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 CONTRACEPTION

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

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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

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;

(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;

[(E)] □(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,)] 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;

[(E)] □(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.
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.

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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 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;

(11) rational therapy-contraindications;

(12) reasonable dose and route of administration;

(13) reasonable directions for use;

(14) duplication of therapy;

(15) drug-drug, drug-food, and drug-disease interactions;

(16) adverse drug reactions; and

(17) proper utilization, including over- or under-utilization, and optimum therapeutic outcomes;

(18) "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, repacker, 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.

Note to HTML Version:
The Alaska Statutes were automatically converted to HTML from a plain text format. Every effort has been made to ensure their accuracy, but neither Touch N' Go Systems nor the Law Offices of James B. Gottstein can be held responsible for any possible errors. This version of the Alaska Statutes is current through December, 2002.

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.

Last modified 12/18/2002
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.
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.]
PATH : Resources : Emergency Contraception

Emergency Contraception Collaborative Agreement Pilot Project

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

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.

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/
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.

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.
Tools for Expanding EC Pill Access

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:
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.
contraceptives for use as postcoital emergency contraception

- [http://www.fda.gov/opacom/fedregister/cd96107.htm](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)


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**