,⁷ and no state requires that ERs give EC to all women upon request.
- Many women do not know about EC.⁸

¹ See e.g. Stanley K. Henshaw, *Unintended Pregnancy in the United States*, 30 *Family Planning Perspectives* 24-29, 46 (January/February 1998); see also Rachel K. Jones, Jacqueline E. Darroch and Stanley K. Henshaw, *Contraceptive Use Among U.S. Women Having Abortions in 2000-2001*, 34 *Perspectives on Sexual and Reproductive Health* (November/December 2002) (estimating that EC is responsible for up to 43% of the 11% decline in abortion rates between 1994 & 2000).

² Plan B is 95% effective if taken within 24 hours, 85% effective between 25-48 hours and 61% effective if more than 48 hours have passed. See http://www.go2planb.com/tools_for_clinicians/tools_for_clinicians_faq.html#5. Preven is 75% effective if taken within 72 hours. See <http://www.preven.com/prodinfo/prescinfo.asp>.

³ See e.g. Rachel K. Jones, Jacqueline E. Darroch and Stanley K. Henshaw, *Contraceptive Use Among U.S. Women Having Abortions in 2000-2001*, 34 *Perspectives on Sexual and Reproductive Health* (November/December 2002). Another recent study showed that two-thirds of unplanned pregnancies occur when contraception is used. Nathalie Bajos, Henri Leridon, Helene Goulard et. al, *Contraception: from Accessibility to Efficiency*, 18 *Human Reproduction* 994-999 (2003).

⁴ See e.g., Rebecca Jackson, Eleanor Schwarz, Lori Freedman and Philip Darney, *Advance Supply of Emergency Contraception: Effect on Use and Usual Contraception – A Randomized Trial*, 102 *Obstetrics & Gynecology* 8-16 (July 2003); Anna Glasier and David Baird, *The Effects of Self-Administering Emergency Contraception*, 339 *New England Journal of Medicine* 1-4 (July 1998); see also Kaiser Daily Reproductive Health Report, *Contraceptive Use Does Not Decline Among Teenage Mothers Supplied with Emergency Contraception*, *Study Says* (March 21, 2003) at http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=2&DR_ID=16724.

⁵ S. K. McCarthy, *Availability of Emergency Contraceptive Pills at University and College Student Health Centers*, 51 *Journal of American College Health* 15-22 (2002).

⁶ These states are Alaska, California, New Mexico, New York and Washington.

⁷ These states are California, New Mexico, New York and Washington. Illinois mandates that ERs provide women with information about EC but does not mandate provision of EC upon request.

⁸ A 2003 survey found that only 68% of women are aware that they can prevent pregnancy after intercourse, and only 6% have ever used EC. See Kaiser Family Foundation/SELF magazine, *National Survey of Women on their Sexual Health* (June 2003); see generally Kate Zernike, *Use of Morning-After Pill Rising And It May Go Over the Counter*, *New York Times*, May 19, 2003, at A1. A 2000 study found that one-fourth of the women aged 18-44 surveyed said they had never heard of EC, and nearly two-thirds said they didn't realize it was available in the United States. See e.g., Leslie Lawrence, *Special Report: The Last Chance Contraceptive*, Kaiser Daily Reproductive Health Report (January 2002), at http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=2&DR_ID=8923 (discussing 2000 study). A 1997 study by the Kaiser Family Foundation showed that 66% of women surveyed had heard of EC but only 52% of the 66% knew that EC could prevent pregnancy after intercourse; 72% were unaware that EC was available in the U.S.; and only 11% actually knew the key facts about EC. See *Summary of Findings: Survey of Americans on Emergency Contraception* at http://www.kff.org/content/archive/1352/contraception_2.html.



EMERGENCY CONTRACEPTION EDUCATION

Polls show that most American women are unaware that emergency contraception (EC) can prevent pregnancy after unprotected sexual intercourse or contraceptive failure. Therefore, there is a strong need for education about EC. A majority of Americans support legislation to create an EC educational campaign to raise public awareness about EC.

Packet Contents Include:

- 1) Model Legislation
- 2) Introduced New Mexico House Bill 315
- 3) Introduced U.S. Senate Bill 896
- 4) Factsheets

Strategy Points:

- 1) You should cater this bill to the needs in your state. Polling done within your state as to the lack of awareness about EC, or public support for EC education efforts, will make this a much easier bill to sell. Therefore, you should consider organizing a polling effort within your state, and include the state findings within the “Findings” section of the bill.
- 2) Ideally, the state should dedicate specific dollars for the EC educational campaign. However, in the current budgetary climate, it is unlikely in many states that an EC education bill will move if there are fiscal implications. Therefore, an alternative is to include a provision that the Department should locate funding for this project within its existing budget. For example, money could be used from existing family planning funds, pregnancy prevention programs, women’s health initiatives or public health programs.
- 3) The goal of this bill is to increase awareness about EC amongst both women and health professionals – so that use of EC becomes more widespread and EC becomes a common standard of care for all women.



MODEL LEGISLATION: **EMERGENCY CONTRACEPTION EDUCATION¹**

An ACT relating to education about emergency contraception.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF _____

Section 1: SHORT TITLE

This Act may be cited as the “Emergency Contraception Education Act”

Section 2: FINDINGS

The legislature finds that:

- (A) Each year, 3 million pregnancies in the United States are unintended. This is half of all pregnancies in the United States. Half of these unintended pregnancies end in abortion.
- (B) Widespread use of emergency contraception (EC) could significantly reduce the incidence of unintended pregnancy in the United States and could prevent an estimated 700,000 abortions in this country each year.
- (C) Studies have shown EC to be effective in preventing pregnancy up to 120 hours after unprotected sexual intercourse or contraceptive failure.
- (D) EC has been proven to be 95% effective if taken within 24 hours and 75-89% effective if taken within 72 hours.
- (E) EC prevents pregnancy by blocking ovulation, fertilization or implantation.
- (F) EC does not cause abortion and will not affect an established pregnancy.
- (G) EC has been deemed by the Food and Drug Administration (FDA) to be safe and effective in preventing pregnancy.
- (H) The American Medical Association and the American College of Obstetricians and Gynecologists have endorsed more widespread availability of EC.
- (I) Studies show that most American women do not know that EC can prevent pregnancy after intercourse.
- (J) Fewer than 10% of American women have ever used EC.

Section 3: DEFINITIONS

As used in this chapter, the following words and phrases have the following meanings unless the context clearly indicates otherwise:

- (A) “Department” means the [your state] Department of Health [or insert similar agency in your state].
- (B) “Emergency contraception”, or EC, means any medicine that prevents pregnancy after sexual intercourse.
- (C) “Health care provider” means an individual who is licensed or certified under state law [or put in specific state law provision] to provide health care services and who is operating within the scope of such license. [Note: this term may be defined in another section of your law; if it is, and the definition is appropriate, omit this definition and refer to that section number specifically].
- (D) “Secretary” means the Secretary of Health [or insert equivalent officeholder in your state].

¹ This model bill is intended to be used as an aid in drafting legislation. You may need to alter the language so the bill adheres to the existing laws and circumstances of your particular state

Section 4: EMERGENCY CONTRACEPTION PUBLIC HEALTH PROGRAM

- (A) The Department shall develop and disseminate information on EC to the public.
 - (1) Informational materials on EC shall be developed by the Department in consultation with medical groups, public health groups, clinics, doctors, other health professionals, women's advocacy groups, women's health groups, scientists and other relevant stakeholders.
 - (2) Informational materials on EC shall include, at minimum, a discussion of how EC can prevent pregnancy, how EC can be obtained, where EC can be obtained, and whether any public funding is available to pay for EC.
 - (3) Informational materials on EC shall be clearly written, readily comprehensible, and available in the following languages: English, Spanish [specify other languages that are commonly used in your state].
 - (4) Informational materials on EC shall be widely disseminated to the public by the Department, and shall be available for no charge. The Department shall disseminate informational materials through medical/ public health organizations, medical/public health facilities (including clinics and hospitals), nonprofit organizations (including women's groups, advocacy groups and consumer groups), educational facilities, government agencies and the media.
 - (5) The Department shall develop a public service announcement, to be aired on television and radio, and/or published through print advertising in public venues, describing EC and its ability to prevent pregnancy after intercourse, and identifying how and where informational materials on EC can be obtained.
- (B) The Department shall develop and disseminate information on EC to health care providers.
 - (1) Informational materials on EC shall include the contents as listed in Section 4(A)(2), as well as a discussion of medical issues pertaining to the use of EC and recommendations regarding the use of EC in appropriate cases. A list of sources of further information shall also be provided.
 - (2) Informational materials on EC discussed in Section 4(B)(1) shall be widely disseminated to health care providers by the Department and shall be available for no charge. The Department shall disseminate informational materials through medical/public health organizations, medical/public health facilities (including clinics and hospitals), government agencies and medical schools.
 - (3) The Department shall also provide health care providers with information as to how the informational materials on EC discussed in Section 4(A)(2) can be obtained. The Department shall encourage health care providers to disseminate these materials to their patients.
- (C) FUNDING: \$ [insert appropriate amount] for each of fiscal years 2004 through 2014 [or insert alternate period of time] shall be appropriated to carry out this section - **OR** - The Department shall dedicate funds from its budget [or insert existing programs, such as family planning, pregnancy prevention, women's health or public health programs] to fund the Emergency Contraception Public Health Program.
- (D) The Secretary shall adopt rules necessary to implement this section.

Section 5: EFFECTIVE DATE

This Act shall take effect [insert appropriate information].

HOUSE BILL 315

46TH LEGISLATURE - STATE OF NEW MEXICO - FIRST SESSION, 2003

INTRODUCED BY

Gail C. Beam

AN ACT

RELATING TO HEALTH EDUCATION; ENACTING THE EMERGENCY
CONTRACEPTION ACT; MAKING AN APPROPRIATION; DECLARING AN
EMERGENCY.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF NEW MEXICO:

Section 1. SHORT TITLE. -- This act may be cited as the
"Emergency Contraception Act".

Section 2. LEGISLATIVE FINDINGS. -- The legislature finds
that:

A. each year, three million pregnancies, or one-
half of all pregnancies, in the United States are unintended,
and one-half of all of those unintended pregnancies end in
abortion;

B. the federal food and drug administration has
declared emergency contraception to be safe and effective in

1 preventing unintended pregnancy, reducing that risk by as much
2 as eighty-nine percent;

3 C. the most commonly used forms of emergency
4 contraception are regimens of ordinary birth control pills
5 taken at specific doses within seventy-two hours of unprotected
6 intercourse or contraception failure;

7 D. emergency contraception, also known as post-
8 coital contraception, is a responsible means of preventing
9 pregnancy that works like other hormonal contraception to delay
10 ovulation, prevent fertilization or prevent implantation;

11 E. emergency contraception does not cause abortion
12 and will not affect an established pregnancy;

13 F. it is estimated that the use of emergency
14 contraception could cut the number of unintended pregnancies in
15 half, thereby reducing requests for abortion;

16 G. emergency contraception use in the United States
17 remains low because as many as nine out of ten women of
18 childbearing age are unaware of the availability of this method
19 of contraception;

20 H. although the American college of obstetricians
21 and gynecologists recommends that doctors routinely offer women
22 of reproductive age a prescription for emergency contraception
23 pills during their annual visit, only one in five obstetricians
24 or gynecologists routinely discusses emergency contraception
25 with patients, suggesting a need for greater provider and

1 patient education;

2 I. in light of their safety and efficacy, both the
3 American medical association and the American college of
4 obstetricians and gynecologists have endorsed more widespread
5 availability of emergency contraceptive pills and have
6 recommended that emergency contraceptive products be available
7 without a prescription;

8 J. a publication of the federal office of the
9 surgeon general, *Healthy People 2010*, establishes a ten-year
10 national public goal of increasing the proportion of health
11 care providers who provide emergency contraception to their
12 patients; and

13 K. public awareness campaigns targeting women and
14 health care providers will help remove many of the barriers to
15 emergency contraception and will help bring this important
16 means to prevent unintended pregnancy to American women.

17 Section 3. DEFINITIONS.--As used in the Emergency
18 Contraception Act:

19 A. "department" means the department of health;

20 B. "emergency contraception" means a drug or device
21 that is:

22 (1) used after unprotected sexual intercourse
23 or after contraception failure;

24 (2) taken to prevent pregnancy by preventing
25 ovulation or fertilization or implantation of an egg in a

uterus; and

(3) approved by the federal food and drug
administration that prevents pregnancy;

C. "health care provider" means a person licensed
or certified pursuant to state law to provide health care
services who is operating within the scope of that license; and

D. "medically and factually accurate and objective"
means verified or supported by the weight of research conducted
in compliance with accepted scientific methods and standards;
published in peer-reviewed journals; and recognized as accurate
and objective by leading professional organizations and
agencies with relevant expertise in the field of obstetrics and
gynecology, such as the American college of obstetricians and
gynecologists.

Section 4. DEPARTMENT PUBLIC EDUCATION PLAN. --

A. The department shall develop and implement a
public education plan to increase both awareness about and
accessibility to emergency contraception in New Mexico. The
plan shall be completed on or before September 30, 2003.

B. The department's plan shall include a public
information program about emergency contraception providing, at
minimum:

- (1) a description of emergency contraception;
- (2) an explanation of the safety, efficacy and
availability of emergency contraception; and

1 (3) an explanation of the dosage required and
2 the timing of the use of emergency contraception to obtain the
3 greatest probability of preventing an unintended pregnancy.

4 C. Outreach efforts included in the department's
5 plan shall provide public education about emergency
6 contraception through the use of radio or television public
7 service announcements, information booths at public events or
8 places, outdoor advertising and other methods of reaching the
9 public with information about emergency contraception.

10 Section 5. HEALTH CARE PROVIDER PROGRAM -- The department,
11 at minimum, shall:

12 A. develop and implement an emergency contraception
13 information and training program to enable health care
14 providers to effectively disseminate emergency contraception in
15 a medically and factually accurate and objective manner;

16 B. provide materials that can be used by health
17 care providers that explain the use, safety, efficacy,
18 availability and prescription protocols for use of emergency
19 contraception;

20 C. provide health care providers with materials
21 that may be disseminated to patients and with information about
22 obtaining additional information and public education materials
23 for dissemination to patients and staff;

24 D. recommend and actively encourage the appropriate
25 use and prescribing of emergency contraception by health care

1 providers; and

2 E. provide information to health care providers.

3 Section 6. APPROPRIATION.--Fifty thousand dollars
4 (\$50,000) is appropriated from the general fund to the
5 department of health for expenditure in fiscal year 2004 to
6 implement the Emergency Contraception Education Act. Any
7 unexpended or unencumbered balance remaining at the end of
8 fiscal year 2004 shall revert to the general fund.

9 Section 7. EMERGENCY.--It is necessary for the public
10 peace, health and safety that this act take effect immediately.

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108TH CONGRESS
1ST SESSION

S. 896

To establish a public education and awareness program relating to emergency contraception.

IN THE SENATE OF THE UNITED STATES

APRIL 11, 2003

Mrs. MURRAY (for herself and Ms. CANTWELL) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To establish a public education and awareness program relating to emergency contraception.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Emergency Contracep-
5 tion Education Act”.

6 **SEC. 2. FINDINGS.**

7 Congress finds as follows:

8 (1) Each year, 3,000,000 pregnancies, or one
9 half of all pregnancies, in the United States are un-

1 intended, and half of all of these unintended preg-
2 nancies end in abortion.

3 (2) The Food and Drug Administration has de-
4 clared emergency contraception to be safe and effec-
5 tive in preventing unintended pregnancy.

6 (3) The most commonly used forms of emer-
7 gency contraception are regimens of ordinary birth
8 control pills. Taken within 72 hours of unprotected
9 intercourse or contraceptive failure, emergency con-
10 traception can reduce the risk of pregnancy by as
11 much as 89 percent. Recent medical evidence con-
12 firms that emergency contraception can be effective
13 up to five days after unprotected intercourse or con-
14 traception failure.

15 (4) Emergency contraception, also known as
16 post-coital contraception, is a responsible means of
17 preventing pregnancy that works like other hormonal
18 contraception to delay ovulation, prevent fertilization
19 or prevent implantation.

20 (5) Emergency contraception does not cause
21 abortion and will not affect an established preg-
22 nancy.

23 (6) It is estimated that the use of emergency
24 contraception could cut the number of unintended

1 pregnancies in half, thereby reducing the need for
2 abortion.

3 (7) New data from the Alan Guttmacher Insti-
4 tute estimates that 51,000 abortions were prevented
5 by use of emergency contraception in 2000 and that
6 increased use of emergency contraception accounted
7 for up to 43 percent of the total decline in abortion
8 rates between 1994 and 2000.

9 (8) Emergency contraceptive use in the United
10 States remains low, and 9 in 10 women of reproduc-
11 tive age remain unaware of the method.

12 (9) Although the American College of Obstetri-
13 cians and Gynecologists recommends that doctors
14 routinely offer women of reproductive age a prescrip-
15 tion for emergency contraceptive pills during their
16 annual visit, only 1 in 5 ob/gyns routinely discuss
17 emergency contraception with their patients, sug-
18 gesting the need for greater provider and patient
19 education.

20 (10) In light of their safety and efficacy, both
21 the American Medical Association and the American
22 College of Obstetricians and Gynecologists have en-
23 dored more widespread availability of emergency
24 contraceptive pills, and have recommended that dedi-

1 cated emergency contraceptive products be available
2 without a prescription.

3 (11) Healthy People 2010, published by the Of-
4 fice of the Surgeon General, establishes a 10-year
5 national public health goal of increasing the propor-
6 tion of health care providers who provide emergency
7 contraception to their patients.

8 (12) Public awareness campaigns targeting
9 women and health care providers will help remove
10 many of the barriers to emergency contraception and
11 will help bring this important means of pregnancy
12 prevention to American women.

13 **SEC. 3. EMERGENCY CONTRACEPTION EDUCATION AND IN-**
14 **FORMATION PROGRAMS.**

15 (a) DEFINITIONS.—In this section:

16 (1) EMERGENCY CONTRACEPTION.—The term
17 “emergency contraception” means a drug or device
18 (as the terms are defined in section 201 of the Fed-
19 eral Food, Drug, and Cosmetic Act (21 U.S.C. 321))
20 or a drug regimen that is—

21 (A) used after sexual relations; and

22 (B) prevents pregnancy, by preventing ovu-
23 lation, fertilization of an egg, or implantation of
24 an egg in a uterus.

1 (2) HEALTH CARE PROVIDER.—The term
2 “health care provider” means an individual who is li-
3 censed or certified under State law to provide health
4 care services and who is operating within the scope
5 of such license.

6 (3) INSTITUTION OF HIGHER EDUCATION.—The
7 term “institution of higher education” has the same
8 meaning given such term in section 1201(a) of the
9 Higher Education Act of 1965 (20 U.S.C. 1141(a)).

10 (4) SECRETARY.—The term “Secretary” means
11 the Secretary of Health and Human Services.

12 (b) EMERGENCY CONTRACEPTION PUBLIC EDU-
13 CATION PROGRAM.—

14 (1) IN GENERAL.—The Secretary, acting
15 through the Director of the Centers for Disease
16 Control and Prevention, shall develop and dissemi-
17 nate to the public information on emergency contra-
18 ception.

19 (2) DISSEMINATION.—The Secretary may dis-
20 seminate information under paragraph (1) directly
21 or through arrangements with nonprofit organiza-
22 tions, consumer groups, institutions of higher edu-
23 cation, Federal, State, or local agencies, clinics and
24 the media.

1 (3) INFORMATION.—The information dissemi-
 2 nated under paragraph (1) shall include, at a min-
 3 imum, a description of emergency contraception, and
 4 an explanation of the use, safety, efficacy, and avail-
 5 ability of such contraception.

6 (c) EMERGENCY CONTRACEPTION INFORMATION
 7 PROGRAM FOR HEALTH CARE PROVIDERS.—

8 (1) IN GENERAL.—The Secretary, acting
 9 through the Administrator of the Health Resources
 10 and Services Administration and in consultation
 11 with major medical and public health organizations,
 12 shall develop and disseminate to health care pro-
 13 viders information on emergency contraception.

14 (2) INFORMATION.—The information dissemi-
 15 nated under paragraph (1) shall include, at a min-
 16 imum—

17 (A) information describing the use, safety,
 18 efficacy and availability of emergency contra-
 19 ception;

20 (B) a recommendation regarding the use of
 21 such contraception in appropriate cases; and

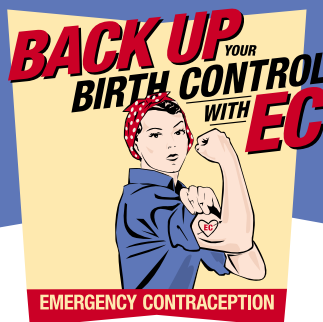
22 (C) information explaining how to obtain
 23 copies of the information developed under sub-
 24 section (b), for distribution to the patients of
 25 the providers.

1 (d) AUTHORIZATION OF APPROPRIATIONS.—There is
2 authorized to be appropriated to carry out this section,
3 \$10,000,000 for each of fiscal years 2004 through 2008.

○

For more information, contact the campaign at
1300 19th Street, N.W., Second Floor, Washington D.C. 20036

backupyourbirthcontrol.org



1-888-NOT-2-LATE

Public Support for Government Involvement in Emergency Contraception Education Initiatives

Introduction

A survey¹ conducted in July 2002 found a majority of likely voters supports an active role for government in educating the public about emergency contraception (EC). All voters—male and female—believe this information should be broadly available to the general public and to all women of childbearing age, including teenagers.

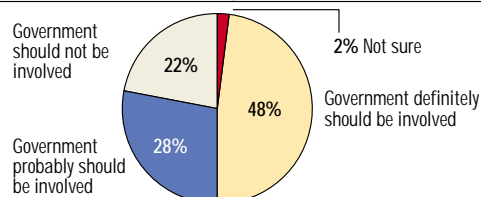
EC is a safe, effective back-up birth control method that can significantly reduce the risk of pregnancy when used within days after contraceptive failure, unprotected intercourse, or sexual assault. Each year, about 3 million pregnancies (or one-half of all pregnancies) in the United States are unintended, and almost half of these unintended pregnancies end in abortion. Fifty-three percent of women with unintended pregnancies were using contraception.

Sen. Patty Murray (D-WA) and Rep. Louise Slaughter (D-NY) introduced the Emergency Contraception Education Act on March 6, 2002. This bi-partisan legislation, with 6 Senators co-sponsors and 85 House co-sponsors, authorizes \$10 million a year for five years to the Centers for Disease Control and Prevention (CDC) and the Health Resources and Services Administration (HRSA) to develop and distribute information on EC to the public and to health care providers.

Summary of Findings

Voters strongly believe that government has an appropriate and important role in informing women about issues concerning their health. In fact, more than three in four voters say government should be involved in providing more complete information about health options so women can make decisions about their own medical needs.

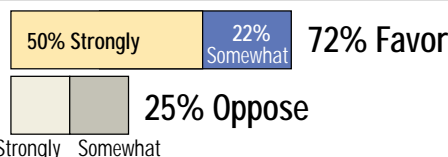
Figure 1. Government Role in Informing Women About Health



Few voters have adequate and consistent knowledge about EC and its availability. More than 60% of voters say they do not know of a product or drug that has been proven effective in preventing pregnancy if used within days after unprotected sex or contraceptive failure. When asked to specify an EC product, almost one-third of voters who said they knew of such a product responded “RU-486,” indicating EC is often mistakenly confused with other drugs.²

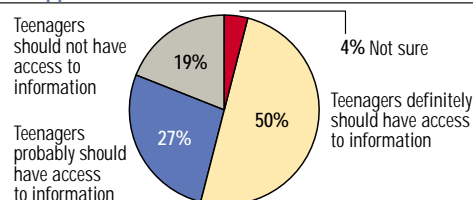
Once voters are informed about EC, they overwhelmingly (72%) favor legislation aimed at expanding public health information about EC and its availability. A majority of voters from all partisan backgrounds respond favorably to such legislation, including 81% of Democrats, 76% of independents, and 60% of Republicans. Pro-choice voters are strongly united in their support for the measure (87% favor, 11% oppose), while anti-choice voters are less cohesive in their opposition (45% support; 51% oppose).

Figure 2. Public Support of EC Legislation



Voters believe that knowledge about emergency contraception should be shared broadly and not restricted to certain groups. In fact, about as many voters say the “general public” would benefit most from the information as those who say “all women of childbearing age” and as those who say “teenagers and young women in high school.” More than three-quarters of all voters say teens should have access to information about EC, with half saying that teens definitely should have access to this information.

Figure 3. Public Support of Teen Access to Information About EC



The advantage that voters see in making information about EC widely available outweighs their concerns about any possible mixed messages that could be sent on this issue.

Similarly, when presented with two different views about government's role in providing information about EC, by two to one voters say government involvement is a good idea because it is an important way to reduce the number of unintended pregnancies in our country.

Over 70% of voters consider the 72-hour window of effectiveness a compelling reason for a public education initiative. Given EC's narrow window of effectiveness, voters believe it is important for women to know about a back-up birth control in advance of an emergency situation. Voters also believe improving EC awareness will significantly reduce the number of unintended pregnancies and the need for abortion.

Voters overwhelmingly support legislation requiring hospitals to inform sexual assault victims about the availability of EC. Introduced on March 21, 2002, the Emergency Contraception for Female Sexual Assault Survivors Act would require hospitals to offer EC to survivors of sexual assault. A majority of voters in all demographic and attitudinal subgroups, including more than three quarters of Catholic voters, say they favor such a proposal.

The mission of the Reproductive Health Technologies Project to advance the ability of every woman to achieve full reproductive freedom with access to the safest, most effective, appropriate and acceptable technologies for ensuring her own health and controlling her fertility.

“Back Up Your Birth Control” is a public education and activist campaign led by the Project that involves a broad coalition of medical, public health and advocacy organizations to increase awareness of and expand access to EC—a second chance to prevent unintended pregnancies. For more information and how to get involved, visit www.backupyourbirthcontrol.org.

¹ On behalf of the Reproductive Health Technologies Project, Peter D. Hart Research Associates interviewed 503 likely voters. The interviews were conducted from July 11 to 14, 2002. The margin of error for the overall results is +/-4.5%.

² RU-486, also known as Mifeprex® or the abortion pill, is a different drug than EC. Mifeprex® is used to terminate an established pregnancy, whereas EC works to prevent pregnancy.



PHARMACY ACCESS TO EMERGENCY CONTRACEPTION

Because emergency contraception (EC) is not available over-the-counter, women in most states must obtain a prescription from their doctor before obtaining EC from the pharmacy. Following Washington state's model, a number of states have started programs to allow pharmacists to dispense EC pursuant to collaborative practice agreements with physicians or other health care providers. Such agreements enable women to obtain EC directly from the pharmacy without a prior doctor's visit, and therefore reduce the incidence of unwanted pregnancy significantly – especially for women in rural areas or during nights and weekends when doctors and other health care providers are unavailable.

Packet Contents Include:

- 1) Model legislation
- 2) Hawaii law, enacted in 2003
- 3) California law, enacted in 2001
- 4) Alaska regulations, promulgated in 2002
- 5) Information on Washington pilot project
- 6) Background article

Strategy Points:

- 1) Before drafting and introducing legislation, you should analyze whether current law allows for collaborative practice agreements already. Check both the statute and regulations. In some states, statutes or regulations already exist to allow EC collaborative practice agreements. In other states, there is statutory authority for collaborative practice agreements but new regulations will be needed. (Bear in mind that it is usually easier to change regulations than to enact new laws). If no statutory authority exists, the legislature will most likely have to enact legislation to permit collaborative practice agreements for EC.
- 2) Most programs that currently exist require that individual pharmacists establish agreements with individual doctors; however, in your state, consider whether it is possible to establish one state-wide protocol which can be used by all pharmacists.
- 3) An important component to success is education – most pharmacists will need to be educated about the availability of collaborative practice agreements once the programs are in place.



MODEL LEGISLATION: **COLLABORATIVE PRACTICE FOR** **EMERGENCY CONTRACEPTION¹**

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF _____

Section 1: SHORT TITLE

This Act may be cited as the “Collaborative Practice for Emergency Contraception Act”

Section 2: COLLABORATIVE PRACTICE

Chapter ____ is amended by adding a new section to read as follows:

- (A) Notwithstanding any other provision of law, a pharmacist may dispense emergency contraception in accordance with protocols developed by the pharmacist and a physician or other prescriber who is acting within his or her scope of practice.
- (B) In order for a pharmacist to dispense emergency contraception in accordance with this section:
 - (1) the pharmacist and physician or other prescriber shall develop a written protocol authorizing the pharmacist to dispense emergency contraception to women who have recently had unprotected sexual intercourse or contraceptive failure, and who wish to prevent pregnancy;
 - (2) the physician or other prescriber shall define in the protocol, on the basis of his or her medical judgment and the available scientific evidence, the maximum number of days after unprotected sexual intercourse or contraceptive failure that the pharmacist may dispense emergency contraception; and
 - (3) the pharmacist and physician or other prescriber shall each maintain a copy of the written protocol in their office files.
- (C) Prior to dispensing emergency contraception, the pharmacist shall:
 - (1) screen the woman for appropriateness of emergency contraception in accordance with the written protocol; and
 - (2) provide the woman with the printed materials and package inserts that accompany the emergency contraception.
- (D) The pharmacist shall record the number of women receiving emergency contraception, and shall forward those numbers quarterly to the physician or other prescriber.
- (E) The physician or other prescriber shall modify the protocol as needed pursuant to his or her medical judgment. The physician or other prescriber shall review the protocol at least

¹ This model bill is intended to be used as an aid in drafting legislation. You may need to alter the language so the bill adheres to the existing laws and circumstances of your particular state.

annually to determine whether modifications are appropriate. The physician or other prescriber may withdraw from participation in the protocol at any time by providing written notice to the pharmacist. Should the physician or other prescriber withdraw, the pharmacist must enter into a new protocol with another physician or other prescriber prior to dispensing emergency contraception.

- (F) Nothing in this section shall affect the requirements of existing law relating to maintaining the confidentiality of medical records.

Section 3: DEFINITIONS

As used in this chapter, the following words and phrases have the following meanings unless the context clearly indicates otherwise:

- (A) “Emergency contraception” means medication that prevents pregnancy after sexual intercourse.
- (B) “Other prescriber” means a person other than a physician who is authorized under state law to prescribe drugs.

Section 4: EFFECTIVE DATE

This Act shall take effect [fill in appropriate information].

Report Title:

Emergency Contraceptives; Collaborative Pharmacist-Physician Agreement

Description:

Allows pharmacists to dispense emergency contraceptives in accordance with approved procedures and protocols developed by a pharmacist and physician. (SD1)

HOUSE OF REPRESENTATIVES
TWENTY-SECOND LEGISLATURE,
2003
STATE OF HAWAII

H.B. NO. 123
H.D. 1
S.D. 1

A BILL FOR AN ACT

RELATING TO THE PRACTICE OF PHARMACY.

□

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

SECTION 1. In 2002, the legislature passed H.B.□1842,□H.D.□1, S.D.□2, C.D.□1, which became Act 256, Session Laws of Hawaii 2002, to enable pharmacists to provide services in a broader range of clinical settings. The legislature noted that the increasing complexity of drug therapy required pharmacists to participate in the treatment of, and be the advocate for, the patient, in collaboration with other health care professionals.

Unintended pregnancies are a major public health concern affecting individuals and society in general. Each year, about three million

five hundred thousand unintended pregnancies occur in this country, half of which result from contraceptive failure or inadequate contraceptive technique. According to the department of health's office of health status monitoring, in 2000, fifty-three per cent of pregnancies were unintended for women of all ages in Hawaii, and seventy-eight per cent were unintended among women under twenty years of age.

Emergency contraception is a highly cost-effective method of reducing unintended pregnancies, if taken within seventy-two hours after unprotected sex. However, in a statewide study conducted in early January of 2002, the Healthy Mothers, Healthy Babies Coalition of Hawaii learned that there are significant barriers to accessing emergency contraceptives in Hawaii within the recommended seventy-two hour time frame. The American College of Obstetricians and Gynecologists, American Academy of Pediatricians, American Public Health Association, and more than fifty other national organizations support increased access to emergency contraception.

The purpose of this Act is to enable pharmacists with appropriate training and who are working in collaboration with a physician to initiate emergency contraception oral drug therapy.

SECTION 2. Section 461-1, Hawaii Revised Statutes, is amended as follows:

1. By adding a new definition to be appropriately inserted and to read:

"Emergency contraception" means a drug that:

(1) Is used postcoitally;

(2) Prevents pregnancy by delaying ovulation, preventing fertilization of an egg, or preventing implantation of an egg in a uterus; and

(3) Is approved by the United States Food and Drug Administration."

2. By amending the definition of "licensed medical doctor" and "practice of pharmacy" to read:

~~"Licensed [medical-~~
~~doctor"] physician" means a [medical-doctor] physician~~ licensed by the board of medical examiners pursuant to chapter 453 or ~~[the board of osteopathic examiners under chapter]~~ 460.

"Practice of pharmacy" means:

(1)□The interpretation and evaluation of prescription orders; the compounding, dispensing, and labeling of drugs and devices (except labeling by a manufacturer, packer, or distributor of nonprescription drugs and commercially legend drugs and devices); the participation in drug selection and drug utilization reviews; the proper and safe storage of drugs and devices and the maintenance of proper records therefore; the responsibility for advising when necessary or where regulated, of therapeutic values, content, hazards, and use of drugs and devices;

(2)□Performing the following procedures or functions as part of the care provided by and in concurrence with a "health care facility" and "health care service" as defined in section 323D-2, or a "pharmacy" or a licensed ~~[medical doctor,]~~ physician, or a "managed care plan" as defined in section 432E-1, in accordance with policies, procedures, or protocols developed collaboratively by health professionals, including physicians and surgeons, pharmacists, and registered nurses, and for which a pharmacist has received appropriate training required by these policies, procedures, or protocols:

(A)□Ordering or performing routine drug therapy related patient assessment procedures;

(B)□Ordering drug therapy related laboratory tests;

(C) Initiating emergency contraception oral drug therapy in accordance with a written collaborative agreement approved by the board, between a licensed physician and a pharmacist who has received appropriate training that includes programs approved by the American Council of Pharmaceutical Education (ACPE), curriculum-based programs from an ACPE-accredited college of pharmacy, state or local health department programs, or programs recognized by the board of pharmacy;

~~[-(C)-]~~□(D) Administering drugs orally,

topically, or by injection, pursuant to the patient's licensed ~~[medical doctor's]~~ physician's order, by a pharmacist having appropriate training that includes programs approved by the ~~[American Council of Pharmaceutical Education (]ACPE[)]~~, curriculum-based programs from an ~~[American Council of Pharmaceutical Education accredited]~~ ACPE-accredited college of pharmacy, state or local health department programs, or programs recognized by the board of pharmacy;

~~[(D)]~~ ☐ (E) Administering immunizations by injection to persons eighteen years of age or older, by a pharmacist having appropriate training that includes programs approved by the ~~[American Council of Pharmaceutical Education,]~~ ACPE, curriculum-based programs from an ~~[American Council of Pharmaceutical Education accredited]~~ ACPE-accredited college of pharmacy, state or local health department programs, or programs recognized by the board of pharmacy;

~~[(E)]~~ ☐ (F) As authorized by a licensed ~~[medical doctor's]~~ physician's written instructions, initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's licensed ~~[medical doctor]~~ physician and related to the condition for which the patient has been seen by the licensed ~~[medical doctor,]~~ physician; provided that the pharmacist shall issue written notification to the patient's licensed ~~[medical doctor]~~ physician or enter the appropriate information in an electronic patient record system shared by the licensed ~~[medical doctor,]~~ physician, within twenty-four hours;

~~[(F)]~~ ☐ (G) Transmitting a valid prescription to another pharmacist for the purpose of filling or dispensing; or

~~[(G)]~~ ☐ (H) Providing consultation, information, or education to patients and

health care professionals based on the pharmacist's training and for which no other licensure is required; and

(3) The offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management, and control of pharmacy."

SECTION 3. Section 431:10A-116.6, Hawaii Revised Statutes, is amended by amending subsection (d) to read as follows:

"(d) For purposes of this section:

"Contraceptive services" means physician-delivered, physician-supervised, physician assistant-delivered, nurse practitioner-delivered, certified nurse midwife-delivered, ~~[or]~~ nurse-delivered, or pharmacist-delivered medical services intended to promote the effective use of contraceptive supplies or devices to prevent unwanted pregnancy.

"Contraceptive supplies" means all United States Food and Drug Administration-approved contraceptive drugs or devices used to prevent unwanted pregnancy."

SECTION 4. Section 431:10A-116.7, Hawaii Revised Statutes, is amended by amending subsection (g) to read as follows:

"(g) For purposes of this section:

"Contraceptive services" means physician-delivered, physician-supervised, physician assistant-delivered, nurse practitioner-delivered, certified nurse midwife-delivered, ~~[or]~~ nurse-delivered, or pharmacist-delivered medical services intended to promote the effective use of contraceptive supplies or devices to prevent unwanted pregnancy.

"Contraceptive supplies" means all United States Food and Drug Administration-approved contraceptive drugs or devices used to prevent unwanted pregnancy."

SECTION 5. Statutory material to be repealed is bracketed and stricken. New statutory material is underscored.

SECTION 6. This Act shall take effect upon its approval.

CALIFORNIA

BUSINESS AND PROFESSIONS CODE

SECTION 4052

4052. (a) Notwithstanding any other provision of law, a pharmacist may:

(1) Furnish a reasonable quantity of compounded medication to a prescriber for office use by the prescriber.

(2) Transmit a valid prescription to another pharmacist.

(3) Administer, orally or topically, drugs and biologicals pursuant to a prescriber's order.

(4) Perform the following procedures or functions in a licensed health care facility in accordance with policies, procedures, or protocols developed by health professionals, including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:

(A) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(B) Ordering drug therapy-related laboratory tests.

(C) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).

(D) Initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility.

(5) (A) Perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, in accordance, as applicable, with policies, procedures, or protocols of that facility, the home health agency, the licensed clinic, the health care service plan, or that physician, in accordance with subparagraph (C):

(i) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(ii) Ordering drug therapy-related laboratory tests.

(iii) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).

(iv) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the patient's prescriber for the individual patient, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to

the patient's prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this clause within 24 hours.

(B) A patient's prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.

(C) The policies, procedures, or protocols referred to in this paragraph shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and, at a minimum, meet all of the following requirements:

(i) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.

(ii) Require that the medical records of the patient be available to both the patient's prescriber and the pharmacist.

(iii) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.

(iv) Except for procedures or functions provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.

(6) Manufacture, measure, fit to the patient, or sell and repair dangerous devices or furnish instructions to the patient or the patient's representative concerning the use of those devices.

(7) Provide consultation to patients and professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals.

(8) Initiate emergency contraception drug therapy in accordance with standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice. Prior to performing any procedure authorized under this paragraph, a pharmacist shall have completed a training program on emergency contraception, which includes, but is not limited to, conduct of sensitive communications, quality assurance, referral to additional services, and documentation.

(b) (1) Prior to performing any procedure authorized by paragraph (4) of subdivision (a), a pharmacist shall have received appropriate training as prescribed in the policies and procedures of the licensed health care facility.

(2) Prior to performing any procedure authorized by paragraph (5) of subdivision (a), a pharmacist shall have either (A) successfully completed clinical residency training or (B) demonstrated clinical experience in direct patient care delivery.

(3) For each emergency contraception drug therapy initiated pursuant to paragraph (8) of subdivision (a), the pharmacist shall provide the recipient of the emergency contraception drugs with a standardized factsheet that includes, but is not limited to, the indications for use of the drug, the appropriate method for using the

drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Health Services, the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. The provisions of this section do not preclude the use of existing publications developed by nationally recognized medical organizations.

(c) Nothing in this section shall affect the requirements of existing law relating to maintaining the confidentiality of medical records.

(d) Nothing in this section shall affect the requirements of existing law relating to the licensing of a health care facility.

12 AAC 52.240. Pharmacist Collaborative Practice Authority

- (a) A pharmacist planning to exercise collaborative practice authority in the pharmacist's practice by initiating or modifying drug therapy in accordance with a written protocol established and approved for the pharmacist's practice by a practitioner authorized to prescribe drugs under AS [08](#) must submit the completed written protocol to the board and be approved by the board before implementation.
- (b) A written protocol must include
- (1) an agreement in which practitioners authorized to prescribe legend drugs in this state authorize pharmacists licensed in this state to administer or dispense in accordance with that written protocol;
 - (2) a statement identifying the practitioners authorized to prescribe and the pharmacists who are party to the agreement;
 - (3) the time period during which the written protocol will be in effect, not to exceed two years;
 - (4) the types of collaborative authority decisions that the pharmacists are authorized to make, including
 - (A) types of diseases, drugs, or drug categories involved and the type of collaborative authority authorized in each case; and
 - (B) procedures, decision criteria, or plans the pharmacists are to follow when making therapeutic decisions, particularly when modification or initiation of drug therapy is involved;
 - (5) activities the pharmacists are to follow in the course of exercising collaborative authority, including documentation of decisions made, and a plan for communication and feedback to the authorizing practitioners concerning specific decisions made;
 - (6) a list of the specific types of patients eligible to receive services under the written protocol;
 - (7) a plan for the authorizing practitioners to review the decisions made by the pharmacists at least once every three months; and
 - (8) a plan for providing the authorizing practitioners with each patient record created under the written protocol.
- (c) To enter into a written protocol under this section, practitioners authorized to prescribe must be in active practice, and the authority granted must be within the scope of the practitioners' practice.
- (d) Unless the board is satisfied that the pharmacist has been adequately trained in the procedures outlined in the written protocol, the board will specify and require completion of additional training that covers those procedures before issuing approval of the protocol.
- (e) Documentation related to the written protocol must be maintained for at least two years.
- (f) The written protocol may be terminated upon written notice by the authorizing practitioners or pharmacists. The pharmacists shall notify the board in writing within 30 days after a written protocol is terminated.
- (g) Any modification to the written protocol must be approved by the board as required by this section for a new written protocol.

Authority:

AS [08.80.030](#)

AS [08.80.480](#)

12 AAC 52.995. Definitions

- (a) In this chapter, unless the context requires otherwise,
- (1) "ACPE" means American Council on Pharmaceutical Education;
 - (2) "approved program" means a continuing education activity that is a live program, home study, or other mediated instruction delivered by an approved provider;

- (3) "approved provider" means an individual, institution, organization, association, corporation, or agency that is recognized by the American Council on Pharmaceutical Education as able to provide quality continuing education programs;
- (4) "authorized inspector" means a member of the board or an investigator with the division of occupational licensing in the department;
- (5) "blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing;
- (6) "blood component" means that part of blood separated by physical or mechanical means;
- (7) "board" means the Alaska Board of Pharmacy;
- (8) "care provider" means a person or organization that by the nature of experience and training is qualified, in the opinion of the board, to provide substance abuse counseling, rehabilitation, or related services to the public through established and recognized treatment programs;
- (9) "consultant pharmacist" means a licensed pharmacist retained by written agreement with an institutional facility to consult on a routine basis with an institutional facility about the practice of pharmacy as it relates to that facility;
- (10) "contact hour" means a unit of measure of educational credit that is equivalent to approximately 50 minutes of participation in an organized learning experience; a continuing education unit or "CEU" is equivalent to ten contact hours;
- (11) "DEA" means the United States Drug Enforcement Agency;
- (12) "department" means the Department of Community and Economic Development;
- (13) "direct supervision" means visual or physical proximity that insures adequate safety controls;
- (14) "home study" and "other mediated instruction" mean continuing education activities that are not conducted as live programs, including audio tapes, video tapes, television, computer assisted instruction, journal articles, or monographs;
- (15) "institutional facility" means a
- (A) hospital;
 - (B) long-term care facility, including a nursing home, convalescent home, or other related facility;
 - (C) mental health facility;
 - (D) rehabilitation center;
 - (E) psychiatric center;
 - (F) developmental disability center;
 - (G) drug abuse treatment center;
 - (H) family planning clinic;
 - (I) penal institution;
 - (J) hospice; or
 - (K) public health facility;
- (16) "institutional pharmacy" means a pharmacy located in an institutional facility;
- (17) "licensee" means a person who is licensed under AS [08.80](#) and this chapter;
- (18) "live program" means an on-site continuing education activity, including a lecture, symposium, live teleconference, or workshop;
- (19) "sterile pharmaceutical" means a drug dosage form free from living microorganisms (aseptic);
- (20) "wholesale distribution" means distribution of prescription drugs to a person other than a consumer or patient, but does not include an activity described in [12 AAC 52.695](#).
- (b) In AS [08.80.315](#) (3), "other persons or governmental agencies" include investigators for the department who are assigned to conduct investigations under AS [08](#).
- (c) In AS [08.80.030](#) (b)(7), "monitoring of drug therapy" means a review of the drug therapy regimen of patients by a pharmacist for the purpose of evaluating and rendering advice to the prescribing practitioner regarding adjustment of the regimen. "Monitoring of drug therapy" includes
- (1) collecting and reviewing records of patient drug use histories;
 - (2) measuring and reviewing routine patient vital signs, including pulse, temperature, blood pressure, and respiration; and
 - (3) ordering and evaluating the results of laboratory tests relating to drug therapy, including blood chemistries and cell counts, drug levels in blood, urine, tissue, or other body fluids, and culture and sensitivity tests that are performed in accordance with a written protocol approved under [12 AAC 52.240](#).

Authority:

AS [08.80.005](#)

AS [08.80.030](#)

AS [08.80.157](#)

Editor's Note:

As of Register 151 (October 1999), the regulations attorney made technical revisions under AS [44.62.125](#)(b)(6) to reflect the name change of the Department of Commerce and Economic Development to the Department of Community and Economic Development made by ch. 58, SLA 1999 and the corresponding title change of the commissioner of commerce and economic development.

AS 08.80.480. Definitions.

In this chapter, unless the context otherwise requires,

- (1) "administer" means the direct application of a drug to the body of a patient or research subject by injection, inhalation, ingestion, or other means;
- (2) "board" means the Board of Pharmacy;
- (3) "compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device (A) as the result of a practitioner's prescription drug order or initiative based on the relationship of the practitioner, patient, and pharmacist in the course of professional practice or (B) for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing; "compounding" also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns;
- (4) "controlled substance" has the meaning given in AS [11.71.900](#) ;
- (5) "deliver" or "delivery" means the actual, constructive, or attempted transfer of a drug or device from one person to another, whether or not for consideration;
- (6) "device" means an instrument, apparatus, implement, machine, contrivance, implant, or other similar or related article, including a component part or accessory, that is required under federal law to bear the label "Caution: Federal or state law requires dispensing by or on the order of a physician";
- (7) "dispense" or "dispensing" means the preparation and delivery of a drug or device to a patient or patient's agent under a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to, or use by, a patient;
- (8) "distribute" means the delivery of a drug or device other than by administering or dispensing;
- (9) "drug" means an article recognized as a drug in an official compendium, or supplement to an official compendium; an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animal; an article other than food, intended to affect the structure or function of the body of man or animal; and an article intended for use as a component of an article specified in this paragraph but does not include devices or their components, parts, or accessories;
- (10) "drug regimen review" includes evaluation of the prescription drug order and patient record for
 - (A) known allergies;
 - (B) rational therapy-contraindications;
 - (C) reasonable dose and route of administration;
 - (D) reasonable directions for use;
 - (E) duplication of therapy;
 - (F) drug-drug, drug-food, and drug-disease interactions;
 - (G) adverse drug reactions; and
 - (H) proper utilization, including over- or under-utilization, and optimum therapeutic outcomes;
- (11) "equivalent drug product" means a drug product that has the same established name, active ingredients, strength or concentration, dosage form, and route of administration and that is formulated to contain the same amount of active ingredients in the same dosage form and to meet the same compendia or other applicable standards for strength, quality, purity, and identity, but that may differ in characteristics

such as shape, scoring configuration, packaging, excipients including colors, flavors, preservatives, and expiration time;

(12) "intern" means an individual who is

(A) currently licensed by this state to engage in the practice of pharmacy while under the personal supervision of a pharmacist and is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist; or

(B) a graduate from a college of pharmacy who is currently licensed by the board for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist;

(13) "labeling" means the process of preparing and affixing a label to a drug container, exclusive, however, of the labeling by a manufacturer, packer, or distributor of a nonprescription drug or commercially packed legend drug or device;

(14) "legend drug" means a prescription drug;

(15) "manufacturing" means the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from a substance of natural origin or independently by means of chemical or biological synthesis, and includes packaging or repackaging of a substance or labeling or relabeling of its container, and the promotion and marketing of drugs or devices;

"manufacturing" also includes the preparation and promotion of commercially available products from bulk compounds for resale by pharmacies, practitioners, or other persons;

(16) "nonprescription drug" means a nonnarcotic medicine or drug that may be sold without a prescription and that is prepackaged for use by the consumer and labeled in accordance with the requirements of the statutes and regulations of the state and the federal government;

(17) "outpatient dispensing" means dispensing drugs for administration outside of the hospital pharmacy's control;

(18) "owner" means the owner of a place of business for wholesaling, retailing, compounding, or dispensing drugs, medicines, or poisons;

(19) "patient counseling" means the communication by the pharmacist of information, as defined in the regulations of the board, to the patient or care giver in order to improve therapy by ensuring proper use of drugs and devices;

(20) "person" has the meaning given in AS [01.10.060](#) and also includes a governmental agency;

(21) "pharmaceutical care" is the provision of drug therapy and other pharmaceutical patient care services intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process as defined in regulations of the board;

(22) "pharmacist" means an individual currently licensed by this state to engage in the practice of pharmacy;

(23) "pharmacist-in-charge" means a pharmacist who accepts responsibility for operation of a pharmacy in a manner that complies with laws and regulations applicable to the practice of pharmacy and the distribution of drugs and who is personally in charge of the pharmacy and the pharmacy's personnel;

(24) "pharmacy" means a place in this state where drugs are dispensed and pharmaceutical care is provided and a place outside of this state that is subject to licensure or registration under AS [08.80.157](#) (b);

(25) "pharmacy located outside of the state" means a pharmacy that prepares or mixes prescription drugs outside of the state, regardless of the location at which those drugs may be shipped, mailed, or delivered to the consumer;

(26) "pharmacy technician" means a supportive staff member who works under the immediate supervision of a pharmacist;

(27) "practice of pharmacy" means the interpretation, evaluation, and dispensing of prescription drug orders in the patient's best interest; participation in drug and device selection, drug administration, drug regimen reviews, and drug or drug-related research; provision of patient counseling and the provision of those acts or services necessary to provide pharmaceutical care; and the responsibility for: compounding and labeling of drugs and devices except labeling by a manufacturer, repackager, or distributor of nonprescription drugs and commercially packaged legend drugs and devices; proper and safe storage of drugs and devices; and maintenance of proper records for them;

(28) "practitioner" means an individual currently licensed, registered, or otherwise authorized by the jurisdiction in which the individual practices to prescribe and administer drugs in the course of professional practice;

- (29) "preceptor" means an individual who is currently licensed by the board, meets the qualifications as a preceptor under the regulations of the board, and participates in the instructional training of pharmacy interns;
- (30) "prescription drug" means a drug that, under federal law, before being dispensed or delivered, is required to be labeled with either of the following statements: (A) "Caution: Federal law prohibits dispensing without prescription"; (B) "Caution: Federal law restricts this drug to use by, or on the order of, a licensed veterinarian"; or a drug that is required by an applicable federal or state law or regulation to be dispensed only under a prescription drug order or is restricted to use by practitioners only;
- (31) "prescription drug order" means a lawful order of a practitioner for a drug or device for a specific patient;
- (32) "prospective drug use review" means a review of the patient's drug therapy and prescription drug order, as defined in the regulations of the board, before dispensing the drug as part of a drug regimen review;
- (33) "significant adverse drug reaction" means a drug-related incident that may result in serious harm, injury, or death to the patient;
- (34) "substitution" means to dispense without the prescriber's expressed authorization, an equivalent drug product in place of the prescribed drug;
- (35) "wholesale" means sale by a manufacturer, wholesale dealer, distributor, or jobber to a person who sells, or intends to sell, directly to the user;
- (36) "wholesale drug distributor" means anyone engaged in wholesale distribution of drugs, including but not limited to manufacturers; repackagers; own-label distributors; private label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses; chain drug warehouses; wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.
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Note to HTML Version:

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If it is critical that the precise terms of the Alaska Statutes be known, it is recommended that more formal sources be consulted. For statutes adopted after the effective date of these statutes, see, [Alaska State Legislature](#) If any errors are found, please e-mail Touch N' Go systems at touchngo@touchngo.com. We hope you find this information useful.

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RCW 18.64.011

Definitions.

Unless the context clearly requires otherwise, definitions of terms shall be as indicated when used in this chapter.

(1) "Person" means an individual, corporation, government, governmental subdivision or agency, business trust, estate, trust, partnership or association, or any other legal entity.

(2) "Board" means the Washington state board of pharmacy.

(3) "Drugs" means:

(a) Articles recognized in the official United States pharmacopoeia or the official homeopathic pharmacopoeia of the United States;

(b) Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;

(c) Substances (other than food) intended to affect the structure or any function of the body of man or other animals; or

(d) Substances intended for use as a component of any substances specified in (a), (b), or (c) of this subsection, but not including devices or their component parts or accessories.

(4) "Device" means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (a) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, or (b) to affect the structure or any function of the body of man or other animals.

(5) "Nonlegend" or "nonprescription" drugs means any drugs which may be lawfully sold without a prescription.

(6) "Legend drugs" means any drugs which are required by any applicable federal or state law or regulation to be dispensed on prescription only or are restricted to use by practitioners only.

(7) "Controlled substance" means a drug or substance, or an immediate precursor of such drug or substance, so designated under or pursuant to the provisions of chapter [69.50](#) RCW.

(8) "Prescription" means an order for drugs or devices issued by a practitioner duly authorized by law or rule in the state of Washington to prescribe drugs or devices in the course of his or her professional practice for a legitimate medical purpose.

(9) "Practitioner" means a physician, dentist, veterinarian, nurse, or other person duly authorized by law or rule in the state of Washington to prescribe drugs.

(10) "Pharmacist" means a person duly licensed by the Washington state board of pharmacy to engage in the practice of pharmacy.

(11) "Practice of pharmacy" includes the practice of and responsibility for: Interpreting prescription orders; the compounding, dispensing, labeling, administering, and distributing of drugs and devices; the monitoring of drug therapy and use; the initiating or modifying of drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs; the participating in drug utilization reviews and drug product selection; the proper and safe storing and distributing of drugs and devices and

maintenance of proper records thereof; the providing of information on legend drugs which may include, but is not limited to, the advising of therapeutic values, hazards, and the uses of drugs and devices.

(12) "Pharmacy" means every place properly licensed by the board of pharmacy where the practice of pharmacy is conducted.

(13) The words "drug" and "devices" shall not include surgical or dental instruments or laboratory materials, gas and oxygen, therapy equipment, X-ray apparatus or therapeutic equipment, their component parts or accessories, or equipment, instruments, apparatus, or contrivances used to render such articles effective in medical, surgical, or dental treatment, or for use or consumption in or for mechanical, industrial, manufacturing, or scientific applications or purposes, nor shall the word "drug" include any article or mixture covered by the Washington pesticide control act (chapter [15.58](#) RCW), as enacted or hereafter amended, nor medicated feed intended for and used exclusively as a feed for animals other than man.

(14) The word "poison" shall not include any article or mixture covered by the Washington pesticide control act (chapter [15.58](#) RCW), as enacted or hereafter amended.

(15) "Deliver" or "delivery" means the actual, constructive, or attempted transfer from one person to another of a drug or device, whether or not there is an agency relationship.

(16) "Dispense" means the interpretation of a prescription or order for a drug, biological, or device and, pursuant to that prescription or order, the proper selection, measuring, compounding, labeling, or packaging necessary to prepare that prescription or order for delivery.

(17) "Distribute" means the delivery of a drug or device other than by administering or dispensing.

(18) "Compounding" shall be the act of combining two or more ingredients in the preparation of a prescription.

(19) "Wholesaler" shall mean a corporation, individual, or other entity which buys drugs or devices for resale and distribution to corporations, individuals, or entities other than consumers.

(20) "Manufacture" means the production, preparation, propagation, compounding, or processing of a drug or other substance or device or the packaging or repackaging of such substance or device, or the labeling or relabeling of the commercial container of such substance or device, but does not include the activities of a practitioner who, as an incident to his or her administration or dispensing such substance or device in the course of his or her professional practice, prepares, compounds, packages, or labels such substance or device.

(21) "Manufacturer" shall mean a person, corporation, or other entity engaged in the manufacture of drugs or devices.

(22) "Labeling" shall mean the process of preparing and affixing a label to any drug or device container. The label must include all information required by current federal and state law and pharmacy rules.

(23) "Administer" means the direct application of a drug or device, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject.

(24) "Master license system" means the mechanism established by chapter [19.02](#) RCW by which master licenses, endorsed for individual state-issued licenses, are issued and renewed utilizing a master application and a master license expiration date common to each renewable license endorsement.

(25) "Department" means the department of health.

(26) "Secretary" means the secretary of health or the secretary's designee.

(27) "Health care entity" means an organization that provides health care services in a setting that is not otherwise licensed by the state. Health care entity includes a free-standing outpatient surgery center or a free-standing cardiac care center. It does not include an individual practitioner's office or a multipractitioner clinic.

[1997 c 129 § 1; 1995 c 319 § 2; 1989 1st ex.s. c 9 § 412; 1984 c 153 § 3; 1982 c 182 § 29; 1979 c 90 § 5; 1963 c 38 § 1.]

NOTES:

Effective date -- Severability -- 1989 1st ex.s. c 9: See RCW [43.70.910](#) and [43.70.920](#).

Severability -- 1982 c 182: See RCW [19.02.901](#).



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WAC 246-863-095 Pharmacist's professional responsibilities. (1) A pharmacist shall not delegate the following professional responsibilities:

- (a) Receipt of a verbal prescription other than refill authorization from a prescriber.
 - (b) Consultation with the patient regarding the prescription, both prior to and after the prescription filling and/or regarding any information contained in a patient medication record system provided that this shall not preclude a pharmacy assistant from providing to the patient or the patient's health care giver certain information where no professional judgment is required such as dates of refills or prescription price information.
 - (c) Consultation with the prescriber regarding the patient and the patient's prescription.
 - (d) Extemporaneous compounding of the prescription provided that bulk compounding from a formula and IV admixture products prepared in accordance with chapter [246-871](#) WAC may be performed by a level A pharmacy assistant when supervised by a pharmacist.
 - (e) Interpretation of data in a patient medication record system.
 - (f) Ultimate responsibility for all aspects of the completed prescription and assumption of the responsibility for the filled prescription, such as: Accuracy of drug, strength, labeling, proper container and other requirements.
 - (g) Dispense prescriptions to patient with proper patient information as required by WAC [246-869-220](#).
 - (h) Signing of the poison register and the Schedule V controlled substance registry book at the time of sale in accordance with RCW [69.38.030](#) and WAC [246-887-030](#) and any other item required by law, rule or regulation to be signed or initialed by a pharmacist.
 - (i) Professional communications with physicians, dentists, nurses and other health care practitioners.
- (2) Utilizing personnel to assist the pharmacist.
- (a) The responsible pharmacist manager shall retain all professional and personal responsibility for any assisted tasks performed by personnel under his or her responsibility, as shall the pharmacy employing such personnel. The responsible pharmacist manager shall determine the extent to which personnel may be utilized to assist the pharmacist and shall assure that the pharmacist is fulfilling his or her supervisory and professional responsibilities.
 - (b) This does not preclude delegation to an intern or extern.

[Statutory Authority: RCW [18.64.005](#). 96-02-005, § 246-863-095, filed 12/20/95, effective 1/20/96.]

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Emergency Contraception Collaborative Agreement Pilot Project

Expanding women's access to emergency contraceptive pills through direct pharmacy provision.



See also:

[Tools for Expanding EC Pill Access](#)

[Provider Attitudes toward ECPs: Executive Summary of Findings](#)

[EC Client Materials for Diverse Audiences](#)

[EC for Diverse Communities Project](#)

[Consortium for Emergency Contraception Web Site](#)

[Collaborative Drug Therapy Agreements Between Pharmacists and Authorized Prescribers](#)

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While efforts are underway across the country to reduce unintended pregnancy by improving 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 can present unnecessary barriers to women seeking treatment. Given that the treatment must be initiated within 120 hours (5 days) of unprotected sex, and that the pills are more effective the sooner they are used, establishing prescription and dispensing mechanisms that are convenient to women is crucial to their ability to use the therapy effectively.

Project Advisory Committee
Representatives include:

Washington State Department of Health

Family Practice Physician

Washington State Representative

Women's Law Center

Pharmacist & Pharmacy Owner

Department of Health and Human Services, Region X

Seattle-King County Department of Public Health

The Collaborative Agreement ECP Pilot Project has made emergency contraceptive pills more readily available to women in Washington State. The two-year project in Washington State, completed in July 1999, was a collaboration among PATH, Washington State Pharmacists Association, University of Washington Department of Pharmacy, Washington State Board of Pharmacy, and DDB Seattle and was funded by the David and Lucile Packard Foundation. The project also had a

distinguished advisory committee that included representatives from the public health, pharmacy, insurance, and legislative areas. The project enabled women to receive ECPs directly from pharmacists through the promotion and facilitation of collaborative drug therapy agreements between pharmacists and other contraceptive care providers such as physicians.

The project has been of great interest to other states with similar prescriptive practices. In May 1999, PATH hosted a workshop to help states increase access to ECPs directly through pharmacy providers. Materials created for the workshop are designed to help other states develop and implement similar projects and are [available for downloading](#).

Evaluation data analyzed in 1999 indicate that women receiving the service were satisfied with the quality of care they received and they valued the accessibility afforded through the pharmacy-based services. User-survey data, as well as pharmacy records, indicate many women went the pharmacy on weekends or after normal business hours for their ECP prescriptions.

Almost all participating independent prescribers and pharmacists (over 90% in both cases) reported that they were satisfied or very satisfied with their ECP collaborative agreements. Sixty percent of pharmacists who had prescribed ECPs at least once reported referring patients for additional care — the majority for ongoing contraception. User data also suggest that many women who received ECPs directly from a pharmacist did not have a health care provider. By referring these women, the pharmacist served to link them with ongoing health care services.

The project benefited significantly from the willingness of Washington State prescribers (primarily physicians and advanced registered nurse practitioners) and pharmacists to work together to address the problem of unintended pregnancy. The pilot project has shown that access to ECPs directly from a pharmacist is not only a viable, but a valued service.

From Pilot Project to Statewide Practice

Although the pilot project was completed in 1999, women in Washington State are still able to obtain ECPs directly from pharmacists. The state's two university schools of pharmacy now include an EC curriculum, and the Washington State Pharmacy Association offers ongoing training in EC services through their Continuing Education programs. The Medical Assistance Administration provides coverage for ECPs and related pharmacist services, and the Department of Health disseminates information about EC and pharmacist EC services through their programs. In 2000-2001, the Washington State Department of Social and Health Services supported expansion of the pilot project approach to the eastern, rural parts of the state.

As of June 2001, more than 1,500 pharmacists and pharmacy students had been trained and certified to provide emergency contraception services, and approximately 190 pharmacies — including multiple locations of retail, grocery, and pharmacy chains — were providing these services in Washington State. By June 2001, pharmacists working under collaborative drug therapy agreements were providing emergency contraception to women at the rate of about 1,200 prescriptions per month and had provided more than 35,600 prescriptions since February 1998, when pharmacist EC services were initiated.

A sample of pharmacy records reviewed in 1999 revealed that most women received the pills within 24 hours of unprotected intercourse, when the method is most effective. Pregnancy risk can vary, depending on a variety of factors; but, using a base case estimate of 75.4% effectiveness rate and 7.4 % risk of pregnancy, it can be estimated that the 35,600 ECP prescriptions directly provided by pharmacists could have prevented nearly 2,000 unintended pregnancies. In Washington State, statistics show that about half of unintended pregnancies typically end in abortion.

In other states in the U.S., as well as in other countries, advocates of expanded access to ECPs have been able to use the Washington State model to advance their efforts, with good results. Recent legislation in California and Alaska will allow pharmacists trained in ECP services to provide ECPs directly to women beginning in 2002. Legislation allowing ECP collaborative agreements is moving forward in several other states. In the Canadian province of British Columbia, pharmacists are now able to provide ECPs through collaborative agreements, similar to Washington State.

Emergency Contraception Links

Emergency Contraception Website operated by the Office of Population Research at Princeton University

<http://www.not-2-late.com>

Comprehensive information about emergency contraception, as well as a list of clinicians and pharmacists in Washington State who provide this service.

The Association of Reproductive Health Professionals Website

<http://www.arhp.org/ec/>

Special section on emergency contraception, which includes training slides for providers that can be downloaded directly from the site.

The Consortium for Emergency Contraception Website

<http://www.cecinfo.org/>

Includes general information about emergency contraception as well as prototype materials variously designed for family planning clients, health care providers, programme managers, national policy makers, community groups, and the media.

Planned Parenthood's Emergency Contraceptive Page

<http://www.plannedparenthood.org/BIRTH-CONTROL/EC.HTM>

Information about how to use emergency contraceptive pills, the side effects, IUD insertion, and a brief history of emergency contraception.

The Kaiser Family produces a daily Reproductive Health Report:

<http://report.kff.org/repro/>

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Collaborative Drug Therapy Agreements Between Pharmacists and Authorized Prescribers

The backbone of the emergency contraception pilot project in Washington is the application of collaborative drug-therapy agreements or protocols to ECP provision. For almost 20 years, physicians and pharmacists have successfully used these agreements to manage a variety of drug therapies for Washington State patients. Common examples are pharmacokinetic drug monitoring, parenteral nutrition, anticoagulant therapy, pain drug management, and refill medication protocols.

[Expanding Access to ECPs in Washington State](#)

The agreements are written documents in which licensed prescribers (for example physicians) and pharmacists share information and responsibility for a patient's drug therapy. The agreements define pharmacist drug initiation, modification, and monitoring; continuation activities; and documentation requirements. Pharmacists may perform these activities only as agreed to by an authorized prescriber. Often, nationally-recognized, clinical drug-therapy guidelines are incorporated in the agreements. While in many of the collaborative agreements, physicians and pharmacists work in close proximity, that is not always the case. Collaborative agreements have also been used in well-defined situations where there is very low risk associated with drug therapy and a high need for patient access. The ECP collaborative agreement protocol is in this latter category. Pharmacists provide ECPs to women under the agreed upon conditions. If women fall outside of the scope of the ECP agreement or need additional contraceptive services, the pharmacist refers them to the collaborating prescriber or another health care provider.

The ECP protocol was based upon guidelines from both the American College of Obstetricians and Gynecologists and the World Health Organization and was developed in consultation with physicians and pharmacists to meet Washington State requirements for collaborative agreements (WAC 246-863-100). The agreement also serves as the core component of a three-hour continuing education training

program for participating pharmacists. ECP protocols require that the authorizing prescriber and the pharmacist perform a quarterly quality-assurance review of the prescribing decisions. These quarterly briefings enable the prescriber to review with the pharmacist prescribing decisions made during the quarter.

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Tools for Expanding EC Pill Access

Tools for expanding emergency contraceptive pill access through collaborative drug therapy agreements.



Washington State is engaged in a novel approach to expand access to emergency contraceptive pills (ECPs). The program relies on a joint collaborative agreement among pharmacists and other contraceptive care providers, such as physicians, that enable women to receive ECPs directly from a pharmacist. This approach has proved to be very successful in expanding ECP access and has received high approval ratings from women who have used the service, as well as from participating pharmacists and their collaborating partners.

This set of tools was developed as part of a notebook for a workshop in May of 1999 to help other states increase access to emergency contraceptive pills through direct pharmacy provision. The materials in this notebook were designed to help states develop and implement a project similar to Washington's. The tools were developed by PATH in collaboration with the Washington State Pharmacists Association, the University of Washington Department of Pharmacy, the Washington State Board of Pharmacy, and DDB Seattle. The David and Lucile Packard Foundation generously funded the development of this material.

The contents of the notebook include the following (some files require [Adobe Acrobat reader](#) to view and print).

Emergency Contraceptive Pills Information Packet

A set of one-page summaries to help decision-makers understand key issues related to emergency contraception and pharmacist/prescriber collaborative agreements. Topics include: Unintended Pregnancy; What Are Emergency Contraceptive Pills? How Do Emergency Contraceptive Pills work? Collaborative Drug Therapy Agreements; and Expanding Access to Emergency Contraceptive Pills in Washington:

See also:

[EC Collaborative Agreement Pilot Project](#)

[Provider Attitudes toward ECPs: Executive Summary of Findings](#)

[Emergency Contraception for Diverse Communities Project](#)

[EC Client Materials for Diverse Audiences](#)

[Consortium for Emergency Contraception Web Site](#)

PDF files require [Adobe Acrobat Reader](#).



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Promoting Pharmacist/Prescriber Collaborative Agreements

- [Emergency Contraceptive Pills Information Packet](#) (150 Kb .pdf file)

Collaborative Agreements for Public Health

An overview document describing the problem of unintended pregnancy, emergency contraception as part of the solution, ECP mechanism of action and safety, Washington's approach, and the benefits of pharmacy access to ECPs.

- [Collaborative Agreements for Public Health](#) (55 Kb .pdf file)

Framework

A framework that outlines the early steps of developing an approach for facilitating collaborative drug therapy agreements for emergency contraceptive pills.

- [Framework](#) (45 Kb .pdf file)

Model Legislation

A document that highlights legislative elements that can expand the scope of pharmacy practice to include collaborative drug therapy agreements that can be used to increase access to emergency contraceptive pills.

- [Model Legislation](#) (45 Kb .pdf file)

Quality Assurance/Quality Improvement Document

The pharmacist quality assurance/improvement plan used by the Washington State Pharmacists Association for pharmacies participating in collaborative drug therapy management agreements.

- [Quality Assurance](#) (35 Kb .pdf file)

Pharmacist Training Manual

The training manual contains information on the therapeutic, patient care, regulatory, public relations, and reimbursement issues that affect access to emergency contraception. These materials were used to train pharmacists interested in ECPs and in establishing a collaborative agreement for prescribing them in Washington State.

- [Pharmacist Training Manual](#) (155 Kb .pdf file)

Additional Materials included in Training Manual

Practice Patterns: Emergency Oral Contraception ACOG Practice Patterns, ref. #3, December 1996.

- For a copy, contact ACOG at <http://www.acog.org/>. Or [order a copy](#) directly from ACOG's site.

Prescription Drug Products; Certain combined oral

contraceptives for use as postcoital emergency contraception
Food and Drug Administration. Prescription Drug Products;
Certain combined oral contraceptives for use as postcoital
emergency contraception; Notice. Federal Register. February
25, 1997; 62:8610-8612.

- <http://www.fda.gov/opacom/fedregister/cd96107.htm>

Emergency contraceptive pills: safe and effective but not widely used.

This article, published as a Washington State Pharmacy Association Continuing Education correspondence Course, reviews the types of emergency contraceptive regimens in use in the United States

- [Emergency contraceptive pills](#) (1790 Kb .pdf file)

Information on Estrogen -Progestin American Society of Health Systems Pharmacists. AFHS Drug Information 1998. Section 68:12 - Contraceptives: Estrogen-Progestin Combinations, Post-coital Contraceptives, p.2534-2545. Bethesda, MD, 1998.

Department of Social and Health Service Materials Includes a DSHS memo announcing pharmacy reimbursement for emergency contraceptive pills counseling; Pregnancy Risk Assessment emergency contraception information; and a Medical Assistance Administration question and answer sheet.

- [DSHS Materials](#) (110 Kb .pdf file)

Public Relations/Contingency Plans

This section includes information about: the pilot project's media campaign, talking to the media, enlisting support from the medical community, how to handle anti-choice opposition, as well as answers to frequently asked questions. The workshop notebook also included an illustrative group of press clippings.

- [Public Relations/Contingency Plans](#) (60 Kb .pdf file)

"Sweet Nothings"

A transcript of a 60 second radio script used as part of a media campaign.

- ["Sweet Nothings"](#) (20 Kb .pdf file)

Resources

This section provides an overview of the organizations, resources, and publications that offer information on emergency contraception and collaborative drug therapy agreements.

- [Resources](#) (65 Kb .pdf file)

Presenter's slides

Slides of the presentations given at the workshop.

- [Presenter's Slides](#) (Microsoft Powerpoint file in 955 K self extracting-archive) Includes The Role of the Pharmacist in Reproductive Health Care; Collaborative Drug Therapy Management; Communication and Outreach; and Pharmacist Training for EC Services.
- [Felicia Stewart's Key Note Presentation](#) (Microsoft Powerpoint file in 655 K self-extracting archive)

Additional Materials Included in Notebook

- [EC Materials for Diverse Audiences](#)
- [Emergency Contraception Resources for Providers](#)

[Home](#) | [About](#) | [Programs](#) | [Technologies](#) | [Resources](#) | [Contact](#)



MAKING EMERGENCY CONTRACEPTION AVAILABLE IN EMERGENCY ROOMS

Surveys show that women have difficulty learning about and obtaining emergency contraception (EC). Mandating that emergency rooms inform women about EC and dispense EC upon request is an important step towards addressing this need.

Several states have enacted legislation requiring that emergency rooms inform sexual assault survivors about EC and dispense EC upon request. This is an important step in improving access. However, emergency rooms should provide EC as a standard of care to *all* women, not just sexual assault survivors. In drafting legislation, consider language that would mandate provision of information and EC to all women who wish to prevent unwanted pregnancy.

Packet Contents Include:

- 1) New Mexico bill (H 119), enacted 2003*
- 2) Washington bill (S 6537), enacted 2002*
- 3) California bill (A 1860), enacted 2002*
- 4) Model legislation*

* Note: These bills focus on the provision of EC for sexual assault survivors, not all women.

Strategy Points:

- 1) No exemptions: Do not include a refusal clause (or so-called “conscience clause”) in your introduced bill, and do not allow one to be added during the legislative process.
- 2) Framing issue: If your bill focuses on sexual assault survivors only, consider framing the bill as a criminal justice issue/victim’s rights issue rather than as a reproductive rights issue, as this may enable you to form broader coalitions and reduce opposition from anti-choice groups or the Catholic church.
- 3) Possible coalition partners: women’s rights organizations, civil liberties groups, health care groups, church organizations (and law enforcement and sexual assault organizations, if the bill focuses on sexual assault survivors only).

underscored material = new
[bracketed material] = delete

HOUSE BILL 119

46TH LEGISLATURE - STATE OF NEW MEXICO - FIRST SESSION, 2003

INTRODUCED BY

Mimi Stewart

AN ACT

RELATING TO HEALTH CARE; ENACTING THE SEXUAL ASSAULT SURVIVORS
EMERGENCY CARE ACT; PROVIDING PENALTIES; DECLARING AN
EMERGENCY.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF NEW MEXICO:

Section 1. SHORT TITLE. -- This act may be cited as the
"Sexual Assault Survivors Emergency Care Act".

Section 2. LEGISLATIVE FINDINGS. --

A. One out of every five women in the United States
has been sexually assaulted.

B. Each year over three hundred thousand women are
sexually assaulted in the United States.

C. A woman is sexually assaulted every six minutes
in the United States.

D. New Mexico ranks high when compared with other

1 states in the number of sexual assaults reported each year.

2 E. After a woman is sexually assaulted, she may
3 face the additional trauma of an unwanted pregnancy by the
4 rapist.

5 F. Each year over thirty-two thousand women become
6 pregnant as a result of sexual assault and approximately fifty
7 percent of those pregnancies end in abortion.

8 G. Emergency contraception, approved for use by the
9 federal drug administration, prevents pregnancy after
10 unprotected intercourse.

11 H. Emergency contraception cannot and does not
12 cause abortion.

13 I. Emergency contraception pills are the most
14 commonly used method of emergency contraception and are similar
15 to ordinary birth control pills.

16 J. Emergency contraception pills are as much as
17 eighty-nine percent effective in reducing the risk of pregnancy
18 following unprotected intercourse.

19 K. Delaying the first dose of emergency
20 contraception pills by twelve hours increases the odds of
21 pregnancy by almost fifty percent.

22 L. Standards of emergency care established by the
23 American medical association require that sexual assault
24 survivors be counseled about their risk of pregnancy and
25 offered emergency contraception.

1 M Most New Mexico hospitals do not have a clear
2 policy on offering emergency contraception to sexual assault
3 survivors and, therefore, few hospitals require staff to inform
4 sexual assault survivors of the availability of emergency
5 contraception pills.

6 N. Most women of reproductive age do not know about
7 emergency contraception and, therefore, cannot ask for it.
8 Surveys show that only eleven percent of women of reproductive
9 age in the United States have heard of emergency contraception,
10 and fewer still are aware that treatment must begin within
11 seventy-two hours of a sexual assault.

12 Section 3. DEFINITIONS. -- As used in the Sexual Assault
13 Survivors Emergency Care Act:

14 A. "department" means the department of health;

15 B. "emergency care for sexual assault survivors"
16 means medical examinations, procedures and services provided by
17 a hospital to a sexual assault survivor following an alleged
18 sexual assault;

19 C. "emergency contraception" means a drug or device
20 approved by the federal drug administration that prevents
21 pregnancy after sexual intercourse;

22 D. "hospital" means a facility providing emergency
23 or urgent health care;

24 E. "medically and factually accurate and objective"
25 means verified or supported by the weight of research conducted

1 in compliance with accepted scientific methods and standards;
2 published in peer-reviewed journals; and recognized as accurate
3 and objective by leading professional organizations and
4 agencies with relevant expertise in the field of obstetrics and
5 gynecology, such as the American college of obstetricians and
6 gynecologists;

7 F. "sexual assault" means the crime of criminal
8 sexual penetration; and

9 G. "sexual assault survivor" means a female who
10 alleges or is alleged to have been sexually assaulted and who
11 presents as a patient to a hospital.

12 Section 4. EMERGENCY CARE FOR SEXUAL ASSAULT SURVIVORS--
13 STANDARD OF CARE. --

14 A. The standard of care for a hospital that
15 provides emergency care for sexual assault survivors shall be
16 to:

17 (1) provide each sexual assault survivor with
18 medically and factually accurate and objective written and oral
19 information about emergency contraception;

20 (2) orally inform each sexual assault survivor
21 of her option to be provided emergency contraception at the
22 hospital; and

23 (3) provide emergency contraception
24 immediately at the hospital to each sexual assault survivor who
25 requests it.

1 B. The provision of emergency contraception shall
2 include the initial dose that the sexual assault survivor can
3 take at the hospital as well as the subsequent dose that the
4 sexual assault survivor may self-administer twelve hours
5 following the initial dose.

6 Section 5. TRAINING. --A hospital shall ensure that all
7 personnel who provide care to sexual assault survivors are
8 trained to provide medically and factually accurate and
9 objective information about emergency contraception.

10 Section 6. ENFORCEMENT-- ADMINISTRATIVE FINES. --

11 A. Complaints of failure to provide services
12 required by the Sexual Assault Survivors Emergency Care Act may
13 be filed with the department.

14 B. The department shall immediately investigate
15 every complaint it receives regarding failure of a hospital to
16 provide services required by the Sexual Assault Survivors
17 Emergency Care Act to determine the action to be taken to
18 satisfy the complaint.

19 C. The department shall compile all complaints it
20 receives regarding failure to provide services required by the
21 Sexual Assault Survivors Emergency Care Act and shall retain
22 the complaints for at least ten years so that they can be
23 analyzed for patterns of failure to provide services pursuant
24 to that act.

25 D. If the department determines that a hospital is

1 not providing the services required in the Sexual Assault
2 Survivors Emergency Care Act, the department shall:

3 (1) impose on the hospital a fine of five
4 thousand dollars (\$5,000) per sexual assault survivor who is
5 denied medically and factually accurate and objective
6 information about emergency contraception or who is not offered
7 or provided emergency contraception;

8 (2) impose on the hospital a fine of five
9 thousand dollars (\$5,000) for each month that the hospital
10 provides emergency services following the effective date of the
11 Sexual Assault Survivors Emergency Care Act if the department,
12 after investigating a complaint, determines that the hospital
13 has failed to train hospital personnel to provide medically and
14 factually accurate and objective information regarding the
15 availability and effectiveness of emergency contraception; and

16 (3) after a fine has been imposed for a second
17 time pursuant to either Paragraph (1) or (2) of this
18 subsection, suspend or revoke the license issued by the
19 department pursuant to the Public Health Act or impose an
20 intermediate sanction after providing notice to the hospital
21 and affording the hospital an opportunity for a hearing to be
22 held pursuant to the provisions of the Public Health Act and
23 rules of the department.

24 Section 7. SEVERABILITY.--If any part or application of
25 the Sexual Assault Survivors Emergency Care Act is held

underscored material = new
[bracketed material] = delete

1 invalid, the remainder of its application to other situations
2 or persons shall not be affected.

3 Section 8. EMERGENCY.--It is necessary for the public
4 peace, health and safety that this act take effect immediately.

5 - 7 -

CERTIFICATION OF ENROLLMENT

SUBSTITUTE SENATE BILL 6537

57th Legislature
2002 Regular Session

Passed by the Senate February 16, 2002
YEAS 36 NAYS 13

President of the Senate

Passed by the House March 6, 2002
YEAS 75 NAYS 19

**Speaker of the
House of Representatives**

CERTIFICATE

I, Tony M. Cook, Secretary of the Senate of the State of Washington, do hereby certify that the attached is **SUBSTITUTE SENATE BILL 6537** as passed by the Senate and the House of Representatives on the dates hereon set forth.

Secretary

Approved

FILED

Governor of the State of Washington

**Secretary of State
State of Washington**

SUBSTITUTE SENATE BILL 6537

Passed Legislature - 2002 Regular Session

State of Washington

57th Legislature

2002 Regular Session

By Senate Committee on Health & Long-Term Care (originally sponsored by Senators Costa, Winsley, Kohl-Welles, Thibaudeau, Fairley, Kline, Jacobsen, Prentice, B. Sheldon and Keiser)

READ FIRST TIME 02/08/2002.

1 AN ACT Relating to emergency care for victims of sexual assault;
2 amending RCW 70.41.020; adding new sections to chapter 70.41 RCW; and
3 creating a new section.

4 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

5 NEW SECTION. **Sec. 1.** (1) The legislature finds that:

6 (a) Each year, over three hundred thousand women are sexually
7 assaulted in the United States;

8 (b) Nationally, over thirty-two thousand women become pregnant each
9 year as a result of sexual assault. Approximately fifty percent of
10 these pregnancies end in abortion;

11 (c) Approximately thirty-eight percent of women in Washington are
12 sexually assaulted over the course of their lifetime. This is twenty
13 percent more than the national average;

14 (d) Only fifteen percent of sexual assaults in Washington are
15 reported; however, even the numbers of reported attacks are staggering.
16 For example, last year, two thousand six hundred fifty-nine rapes were
17 reported in Washington, this is more than seven rapes per day.

(2) The legislature deems it essential that all hospital emergency rooms provide emergency contraception as a treatment option to any woman who seeks treatment as a result of a sexual assault.

Sec. 2. RCW 70.41.020 and 1991 c 3 s 334 are each amended to read as follows:

Unless the context clearly indicates otherwise, the following terms, whenever used in this chapter, shall be deemed to have the following meanings:

(1) "Department" means the Washington state department of health((+)).

(2) "Emergency care to victims of sexual assault" means medical examinations, procedures, and services provided by a hospital emergency room to a victim of sexual assault following an alleged sexual assault.

(3) "Emergency contraception" means any health care treatment approved by the food and drug administration that prevents pregnancy, including but not limited to administering two increased doses of certain oral contraceptive pills within seventy-two hours of sexual contact.

(4) "Hospital" means any institution, place, building, or agency which provides accommodations, facilities and services over a continuous period of twenty-four hours or more, for observation, diagnosis, or care, of two or more individuals not related to the operator who are suffering from illness, injury, deformity, or abnormality, or from any other condition for which obstetrical, medical, or surgical services would be appropriate for care or diagnosis. "Hospital" as used in this chapter does not include hotels, or similar places furnishing only food and lodging, or simply domiciliary care; nor does it include clinics, or physician's offices where patients are not regularly kept as bed patients for twenty-four hours or more; nor does it include nursing homes, as defined and which come within the scope of chapter 18.51 RCW; nor does it include ((maternity homes)) birthing centers, which come within the scope of chapter 18.46 RCW; nor does it include psychiatric hospitals, which come within the scope of chapter 71.12 RCW; nor any other hospital, or institution specifically intended for use in the diagnosis and care of those suffering from mental illness, mental retardation, convulsive disorders, or other abnormal mental condition. Furthermore, nothing in this chapter or the rules adopted pursuant thereto shall be construed

1 as authorizing the supervision, regulation, or control of the remedial
2 care or treatment of residents or patients in any hospital conducted
3 for those who rely primarily upon treatment by prayer or spiritual
4 means in accordance with the creed or tenets of any well recognized
5 church or religious denominations((+)).

6 ((+3+)) (5) "Person" means any individual, firm, partnership,
7 corporation, company, association, or joint stock association, and the
8 legal successor thereof.

9 (6) "Secretary" means the secretary of health.

10 (7) "Sexual assault" has the same meaning as in RCW 70.125.030.

11 (8) "Victim of sexual assault" means a person who alleges or is
12 alleged to have been sexually assaulted and who presents as a patient.

13 NEW SECTION. **Sec. 3.** A new section is added to chapter 70.41 RCW
14 to read as follows:

15 (1) Every hospital providing emergency care to a victim of sexual
16 assault shall:

17 (a) Provide the victim with medically and factually accurate and
18 unbiased written and oral information about emergency contraception;

19 (b) Orally inform each victim of sexual assault of her option to be
20 provided emergency contraception at the hospital; and

21 (c) If not medically contraindicated, provide emergency
22 contraception immediately at the hospital to each victim of sexual
23 assault who requests it.

24 (2) The secretary, in collaboration with community sexual assault
25 programs and other relevant stakeholders, shall develop, prepare, and
26 produce informational materials relating to emergency contraception for
27 the prevention of pregnancy in rape victims for distribution to and use
28 in all emergency rooms in the state, in quantities sufficient to comply
29 with the requirements of this section. The secretary, in collaboration
30 with community sexual assault programs and other relevant stakeholders,
31 may also approve informational materials from other sources for the
32 purposes of this section. The informational materials must be clearly
33 written and readily comprehensible in a culturally competent manner, as
34 the secretary, in collaboration with community sexual assault programs
35 and other relevant stakeholders, deems necessary to inform victims of
36 sexual assault. The materials must explain the nature of emergency
37 contraception, including that it is effective in preventing pregnancy,
38 treatment options, and where they can be obtained.

1 (3) The secretary shall adopt rules necessary to implement this
2 section.

3 NEW SECTION. **Sec. 4.** A new section is added to chapter 70.41 RCW
4 to read as follows:

5 The department must respond to complaints of violations of section
6 3 of this act. The department shall convene a task force, composed of
7 representatives from community sexual assault programs and other
8 relevant stakeholders including advocacy agencies, medical agencies,
9 and hospital associations, to provide input into the development and
10 evaluation of the education materials and rule development. The task
11 force shall expire on January 1, 2004.

--- END ---

Assembly Bill No. 1860

CHAPTER 382

An act to amend Section 13823.11 of the Penal Code, relating to sexual assault victims.

[Approved by Governor September 5, 2002. Filed
with Secretary of State September 6, 2002.]

LEGISLATIVE COUNSEL'S DIGEST

AB 1860, Migden. Sexual assault victim: pregnancy counseling: emergency contraception.

Existing law sets forth minimum standards for the examination and treatment of victims of sexual assault, including the taking of a baseline gonorrhea culture, a syphilis serology, and specimens for a pregnancy test, if indicated by the history of contact.

This bill would provide, in addition, that where indicated by the history of contact, a female victim of sexual assault shall be provided with the option of postcoital contraception by a physician or other health care provider, and postcoital contraception shall be dispensed by a physician or other health care provider upon the request of the victim.

The people of the State of California do enact as follows:

SECTION 1. Section 13823.11 of the Penal Code is amended to read:

13823.11. The minimum standards for the examination and treatment of victims of sexual assault or attempted sexual assault, including child molestation and the collection and preservation of evidence therefrom include all of the following:

(a) Law enforcement authorities shall be notified.

(b) In conducting the physical examination, the outline indicated in the form adopted pursuant to subdivision (c) of Section 13823.5 shall be followed.

(c) Consent for a physical examination, treatment, and collection of evidence shall be obtained.

(1) Consent to an examination for evidence of sexual assault shall be obtained prior to the examination of a victim of sexual assault and shall include separate written documentation of consent to each of the following:

(A) Examination for the presence of injuries sustained as a result of the assault.



(B) Examination for evidence of sexual assault and collection of physical evidence.

(C) Photographs of injuries.

(2) Consent to treatment shall be obtained in accordance with usual hospital policy.

(3) A victim of sexual assault shall be informed that he or she may refuse to consent to an examination for evidence of sexual assault, including the collection of physical evidence, but that a refusal is not a ground for denial of treatment of injuries and for possible pregnancy and sexually transmitted diseases, if the person wishes to obtain treatment and consents thereto.

(4) Pursuant to Chapter 3 (commencing with Section 6920) of Part 4 of Division 11 of the Family Code, a minor may consent to hospital, medical, and surgical care related to a sexual assault without the consent of a parent or guardian.

(5) In cases of known or suspected child abuse, the consent of the parents or legal guardian is not required. In the case of suspected child abuse and nonconsenting parents, the consent of the local agency providing child protective services or the local law enforcement agency shall be obtained. Local procedures regarding obtaining consent for the examination and treatment of, and the collection of evidence from, children from child protective authorities shall be followed.

(d) A history of sexual assault shall be taken.

The history obtained in conjunction with the examination for evidence of sexual assault shall follow the outline of the form established pursuant to subdivision (c) of Section 13823.5 and shall include all of the following:

(1) A history of the circumstances of the assault.

(2) For a child, any previous history of child sexual abuse and an explanation of injuries, if different from that given by parent or person accompanying the child.

(3) Physical injuries reported.

(4) Sexual acts reported, whether or not ejaculation is suspected, and whether or not a condom or lubricant was used.

(5) Record of relevant medical history.

(e) (1) If indicated by the history of contact, a female victim of sexual assault shall be provided with the option of postcoital contraception by a physician or other health care provider.

(2) Postcoital contraception shall be dispensed by a physician or other health care provider upon the request of the victim.

(f) Each adult and minor victim of sexual assault who consents to a medical examination for collection of evidentiary material shall have a



physical examination which includes, but is not limited to, all of the following:

(1) Inspection of the clothing, body, and external genitalia for injuries and foreign materials.

(2) Examination of the mouth, vagina, cervix, penis, anus, and rectum, as indicated.

(3) Documentation of injuries and evidence collected.

Prepubertal children shall not have internal vaginal or anal examinations unless absolutely necessary (this does not preclude careful collection of evidence using a swab).

(g) The collection of physical evidence shall conform to the following procedures:

(1) Each victim of sexual assault who consents to an examination for collection of evidence shall have the following items of evidence collected, except where he or she specifically objects:

(A) Clothing worn during assault.

(B) Foreign materials revealed by an examination of the clothing, body, external genitalia, and pubic hair combings.

(C) Swabs and slides from the mouth, vagina, rectum, and penis, as indicated, to determine the presence or absence of sperm and sperm motility, and for genetic marker typing.

(2) Each victim of sexual assault who consents to an examination for the collection of evidence shall have reference specimens taken, except when he or she specifically objects thereto. A reference specimen is a standard from which to obtain baseline information (for example: pubic and head hair, blood, and saliva for genetic marker typing). These specimens shall be taken in accordance with the standards of the local criminalistics laboratory.

(3) A baseline gonorrhea culture, and syphilis serology, shall be taken, if indicated by the history of contact. Specimens for a pregnancy test shall be taken, if indicated by the history of contact.

(4) (A) If indicated by the history of contact, a female victim of sexual assault shall be provided with the option of postcoital contraception by a physician or other health care provider.

(B) Postcoital contraception shall be dispensed by a physician or other health care provider upon the request of the victim.

(h) Preservation and disposition of physical evidence shall conform to the following procedures:

(1) All swabs and slides shall be air-dried prior to packaging.

(2) All items of evidence including laboratory specimens shall be clearly labeled as to the identity of the source and the identity of the person collecting them.



(3) The evidence shall have a form attached which documents its chain of custody and shall be properly sealed.

(4) The evidence shall be turned over to the proper law enforcement agency.





NARAL
Pro-Choice America Foundation

MODEL LEGISLATION* TO GUARANTEE SEXUAL ASSAULT VICTIMS ACCESS TO EMERGENCY CONTRACEPTION IN HOSPITAL EMERGENCY DEPARTMENTSⁱ

A BILL

To ensure appropriate emergency health care for sexual assault victims.ⁱⁱ

Be it enacted by [state]:

SECTION 1: SHORT TITLE

This Act may be cited as the “Emergency Care for Sexual Assault Victims Act of [year].”

SECTION 2: FINDINGS

The [state] legislature finds that:

- A. Each year, over 600,000 women are raped in the U.S.
- B. In [most recent year with data], [number] women were [raped] in [state].ⁱⁱⁱ
- C. After a woman is raped, she may face or anxiously fear the additional trauma of an unwanted pregnancy.
- D. Each year, approximately 25,000 women in the United States become pregnant as a result of rape. An estimated 22,000 of these pregnancies — or 88 percent — could be prevented if sexual assault victims had timely access to emergency contraception. [Insert state-specific date if available]
- E. Emergency contraception is a safe, responsible, and effective back-up method of birth control that *prevents* pregnancy after sexual intercourse.
- F. Medical research indicates that the sooner emergency contraception is administered, the better the chance of preventing unintended pregnancy.
- G. Emergency contraception does not cause abortion and does not work if a woman is already pregnant.

- H. Emergency contraception is an integral part of comprehensive and compassionate emergency care for sexual assault victims.
- I. The American College of Emergency Physicians (ACEP) and the American College of Obstetricians and Gynecologists (ACOG) agree that emergency contraception should be offered to all victims of sexual assault if they are at risk of pregnancy.
- J. A nationwide study found that fewer than half of all sexual assault victims eligible for emergency contraception actually received the treatment during a visit to a hospital emergency department. [Or insert state specific information about availability of emergency contraception in emergency departments.]
- K. Most women do not know about emergency contraception: nearly three-quarters of women surveyed have not heard of emergency contraception pills, the most commonly used form of emergency contraception, and only two percent of women have ever used them. Therefore, women who have been raped are unlikely to ask for emergency contraception.
- L. It is essential for all hospitals that provide emergency medical treatment to offer emergency contraception as a treatment option to any woman who seeks medical care as a result of an alleged sexual assault.

SECTION 3: DEFINITIONS

The following words and phrases when used in this Act shall have the meanings given to them in this section unless the context clearly indicates otherwise:

- A. “Emergency contraception” means any drug or device approved by the Food and Drug Administration that prevents pregnancy after sex.
- B. “Emergency care to sexual assault victims” means medical examinations, procedures, or services provided at a hospital [health care facility] to a sexual assault victim following an alleged rape.
- C. “Sexual assault” [“Rape”]^{iv} means [as defined by state statute].
- D. “Sexual assault victim” means a female who alleges or is alleged to have been raped and presents as a patient.
- E. “Medically and factually accurate and objective” means verified or supported by the weight of research conducted in compliance with accepted scientific methods and: (1) published in peer-reviewed journals where applicable; or (2) comprising information that leading professional organizations and agencies with relevant expertise in the field, such as the American College of Obstetricians and Gynecologists (ACOG), recognize as accurate and objective.

SECTION 4: EMERGENCY CARE TO SEXUAL ASSAULT [RAPE] VICTIMS

It shall be the standard of care for hospitals [health care facilities] ^v that provide emergency care to sexual assault victims to:

- A. Provide each sexual assault victim with medically and factually accurate and objective written and oral information about emergency contraception, prepared pursuant to Section 6 of this section;
- B. Orally inform each sexual assault victim of her option to be provided emergency contraception at the hospital [health care facility]; and
- C. Provide the complete regimen of emergency contraception immediately [promptly] at the hospital [health care facility] to each sexual assault victim who requests it.

SECTION 5: TRAINING OF PROVIDERS

Each hospital [health care facility] shall ensure that each person who provides care to sexual assault victims is provided with medically and factually accurate and objective information about emergency contraception.

SECTION 6: PATIENT INFORMATION MATERIALS

- A. The [state department of health] or contracted designee shall develop, prepare, and produce informational materials relating to emergency contraception for the prevention of pregnancy for distribution to and use in all emergency departments in the state, in quantities sufficient to comply with the requirements of this section. The [Secretary], in collaboration with community sexual assault programs and other relevant stakeholders, may also approve informational materials from other sources for the purposes of this section.
- B. The informational materials must:
 - 1. Be medically and factually accurate and objective;
 - 2. Be clearly written and readily comprehensible in a culturally competent manner, as the [state department of health], in collaboration with community sexual assault programs and other relevant stakeholders, deems necessary to inform victims of sexual assault; and
 - 3. Explain the nature of emergency contraception, including its use, safety, efficacy, and availability, and that it does not cause abortion.

SECTION 7: ENFORCEMENT

In addition to any remedies at common law, the [state department of health] shall respond to complaints and shall periodically determine whether hospitals [health care facilities] are complying with this Act. The [state department of health] may use all investigative tools available to it to verify compliance with this Act. If the [state department of health] determines that a hospital is not in compliance with this Act, the [department] shall:

- A. Impose a fine of [\$5,000] per woman who is denied medically and factually accurate and objective information about emergency contraception or who is not offered or provided emergency contraception;
- B. Impose a fine of [\$5,000] for failure to comply with Section 5 of this Act. For every 30 days that a hospital [health care facility] is not in compliance with Section 5, an additional fine of [\$5,000] shall be imposed; and
- C. After two violations, suspend or revoke the certificate of authority or deny the hospital's [health care facility's] application for certificate of authority.

SECTION 8: SEVERABILITY

If any provision, word, phrase or clause of this Act, or the application thereof, to any person, entity or circumstance should be held invalid, such invalidity shall not affect the remaining provisions, words, phrases or clauses of this Act which can be given effect without the invalid provision, word, phrase, clause or application, and to this end, the provisions, words, phrases or clauses of this Act are declared severable.

SECTION 9: CONFLICT

All laws and parts of laws in conflict with this Act are repealed.

SECTION 10: EFFECTIVE DATE

This Act shall be effective [date].

ⁱ Before moving forward with a proactive legislative campaign to guarantee sexual assault victims' access to emergency contraception in hospital emergency departments, consult with the sexual assault community in your state to ensure that such a requirement is consistent with existing sexual assault treatment protocols.

ⁱⁱ The term "victim" is used to underscore the fact that sexual assault survivors are victims of violent crime and to highlight this legislation as an important victims' rights initiative. Sexual assault advocates in your state may use of the term "survivor" as well as "victim" to underscore the resiliency of women who survive the violent crime of rape.

ⁱⁱⁱ State-level data may be limited to the number of reported rather than actual rapes. Consult with the sexual assault coalition in your state to determine whether data exists on the number of actual rapes in your state. If not, consider including in the bill the number of rape victims in your state that are discharged from emergency departments without having received emergency contraception.

^{iv} Because the legal definitions of sexual assault and rape may vary from state to state, check with the sexual assault coalition in your state to identify the appropriate term for your legislation.

^v In some states, sexual assault victims who present at hospitals may be referred to specialized health care facilities for treatment. Consult with the sexual assault community in your state to determine whether the term "hospital" is broad enough to encompass all facilities where sexual assault victims receive emergency medical care.

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