



California State Board of Pharmacy

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Agenda Item 26

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

January 14, 2015

To: Medical Board of California

From: California State Board of Pharmacy, Virginia Herold

A handwritten signature in black ink, reading "Virginia Herold".

Subject: Request for Review and Approval by the Medical Board of California Protocols to Permit Pharmacists to Provide:

1. Self-Administered Hormonal Contraception,
2. Nicotine Replacement Products, and
3. Naloxone Hydrochloride

At your January 30 board meeting, representatives of the Board of Pharmacy will appear to formally request the Medical Board's approval of the three protocols indicated above. We are grateful for this opportunity to work together again with your board on major public health initiatives.

Legislation enacted in 2013 and 2014 (SB 493, Hernandez, Chapter 469, Statutes of 2013; and AB 1535, Bloom, Chapter 326, Statutes of 2014), directed our two boards to develop and approve the protocols. Copies of each of the proposed protocols are provided as attachments to this letter.

Over the last year, the board has convened five public committee meetings to develop these protocols and other components specified in the legislation:

- February 2014: Licensing Committee
- June 2014: SB 493 Implementation Committee
- August: Meeting SB 493 Implementation Committee
- November: Meeting SB 493 Implementation Committee
- December: Meeting SB 493 Implementation Committee

These meetings were well attended and provided opportunities for public comments and participation. Staff of the Medical Board attended some of these meetings. Meeting materials and minutes of these meetings are available from the Pharmacy Board's Web site at www.pharmacy.ca.gov (under about the board, and then board and committee meetings).

The protocols will be formally reviewed and I expect approved by the Board of Pharmacy during the January 28 Meeting. An update on the actions of the Board of Pharmacy will be provided at the Medical Board meeting. If the protocols are approved by both boards, the Board of Pharmacy will initiate rulemakings to adopt the protocols in regulation. The protocol for naloxone is planned to be adopted as an emergency regulation, pursuant to the provisions in the enacting legislation (AB 1535).

If additional review is needed, the protocols will be brought to both boards so that the same version of each protocol is approved by both boards. Comments made during rulemakings that result in changes in the text of any protocol will be returned to the Medical Board for approval.

The California HealthCare Foundation has provided support to the board to develop various components that board needs to meet the requirements of SB 493 and AB 1535. This support was in way of a researcher to develop draft components. One such product is the development of a protocol for self-administered hormonal contraception.

1. FOR REVIEW AND POSSIBLE ACTION Protocol for Pharmacists who Furnish Self-Administered Hormonal Contraceptives

Attachment 1

SB 493 provides for the development of a protocol for self-administered hormonal contraception. The protocol must be developed and approved by both the Medical Board and the Board of Pharmacy, in consultation with the American Congress of Obstetricians and Gynecologists, the California Pharmacists Association and other appropriate entities. It requires a self-screening tool for use by patients based on the current United States Medical Eligibility Criteria (USMEC). A pharmacist must also provide to the patient a fact sheet approved by the same group identified above and the CA Department of Public Health.

Attachment 1 contains the draft protocol for hormonal contraception. The board's SB 493 Implementation Committee believes this draft is ready for final review and referral to adoption as a regulation.

The related statutory provisions are provided below:

SEC. 7.

Section 4052.3 of the Business and Professions Code is amended to read:

4052.3.

- (a) (1) Notwithstanding any other law, a pharmacist may furnish self-administered hormonal contraceptives in accordance with standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American Congress of Obstetricians and Gynecologists, the California Pharmacists Association, and other appropriate entities. The standardized procedure or protocol shall require that the patient use a self-screening tool that will identify patient risk factors for use of self-administered hormonal contraceptives, based on the current United States Medical Eligibility Criteria (USMEC) for Contraceptive Use developed by the federal Centers for Disease Control and Prevention, and that the pharmacist refer the patient to the patient's primary care provider or, if the patient does not have a primary care provider, to nearby clinics, upon furnishing a self-administered hormonal contraceptive pursuant to this subdivision, or if it is determined that use of a self-administered hormonal contraceptive is not recommended.
- (2) The board and the Medical Board of California are both authorized to ensure compliance with this subdivision, and each board is specifically charged with the enforcement of this subdivision with respect to its respective licensees. This subdivision does not expand the authority of a pharmacist to prescribe any prescription medication.

- (b) (1) Notwithstanding any other law, a pharmacist may furnish emergency contraception drug therapy in accordance with either of the following:
- (A) Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.
 - (B) Standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American Congress of Obstetricians and Gynecologists, the California Pharmacists Association, and other appropriate entities. The board and the Medical Board of California are both authorized to ensure compliance with this clause, and each board is specifically charged with the enforcement of this provision with respect to its respective licensees. This subdivision does not expand the authority of a pharmacist to prescribe any prescription medication.
- (2) Prior to performing a procedure authorized under this subdivision, a pharmacist shall complete a training program on emergency contraception that consists of at least one hour of approved continuing education on emergency contraception drug therapy.
- (3) A pharmacist, pharmacist's employer, or pharmacist's agent shall not directly charge a patient a separate consultation fee for emergency contraception drug therapy services initiated pursuant to this subdivision, but may charge an administrative fee not to exceed ten dollars (\$10) above the retail cost of the drug. Upon an oral, telephonic, electronic, or written request from a patient or customer, a pharmacist or pharmacist's employee shall disclose the total retail price that a consumer would pay for emergency contraception drug therapy. As used in this paragraph, total retail price includes providing the consumer with specific information regarding the price of the emergency contraception drugs and the price of the administrative fee charged. This limitation is not intended to interfere with other contractually agreed-upon terms between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health care service plan or insurer. Patients who are insured or covered and receive a pharmacy benefit that covers the cost of emergency contraception shall not be required to pay an administrative fee. These patients shall be required to pay copayments pursuant to the terms and conditions of their coverage. This paragraph shall become inoperative for dedicated emergency contraception drugs if these drugs are reclassified as over-the-counter products by the federal Food and Drug Administration.
- (4) A pharmacist shall not require a patient to provide individually identifiable medical information that is not specified in Section 1707.1 of Title 16 of the California Code of Regulations before initiating emergency contraception drug therapy pursuant to this subdivision.
- (c) For each emergency contraception drug therapy or self-administered hormonal contraception initiated pursuant to this section, the pharmacist shall provide the recipient of the drug with a standardized factsheet that includes, but is not limited to, the indications and contraindications 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 Public Health, the American Congress of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. This section does not preclude the use of existing publications developed by nationally recognized medical organizations.

2. FOR REVIEW AND POSSIBLE ACTION: Draft Protocol for Pharmacists Who Furnish Nicotine Replacement Products

Attachment 2

SB 493 provides that a pharmacist may furnish nicotine replacement products approved by the FDA for use by prescription in accordance with standardized protocols. Implementation of this provision requires:

- Certification of the pharmacist in smoking cessation therapy by an organization recognized by the board

- Development of a protocol developed and approved by this board and the Medical Board of California with other “appropriate entities”
- The pharmacist maintain records of all prescription drugs and devices furnished for at least three years
- The patient’s primary care provider is notified of any drugs or devices furnished, or information is added to a shared patient record. If the patient has no primary care provider, the pharmacist provides the patient with a written record and advises the patient to consult a physician of the patient’s choice
- The pharmacist completes one hour of CE on smoking cessation therapy biennially.

A draft protocol for nicotine replacement products is provided in **Attachment 2**.

The related statutory provisions from SB 493 are provided below:

SEC. 10.

Section 4052.9 is added to the Business and Professions Code, to read:

4052.9.

- (a) A pharmacist may furnish nicotine replacement products approved by the federal Food and Drug Administration for use by prescription only in accordance with standardized procedures and protocols developed and approved by both the board and the Medical Board of California in consultation with other appropriate entities and provide smoking cessation services if all of the following conditions are met:
- (1) The pharmacist maintains records of all prescription drugs and devices furnished for a period of at least three years for purposes of notifying other health care providers and monitoring the patient.
 - (2) The pharmacist notifies the patient’s primary care provider of any drugs or devices furnished to the patient, or enters the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not have a primary care provider, the pharmacist provides the patient with a written record of the drugs or devices furnished and advises the patient to consult a physician of the patient’s choice.
 - (3) The pharmacist is certified in smoking cessation therapy by an organization recognized by the board.
 - (4) The pharmacist completes one hour of continuing education focused on smoking cessation therapy biennially.
- (b) The board and the Medical Board of California are both authorized to ensure compliance with this section, and each board is specifically charged with the enforcement of this section with respect to their respective licensees. Nothing in this section shall be construed to expand the authority of a pharmacist to prescribe any other prescription medication.

3. FOR DISCUSSION AND POSSIBLE ACTION: Pharmacy Protocols for Naloxone, as Provided by AB 1535 (Bloom, Chapter 326, Statutes of 2014)

Attachment 3

Last year’s AB 1535 authorizes the Board of Pharmacy to work with the Medical Board to develop a jointly approved protocol for pharmacists. The California Pharmacists Association and California Society of Addiction Medicine are specifically mentioned to participate in this

process. The board is also authorized to pursue an emergency rulemaking to secure the benefits of this law as soon as possible.

A draft protocol has been vetted publicly and with various experts and is provided in **Attachment 3**. Because the enabling legislation authorizes an emergency rulemaking, the board will file this regulation protocol with the Office of Administrative Law once the same version is approved by the requisite entities. The board will then institute the required (and routine) procedures to adopt the regulation permanently.

The specific statutory authorization for this protocol is provided in section 4052.01 of the Business and Professions Code:

4052.01.

- (a) Notwithstanding any other provision of law, a pharmacist may furnish naloxone hydrochloride in accordance with standardized procedures or protocols developed and approved by both the board and the Medical Board of California, in consultation with the California Society of Addiction Medicine, the California Pharmacists Association, and other appropriate entities. In developing those standardized procedures or protocols, the board and the Medical Board of California shall include the following:
 - (1) Procedures to ensure education of the person to whom the drug is furnished, including, but not limited to, opioid overdose prevention, recognition, and response, safe administration of naloxone hydrochloride, potential side effects or adverse events, and the imperative to seek emergency medical care for the patient.
 - (2) Procedures to ensure the education of the person to whom the drug is furnished regarding the availability of drug treatment programs.
 - (3) Procedures for the notification of the patient's primary care provider with patient consent of any drugs or devices furnished to the patient, or entry of appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider, and with patient consent.
- (b) A pharmacist furnishing naloxone hydrochloride pursuant to this section shall not permit the person to whom the drug is furnished to waive the consultation required by the board and the Medical Board of California.
- (c) Prior to performing a procedure authorized under this section, a pharmacist shall complete a training program on the use of opioid antagonists that consists of at least one hour of approved continuing education on the use of naloxone hydrochloride.
- (d) The board and the Medical Board of California are each authorized to ensure compliance with this section. Each board is specifically charged with enforcing this section with respect to its respective licensees. This section does not expand the authority of a pharmacist to prescribe any prescription medication.
- (e) The board may adopt emergency regulations to establish the standardized procedures or protocols. The adoption of regulations pursuant to this subdivision shall be deemed to be an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. The emergency regulations authorized by this subdivision are exempt from review by the Office of Administrative Law. The emergency regulations authorized by this subdivision shall be submitted to the Office of Administrative Law for filing with the Secretary of State and shall remain in effect until the earlier of 180 days following their effective date or the effective date of regulations adopted pursuant to subdivision (a).

On behalf of the Board of Pharmacy, we look forward to collaborating with the Medical Board and moving forward with these protocols.

Attachment 1

Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraception

(a) A pharmacist furnishing self-administered hormonal contraception pursuant to Section 4052.3 of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraception

(1) Authority: Section 4052.3(a)(1) of the California Business and Professions code authorizes a pharmacist to furnish self-administered hormonal contraceptives in accordance with a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol in this section satisfies that requirement.

(2) Purpose: To provide timely access to self-administered hormonal contraception medication and to ensure that the patient receives adequate information to successfully comply with therapy.

(3) Definition of Self-Administered Hormonal Contraception: Hormonal contraception products with the following routes of administration are considered self-administered:

- Oral;
- Transdermal;
- Vaginal;
- Depot Injection.

(4) Procedure: When a patient requests self-administered hormonal contraception, the pharmacist shall complete the following steps:

- Ask the patient to use and complete the self-screening tool;
- Review the self-screening answers and clarify responses if needed;
- Measure and record the patient's seated blood pressure if combined hormonal contraceptives are requested or recommended.
- Before furnishing self-administered hormonal contraception, the pharmacist shall ensure that the patient is properly and appropriately trained in administration of the requested or recommended contraceptive medication.
- When a self-administered hormonal contraceptive is furnished, the patient shall be provided with appropriate counseling and information on the product furnished, including:
 - Dosage;
 - Effectiveness;
 - Potential side effects;
 - Safety;
 - The importance of receiving recommended preventative health screenings;
 - That self-administered hormonal contraception does not protect against sexually transmitted infections (STIs).

(5) Self-Screening Tool: The pharmacist shall provide the patient with a self-screening tool containing the list of questions specified in this protocol. The patient shall complete the self-screening tool, and the pharmacist shall use the answers to screen for all Category 3 and 4 conditions and characteristics for self-administered hormonal contraception from the current United States Medical Eligibility Criteria for Contraceptive Use (USMEC) developed by the federal Centers for Disease Control and Prevention (CDC). The patient shall complete the self-screening tool annually, or whenever the patient indicates a major health change.

A copy of the most recently completed self-screening tool shall be securely stored within the originating pharmacy for a period of at least three years from the date when the last self-administered hormonal contraception product was furnished.

This self-screening tool should be made available in alternate languages for patients whose primary language is not English.

(6) Fact Sheet: The pharmacist shall provide the patient with the FDA-required patient product information leaflet included in all self-administered hormonal contraception products, as required by the Business and Professions code Section 4052.3(c). The pharmacist shall review any questions the patient may have regarding self-administered hormonal contraception.

Pharmacists are encouraged to provide the patient with a copy of the current consumer-friendly birth control guide, and method-specific factsheet from the Association of Reproductive Professionals, all available on the Board of Pharmacy's website.

(7) Follow-Up Care: Upon furnishing a self-administered hormonal contraceptive, or if it is determined that use of a self-administered hormonal contraceptive is not recommended, the pharmacist shall refer the patient for appropriate follow-up care to the patient's primary care provider or, if the patient does not have a primary care provider, to nearby clinics. A patient who is determined not to be an appropriate candidate for self-administered hormonal contraceptive shall be advised of the potential risk and referred to an appropriate health care provider for further evaluation.

(8) Notifications: The pharmacist shall notify the patient's primary care provider of any drug(s) or device(s) furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with a written record of the drug(s) or device(s) furnished and advise the patient to consult a physician of the patient's choice.

(9) Referrals and Supplies: If self-administered hormonal contraception services are not immediately available at the pharmacy or the pharmacist declines to furnish pursuant to conscience clause, the pharmacist shall refer the patient to another self-administered hormonal contraception provider. The pharmacist shall comply with all state mandatory reporting laws, including sexual abuse laws.

(10) Product Selection: The pharmacist may select any hormonal contraceptive listed in the current version of the USMEC as Category 1 or 2, based on the information reported in the self-screening tool and the blood pressure if recorded by the pharmacist. The USMEC shall be kept current and maintained in the pharmacy. Furthermore, generic equivalent products may be furnished.

(11) Documentation: Each self-administered hormonal contraceptive furnished by a pharmacist pursuant to this protocol shall be documented in a patient medication record and securely stored within the originating pharmacy for a period of at least three years from the date when the last self-administered hormonal contraceptive was furnished. A patient medication record shall be maintained in an automated data processing or manual record mode such that the required information under title 16, sections 1717 and 1707.1 of the California Code of Regulations is readily retrievable during the pharmacy's normal operating hours.

(12) Training: Prior to furnishing self-administered hormonal contraception, pharmacists who participate in this protocol must have completed a minimum of one hour of a Board-approved continuing education program specific to self-administered hormonal contraception, application of the USMEC, and other CDC guidance on contraception. An equivalent curriculum-based training program completed on or after the year 2010 in a California School of Pharmacy is also sufficient training to participate in this protocol.

(13) Patient Privacy: All pharmacists furnishing self-administered hormonal contraception in a pharmacy shall operate under the pharmacy's policies and procedures to ensure that patient confidentiality and privacy are maintained.

(14) Self-Screening Tool Questions

HORMONAL CONTRACEPTION SELF-SCREENING TOOL QUESTIONS

1	What was the first date of your last menstrual period?	/ /	
2	Have you ever taken birth control pills, or used a birth control patch, ring, or shot/injection? (If no, go to question 3)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	Did you ever experience a bad reaction to using hormonal birth control?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	Are you currently using birth control pills, or a birth control patch, ring, or shot/injection?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
3	Have you ever been told by a medical professional not to take hormones?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
4	Do you smoke cigarettes?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
5	Do you think you might be pregnant now?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
6	Have you given birth within the past 6 weeks?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
7	Are you currently breastfeeding an infant who is less than 1 month of age?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
8	Do you have diabetes?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
9	Do you get migraine headaches, or headaches so bad that you feel sick to your stomach, you lose the ability to see, it makes it hard to be in light, or it involves numbness?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
10	Do you have high blood pressure, hypertension, or high cholesterol?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
11	Have you ever had a heart attack or stroke, or been told you had any heart disease?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
12	Have you ever had a blood clot in your leg or in your lung?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
13	Have you ever been told by a medical professional that you are at a high risk of developing a blood clot in your leg or in your lung?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
14	Have you had bariatric surgery or stomach reduction surgery?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
15	Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
16	Do you have or have you ever had breast cancer?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
17	Do you have or have you ever had hepatitis, liver disease, liver cancer, or gall bladder disease, or do you have jaundice (yellow skin or eyes)?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
18	Do you have lupus, rheumatoid arthritis, or any blood disorders?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
19	Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	If yes, list them here:		
20	Do you have any other medical problems or take regular medication?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	If yes, list them here:		

Note: Authority cited: Section 4052.3, Business and Professions Code. Reference: Section 4052(a)(10), Business and Professions Code.

December 16, 2014

Protocol Sources

Centers for Disease Control and Prevention, "United States Medical Eligibility Criteria for Contraceptive Use," (2010) *available at*

<http://www.cdc.gov/reproductivehealth/unintendedpregnancy/USMEC.htm>.

This resources serves as the basis for which self-administered hormonal contraception medications from which a pharmacist may select.

Centers for Disease Control and Prevention, "U.S. Selected Practice Recommendations for Contraceptive Use, 2013," *available at*

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6205a1.htm>.

This document from the CDC offers guidance on how to use contraceptive methods most effectively. It is adapted from a World Health Organization (WHO) publication, and endorsed by the American College of Obstetricians and Gynecologists (ACOG).

S. Shotorbani, et al., "Agreement Between Women's and Providers' Assessment of Hormonal Contraceptive Risk Factors," 73 CONTRACEPTION 501, 501-506 (2006).

This article provided a Medical History Questionnaire that was used in the development of the protocol's self-assessment tool. The article's research found 96% agreement between women's self-administered risk factor questionnaire and their providers' evaluation of their medical eligibility for hormonal contraceptive use.

CPhA/CSHP, "Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraceptives."

This draft protocol was consulted in development of the Board's recommended protocol.

Food and Drug Administration Office of Women's Health, "HPV, HIV, Birth Control" (last updated June 24, 2014), *available at*

<http://www.fda.gov/ForConsumers/ByAudience/ForWomen/WomensHealthTopics/ucm117971.htm>

This site contains a consumer-friendly birth control guide recommended for patient education.

Office on Women's Health, U.S. Department of Health and Human Services, "Birth Control Methods" (last updated Nov. 21, 2011), *available at*

<http://www.womenshealth.gov/publications/our-publications/fact-sheet/birth-control-methods.pdf>.

This fact sheet was consulted in development of the Board's recommended fact sheet.

Division of Reproductive Health, Centers for Disease Control and Prevention, "Contraception" (last updated Oct. 14, 2014),

<http://www.cdc.gov/reproductivehealth/unintendedpregnancy/contraception.htm>.

This website, especially the chart, is recommended as a resource for pharmacists choosing to provide additional user-friendly information on various birth control methods.

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The American College of Obstetricians and Gynecologists, "Birth Control - Especially for Teens," FAQ112 (Dec. 2013), *available at* <http://www.acog.org/Patients/FAQs/Birth-Control-Especially-for-Teens>.

This fact sheet was consulted in development of the Board's recommended fact sheet.

J. McIntosh et al., "Changing Oral Contraceptives from Prescription to Over-the-Counter Status: An Opinion Statement of the Women's Health Practice and Research Network of the American College of Clinical Pharmacy," *Pharmacotherapy* Vol. 31, Number 4, 424-437 (2011).

This opinion paper discusses pharmacist training on page 432. Both pharmacists and pharmacy students generally expressed interest in more education specifically on appropriate product selection.

Fatim Lakha, et al., "The Acceptability of Self-Administration of Subcutaneous Depo-Provera," 72 *CONTRACEPTION* 14-18 (2005).

This research finds that subcutaneous self-injectable hormonal contraception is beneficial for many women with appropriate training and reminder system.

Nicole J. Monastersky Maderas & Sharon Cohen Landau, "Pharmacy and Clinic Partnerships To Expand Access to Injectable Contraception," 47 *J. AM. PHARM. ASSOC.* 527-531 (2007).

This research finds that pharmacy reinjection of contraception is a viable option for many women, and is most successful when combined with primary care provider support and integration.

Sujatha Prabhakaran & Ashley Sweet, "Self-Administration of Subcutaneous Depot Medroxyprogesterone Acetate for Contraception: Feasibility and Acceptability," 85 *CONTRACEPTION* 453-457 (2012).

This research article finds that self-administration injections were easy and convenient for women with training from two Planned Parenthood health centers.

Sharon T. Cameron, et al., "Pilot Study of Home Self-Administration of Subcutaneous Depo-Medroxyprogesterone Acetate for Contraception," 85 *CONTRACEPTION* 458-464 (2012).

This research concludes that self-administration is feasible and has similar continuation and satisfaction rates to clinician-administration injections.

Rebekah L. Williams, et al., "Self-Administration of Subcutaneous Depot Medroxyprogesterone Acetate by Adolescent Women," 88 *CONTRACEPTION* 401-407 (2013).

This research concludes that many adolescents are interested in and capable of self-administration with brief education and minimal assistance.

S. Vinker, et al., "The Effect of Drug Information Leaflets on Patient Behavior," *ISR. MED. ASSOC. J.* 9(5) 383-4386 (May 2007).

This research concludes that reading the leaflet did not greatly affect adherence but aroused anxiety and decreased adherence in some patients.





















21 C.F.R §§ 201 “Labeling,” *available at*
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=201>.
These FDA regulations require manufacturers to include comprehensive patient leaflets in both prescription-only and OTC products.

21 C.F.R. § 310.501 “Patient Package Inserts for Oral Contraceptives,” (Apr. 1, 2014),
available at
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=310.501>.
These FDA regulations are specific to leaflet requirements for oral contraceptives.

Most Effective



Least Effective

Methods	Number of pregnancies expected per 100 women*	Use	Some Risks
 Sterilization Surgery for Women	less than 1	Onetime procedure Permanent	<ul style="list-style-type: none">• Pain• Bleeding• Infection or other complications after surgery• Ectopic (tubal) pregnancy
 Surgical Sterilization Implant for Women	less than 1	Onetime procedure Waiting period before it works Permanent	<ul style="list-style-type: none">• Mild to moderate pain after insertion• Ectopic (tubal) pregnancy
 Sterilization Surgery for Men	less than 1	Onetime procedure Waiting period before it works Permanent	<ul style="list-style-type: none">• Pain• Bleeding• Infection
 Implantable Rod	less than 1	Inserted by a healthcare provider Lasts up to 3 years	<ul style="list-style-type: none">• Changes in bleeding patterns• Weight gain• Breast and abdominal pain
 IUD Copper	less than 1	Inserted by a healthcare provider Lasts up to 10 years	<ul style="list-style-type: none">• Cramps• Bleeding• Pelvic inflammatory disease• Infertility• Tear or hole in the uterus
 IUD w/ Progestin	less than 1	Inserted by a healthcare provider Lasts up to 3-5 years, depending on the type	<ul style="list-style-type: none">• Irregular bleeding• No periods• Abdominal/pelvic pain• Ovarian cysts
 Shot/Injection	6	Need a shot every 3 months	<div><ul style="list-style-type: none">• Bone loss• Bleeding between periods• Weight gain<ul style="list-style-type: none">• Nervousness• Abdominal discomfort• Headaches</div>
 Oral Contraceptives (Combined Pill) "The Pill"	9	Must swallow a pill every day	<div><ul style="list-style-type: none">• Nausea• Breast Tenderness• Headache<ul style="list-style-type: none">• Rare: high blood pressure, blood clots, heart attack, stroke</div>
 Oral Contraceptives (Progestin only) "The MiniPill"	9	Must swallow a pill every day	<div><ul style="list-style-type: none">• Irregular bleeding• Headache• Breast tenderness<ul style="list-style-type: none">• Nausea• Dizziness</div>
 Oral Contraceptives Extended/Continuous Use "The Pill"	9	Must swallow a pill every day.	<ul style="list-style-type: none">• Risks are similar to other oral contraceptives (combined)• Light bleeding or spotting between periods
 Patch	9	Put on a new patch each week for 3 weeks (21 total days). Don't put on a patch during the fourth week.	<ul style="list-style-type: none">• Exposure to higher average levels of estrogen than most oral contraceptives
 Vaginal Contraceptive Ring	9	Put the ring into the vagina yourself. Keep the ring in your vagina for 3 weeks and then take it out for one week.	<ul style="list-style-type: none">• Vaginal discharge• Discomfort in the vagina• Mild irritation• Risks are similar to oral contraceptives (combined)
 Diaphragm with Spermicide	12	Must use every time you have sex.	<div><ul style="list-style-type: none">• Irritation• Allergic reactions<ul style="list-style-type: none">• Urinary tract infection• Toxic shock</div>
 Sponge with Spermicide	12-24	Must use every time you have sex.	<div><ul style="list-style-type: none">• Irritation• Allergic reactions<ul style="list-style-type: none">• Hard time removing• Toxic shock</div>
 Cervical Cap with Spermicide	17-23	Must use every time you have sex.	<div><ul style="list-style-type: none">• Irritation• Allergic reactions<ul style="list-style-type: none">• Abnormal Pap test• Toxic shock</div>
 Male Condom	18	Must use every time you have sex. <small>Except for abstinence, latex condoms are the best protection against HIV/AIDS and other STIs.</small>	<ul style="list-style-type: none">• Allergic reactions
 Female Condom	21	Must use every time you have sex. <small>May give some protection against STIs.</small>	<ul style="list-style-type: none">• Irritation• Allergic reactions
 Spermicide Alone	28	Must use every time you have sex.	<ul style="list-style-type: none">• Irritation• Allergic reactions• Urinary tract infection
Emergency Contraception — If your primary method of birth control fails			
 Plan B One Step Next Choice	7 out of every 8 women who would have gotten pregnant will not become pregnant after taking Plan B, Plan B One-Step, or Next Choice	Swallow the pills within 3 days after having unprotected sex.	<div><ul style="list-style-type: none">• Nausea• Vomiting• Abdominal pain<ul style="list-style-type: none">• Fatigue• Headache</div>
 Ella	6 or 7 out of every 10 women who would have gotten pregnant will not become pregnant after taking Ella.	Swallow the pill within 5 days after having unprotected sex.	<div><ul style="list-style-type: none">• Headache• Nausea• Abdominal pain<ul style="list-style-type: none">• Menstrual pain• Tiredness• Dizziness</div>

*effectiveness of the different methods during typical/actual use (including sometimes using a method in a way that is not correct or not consistent) <http://www.fda.gov/birthcontrol>

ASUNTOS DE SALUD

Preguntas frecuentes sobre el parche anticonceptivo

¿Qué es el parche anticonceptivo?

El parche anticonceptivo es un parche hormonal semanal muy efectivo que se pone sobre la piel para prevenir el embarazo. El parche se usa por una semana y se cambia siempre el mismo día cada semana durante tres semanas. La cuarta semana esta "libre de parche".

¿Que tan efectivo es el parche anticonceptivo?

El parche anticonceptivo es 99 por ciento efectivo cuando se usa correctamente.

¿Cómo previene el embarazo el parche anticonceptivo?

El parche anticonceptivo previene el embarazo de la misma forma que las píldoras anticonceptivas. Funciona principalmente previniendo la ovulación, o que el ovario no libera un óvulo que pueda ser fertilizado. El parche también causa cambios en el moco cervical (haciendo más difícil para que el espermatozoide entre en el útero).

¿Dónde puedo usar el parche anticonceptivo?

Usted puede usar el parche en una de las siguientes cuatro áreas de su cuerpo: las nalgas o caderas, el abdomen, la parte superior del tronco (pecho y espalda, excluyendo los senos o pechos) o en la parte superior externa del brazo. Usted no debería colocar el parche sobre piel que esté roja, irritada o tenga alguna cortada. No debería colocarlo en áreas de su cuerpo donde se vaya a aplicar maquillaje, lociones, cremas, polvos u otros productos.

¿Como se mantiene pegado el parche?

El parche anticonceptivo tiene una capa que contiene tanto la medicina como un adhesivo que mantiene el parche pegado a la piel durante una semana entera.

¿Cuáles son los beneficios de usar el parche anticonceptivo?

Mujeres que usan el parche anticonceptivo pueden beneficiarse en tener un periodo mas liviano y menos doloroso. El parche anticonceptivo puede proteger contra algunos cánceres y enfermedades de los senos.

¿Quien no debe de usar el parche anticonceptivo?

Algunas mujeres no deben de usar el parche anticonceptivo, incluyendo mujeres que tengan cuagulos de sangre, ciertos cánceres, o que tengan antecedentes de ataques del corazon o de cerebro, y aquellas mujeres que podrian estar embarazadas.

¿Cuáles son las desventajas?

Algunas mujeres usando el parche anticonceptivo pueden sentir leves dolores en los senos, dolor de cabeza, y reacciones dermatologicas en el lugar donde ha colocado el parche. La mayoría de efectos secundarios no son serios, y los que son, no son muy comunes. La prevención de un embarazo no planeado con anticonceptivos aprobados

por el FDA es mas sano que un parto or el aborto. Fumar cigaros aumenta los riesgos seriamente.

Algunas drogas pueden hacer los anticonceptivos hormonales, incluyendo el parche anticonceptivo, menos efectivos. Al igual que con cualquier otro producto pharmaceutico, usted debe informar su proveedor o proveedora de la salud de cualquier otro medicamento que usted este tomando. Es posible que usted tenga que usar un anticonceptivo adicional como el condón, espermicida, o diafragma si usted toma medicamentos que pueden reducir la efectividad del parch anticonceptivo.

¿Dónde puedo conseguir el parch anticonceptivo?

Un proveedor or proveedora de servicios de salud (doctor o doctora, enfermera o asistente médico) te puede dar una receta para el parche anticonceptivo.

HEALTH MATTERS

Frequently Asked Questions About the Contraceptive Patch

What is the contraceptive patch?

The contraceptive patch is a highly effective, weekly hormonal birth control patch that is worn on the skin to prevent pregnancy. The patch is worn for one week and replaced on the same day of the week for three consecutive weeks, with the fourth week "patch-free." Your menstrual period should start during the "patch-free" week. The contraceptive patch available in the United States is called OrthoEvra®.

How effective is contraceptive patch?

The contraceptive patch is 99 percent effective when used correctly.

How does it work?

The contraceptive patch prevents pregnancy the same way that birth control pills do. It works primarily by preventing the ovary from releasing an egg to be fertilized. The patch also causes changes to the cervical mucus (making it more difficult for sperm to enter the uterus).

The contraceptive patch keeps you from becoming pregnant by delivering hormones (norelgestromin and ethinyl estradiol) through the skin and into the bloodstream. This is called transdermal administration.

Where can I wear the contraceptive patch?

You can wear the contraceptive patch on one of four areas of the body: your buttocks, abdomen, upper torso (front and back, excluding the breasts), or upper outer arm. The patch should not be worn on any other areas of the body. You should not place the patch on skin that is red, irritated, or cut. You should not place it on areas of your skin where makeup, lotions, creams, powders, or other products are or will be applied.

How does the patch stay on?

The contraceptive patch has a layer containing both the medication and an adhesive that keeps the patch on the skin for an entire week. The patch adheres well to the skin, allowing you to perform your daily activities such as bathing, showering, swimming, and exercising without interruption.

What are the benefits of using the contraceptive patch?

Women who use the contraceptive patch are likely to have lighter and less painful periods. The contraceptive patch may protect against some cancers and breast disease.

Who should not use the contraceptive patch?

Some women should not use the contraceptive patch, including women who have blood clots, certain cancers, or a history of heart attack or stroke, as well as those who are or may be pregnant.

What are the downsides?

Some women using the contraceptive patch experience breast tenderness, headache, and reactions at the application. Most side effects are not serious, and those that are, are very rare. Prevention of an unintended pregnancy with FDA-approved contraceptives is always safer than childbirth or abortion. Serious risks are increased if you smoke cigarettes.

Certain drugs may interact with hormonal birth control, including the contraceptive patch, to make them less effective in preventing pregnancy. As with all prescription products, you should tell your health care professional about any other medications you are taking. You may need to use a non-hormonal backup contraceptive, such as a condom, spermicide, or diaphragm, when you take drugs that can make the contraceptive patch less effective.

Where can I get the contraceptive patch?

A trained health care professional (including doctors, nurses, and nurse midwives) can provide you with the contraceptive patch.

ASUNTOS DE SALUD

Las píldoras anticonceptivas

¿Qué son las píldoras anticonceptivas?

Las píldoras anticonceptivas son una medicina que tomas todos los días para prevenir el embarazo. A veces se les llama “la píldora” o anticonceptivos orales. La mayoría de mujeres que usan la píldora toman “píldoras combinadas”. Estas contienen dos hormonas —estrógeno y progestina—.

Alguna píldoras anticonceptivas contienen solo una hormona, la progestina. Estas son llamadas a veces “mini píldoras”. Las píldoras solo de progestina son buenas para las mujeres que no pueden usar el estrógeno.

¿Qué tan efectivas son las píldoras anticonceptivas?

Si las píldoras anticonceptivas se usan correctamente siempre, menos de 1 de cada 100 mujeres que las usen quedará embarazada cada año. Si no siempre se usan correctamente, 8 de cada 100 mujeres que las usen quedarán embarazadas cada año.

Las píldoras anticonceptivas funcionan mejor si las tomas a la misma hora todos los días. Puedes encontrar que te ayude tomar la píldora cuando hagas algo más cada día —como cepillarte los dientes o cenar—. Esto es muy importante con la píldora solo de progestina.

Cuando comiences a tomar la píldora, esta puede tomar varios días para comenzar a funcionar. Asegúrate de usar un anticonceptivo de respaldo (como un condón) durante los primeros 7 días de la píldora combinada o 2 días de la píldora solo de progestina.

¿Cómo funcionan?

Las hormonas en la píldora impiden que tus ovarios liberen óvulos y espesan tu moco cervical para impedir que el esperma entre al útero.

¿Cuáles son los beneficios del uso de las píldoras anticonceptivas?

- Las píldoras anticonceptiva son seguras, convenientes y muy efectivas.
- No tienes que pensar en el control de la natalidad cada vez que tengas relaciones sexuales.
- La mayoría de mujeres pueden quedar embarazadas rápidamente cuando dejan de usar la píldora.
- Tus menstruaciones puede hacerse más ligeras y menos dolorosas si tomas la píldora.
- Las hormonas en las píldoras ofrecen beneficios a la salud. La píldora puede ofrecer cierta protección contra el acné, los tumores no cancerosos del pecho, el embarazo ectópico, los cánceres endometrial y ovárico, la anemia por deficiencia de hierro, los quistes en los ovarios, la enfermedad inflamatoria pélvica, los síntomas del síndrome premenstrual y las migrañas relacionadas con la menstruación.

¿Cuáles son los aspectos negativos del uso de las píldoras anticonceptivas?

- Las píldoras anticonceptivas no protegen contra las infecciones de transmisión sexual (ITS).

- Necesitas una receta para obtener las píldoras anticonceptivas. Esto requiere una visita a tu proveedor de atención a la salud.
- Algunas mujeres pueden tener efectos secundarios al uso de las píldoras anticonceptivas. Estos incluyen sangrado entre las menstruaciones, sensibilidad en los pechos y náusea. Algunos de los efectos más comunes solo duran los primeros meses.
- Es fácil olvidarse de tomar la píldora todos los días. Podrías necesitar usar anticoncepción de respaldo o tomar anticoncepción de emergencia si te olvidas de tomar una píldora o la tomas tarde. Asegúrate de hablar con tu proveedor de atención a la salud si te olvidas de tomar alguna píldora.
- Mujeres con ciertas condiciones de salud no deberían usar píldoras combinadas. Tu proveedor de atención a la salud te ayudará a decidir si la píldora es apropiada para ti.

¿Dónde puedo obtener las píldoras anticonceptivas?

Un proveedor de atención a la salud puede darte una receta para las píldoras anticonceptivas. Las puedes comprar con una receta en una farmacia, un centro de salud o una clínica.

¿Dónde puedo obtener más información?

Para mayor información sobre las píldoras anticonceptivas, habla con tu proveedor de atención a la salud.

Compara las píldoras anticonceptivas con otras opciones anticonceptivas y ve un corto video sobre cada método, en inglés o en español, en Method Match de ARHP (www.arhp.org/MethodMatch).

HEALTH MATTERS

Birth Control Pills

What are birth control pills?

Birth control pills are a medication you take every day to prevent pregnancy. They are sometimes called “the pill” or oral contraception. Most women using the pill take “combination pills.” These contain two hormones - estrogen and progestin.

Some birth control pills contain only one hormone - progestin. These are sometimes called “mini-pills”. Progestin-only pills are good for women who cannot use estrogen.

How effective are birth control pills?

If birth control pills are always used correctly, less than 1 out of 100 women using them will get pregnant each year. If they are not always used correctly, 8 out of 100 women using them will get pregnant each year.

Birth control pills work best if you take them at the same time every day. You might find it helpful to take the pill when you do something else every day — like brushing your teeth or eating dinner. This is very important with the progestin-only pill.

When you first start the pill, it takes several days to begin working. Be sure to use backup birth control (like a condom) for the first 7 days on the combination pill or 2 days with the progestin-only pill.

How do they work?

The hormones in the pill keep your ovaries from releasing eggs and thicken your cervical mucus to block sperm from getting into the uterus.

What are the benefits of using birth control pills?

- Birth control pills are safe, convenient, and very effective.
- You don’t have to think about birth control each time you have sex.
- Most women can get pregnant quickly when they stop using the pill.
- Your periods may become lighter and less painful if you take the pill.
- The hormones in pills offer health benefits. The pill can offer some protection against acne, non-cancerous breast growths, ectopic pregnancy, endometrial and ovarian cancers, iron deficiency anemia, ovarian cysts, pelvic inflammatory disease, PMS symptoms, and menstrually-related migraine headaches.

What are the downsides of using birth control pills?

- Birth control pills do not protect against sexually transmitted infections (STIs).
- You need a prescription to get birth control pills. This requires a visit to a health care provider.
- Some women may have side effects while using birth control pills. They include bleeding between periods, breast tenderness, and nausea. Some of the most common side effects only last for the first few months.

- It is easy to forget to take the pill every day. You may need to use backup birth control or take emergency contraception if you miss a pill or take it late. Make sure to talk with your health care provider if you miss any pills.
- Women with certain health conditions should not use combination pills. Your healthcare provider will help you decide if the pill is right for you.

Where can I get birth control pills?

A health care provider can give you a prescription for birth control pills. You can purchase birth control pills at a drugstore, health center, or clinic with a prescription.

Where can I get more information?

For more information on the birth control pill, talk to your health care provider.

Compare the pill to other birth control options using ARHP's Method Match at www.arhp.org/MethodMatch.

ASUNTOS DE SALUD

La inyección anticonceptiva

www.arhp.org/healthmatters

Health Matters es una publicación de ARHP para el público general que presenta un breve repaso de datos sobre varios temas con relación a la salud reproductiva.

¿Qué es la inyección?

La inyección anticonceptiva es una inyección de una hormona llamada progestina. Cada inyección previene el embarazo por aproximadamente tres meses.

¿Qué tan efectiva es la inyección?

La inyección anticonceptiva es muy efectiva. Si se usa correctamente siempre, menos de 1 de cada 100 mujeres quedarán embarazadas usando la inyección. Si no siempre se usa correctamente, 3 de cada 100 mujeres quedarán embarazadas cada año usando la inyección.

Cuando comiences a usar la inyección, esta toma varios días para comenzar a funcionar. Usa otra forma de anticoncepción de respaldo durante 7 días después que recibas la inyección.

¿Cómo funciona?

Un proveedor de atención a la salud te administrará la inyección en el brazo cada 12 semanas. La hormona en la inyección impide que tus ovarios liberen óvulos y espesa tu moco cervical para impedir que el espermatozoides entre al útero.

¿Cuáles son los beneficios del uso de la inyección?

- La inyección es segura, conveniente y muy efectiva.
- Si usas la inyección, no tienes que pensar en el control de la natalidad cada día o cada vez que tengas una relación sexual.
- La progestina en la inyección ofrece varios beneficios a la salud, incluyendo menos calambres menstruales y menstruaciones más ligeras, o ausentes del todo. También reduce el riesgo de enfermedad inflamatoria pélvica y cáncer endometrial.
- La inyección puede ser un buen método anticonceptivo para mujeres que no pueden usar el estrógeno.

¿Cuáles son los aspectos negativos del uso de la inyección?

- La inyección no protege contra las infecciones de transmisión sexual (ITS).
- Debes visitar a tu proveedor de atención a la salud cada 12 semanas.
- Algunas mujeres pueden tener efectos secundarios al usar la inyección. El sangrado irregular es el efecto secundario más común, especialmente en los primeros 6 a 12 meses. Otros efectos secundarios menos comunes incluyen cambios de apetito o aumento de peso, sensibilidad en los pechos y náusea y vómitos.
- Las mujeres que usan la inyección anticonceptiva pueden tener adelgazamiento temporal de los huesos. El crecimiento de los huesos comienza nuevamente cuando dejas de usar la inyección. Tú puedes ayudar a proteger tus huesos haciendo ejercicio regularmente y tomando suplementos de calcio y vitamina D.
- Las mujeres pueden quedar embarazadas al dejar de usar la inyección, pero esto puede tomar aproximadamente un año después de la última inyección.

- Mujeres con ciertas condiciones (cáncer del pecho, anorexia y uso de esteroides actuales o historia de los mismos) no deberían usar la inyección.

¿Dónde puedo obtener la inyección?

Un profesional de atención a la salud puede administrarte la inyección en un consultorio médico o una clínica.

¿Dónde puedo obtener más información?

Para mayor información sobre la inyección anticonceptiva, habla con tu proveedor de atención a la salud.

Compara la inyección con otras opciones anticonceptivas y ve un corto video sobre cada método, en inglés o en español, en Method Match de ARHP (www.arhp.org/MethodMatch).

What is the shot?

The birth control shot is an injection of a hormone called progestin. Each shot prevents pregnancy for about three months.

How effective is the shot?

The birth control shot is very effective. If always used correctly, less than 1 out of 100 women will get pregnant each year using the shot. If not always used correctly, 3 out of 100 women will get pregnant each year using the shot.

When you first start on the shot, it takes several days to begin working. Use a backup form of birth control for 7 days after you get the first shot.

How does it work?

A health care provider will give you the shot in your arm every 12 weeks. The hormone in the shot keeps your ovaries from releasing eggs and thickens your cervical mucus to block sperm from getting into the uterus.

What are the benefits of using the shot?

- The shot is safe, convenient, and very effective.
- If you use the shot, you don't have to think about birth control every day or each time you have sex.
- The progestin in the shot offers several health benefits, including fewer menstrual cramps, lighter or no periods. It also reduces the risk of pelvic inflammatory disease and endometrial cancer.
- The shot can be a good birth control method for women who cannot use estrogen.

What are the downsides of using the shot?

- The shot does not protect against sexually transmitted infections (STIs).
- You must visit your health care provider every 12 weeks.
- Some women may have side effects while using the shot. Irregular bleeding is the most common side effect, especially in the first 6 to 12 months. Other, less common, side effects include changes in appetite or weight gain, breast tenderness, and nausea and vomiting.
- Women who use the birth control shot may have temporary bone thinning. Bone growth begins again when you stop using the shot. You can help protect your bones by exercising regularly and getting extra calcium and vitamin D.
- Women can get pregnant after they stop using the shot, but it may take about a year after the last shot.
- Women with certain conditions (history of or current breast cancer, anorexia, and steroid use) should not use the shot.

Where can I get the shot?

A health care professional can give you the shot in a medical office or clinic.

Where can I get more information?

For more information on the birth control shot, talk to your health care provider.

Compare the shot to other birth control options using ARHP's Method Match at www.arhp.org/MethodMatch.

ASUNTOS DE SALUD

El anillo vaginal

¿Qué es el anillo vaginal?

El anillo vaginal es un pequeño anillo flexible que tú pones en tu vagina una vez al mes para prevenir el embarazo. El anillo es fácil de poner y un tamaño le queda a la mayoría de mujeres. El anillo contiene hormonas llamadas estrógeno y progestina. Estas son las mismas hormonas que tienen la mayoría de píldoras anticonceptivas.

¿Qué tan efectivo es el anillo vaginal?

Si se usa correctamente siempre, menos de 1 de cada 100 mujeres quedará embarazada usando el anillo. Si no siempre se usa correctamente, 8 de cada 100 mujeres quedarán embarazadas usando el anillo.

Cuando comienzas a usar el anillo, este toma varios días para comenzar a funcionar. Asegúrate de usar un anticonceptivo de respaldo (como un condón) durante los primeros siete días.

¿Cómo funciona?

Las hormonas en el anillo vaginal impiden que tus ovarios liberen óvulos y espesan tu moco cervical para impedir que el espermatozoides entre al útero.

Introduce el anillo en tu vagina. El anillo permanece en su lugar durante tres semanas seguidas. Tú lo extraes en la cuarta semana y tienes tu menstruación. Después de la semana de descanso, simplemente insertas un nuevo anillo y comienzas el ciclo de nuevo.

Si deseas, puedes saltarte la semana de descanso y mantener el anillo por cuatro semanas seguidas. Esto eventualmente hará que tus menstruaciones sean muy ligeras o desaparezcan del todo. Esto se llama anticoncepción de uso continuo. Si estás interesada en esta opción, habla con tu proveedor de atención a la salud.

Algunas veces el anillo puede salirse de la vagina al remover un tampón, al ir al baño o al tener relaciones sexuales. La mayoría de mujeres usan el anillo durante la relación sexual sin problemas y sin que lo sientan sus parejas. Si el anillo se sale o tú lo sacas, lávalo con agua tibia y pónelo de nuevo en las primeras tres horas.

¿Cuáles son los beneficios del uso del anillo vaginal?

- El anillo vaginal es seguro, conveniente y muy efectivo.
- Si usas el anillo, no tienes que pensar en el control de la natalidad cada día o cada vez que tengas una relación sexual.
- Muchas mujeres que usan el anillo, tienen menstruaciones más ligeras, más cortas y más regulares.
- La mayoría de mujeres pueden quedar embarazadas rápidamente después de dejar de usar el anillo.
- Las hormonas en el anillo ofrecen beneficios a la salud. El anillo puede ofrecer cierta protección contra el acné, los tumores no cancerosos del pecho, el embarazo ectópi-

co, los cánceres endometrial y ovárico, la anemia por deficiencia de hierro, los quistes en los ovarios, la enfermedad inflamatoria pélvica, los síntomas del síndrome premenstrual y las migrañas relacionadas con la menstruación.

¿Cuáles son los aspectos negativos del uso del anillo vaginal?

- El anillo vaginal no protege contra las infecciones de transmisión sexual (ITS).
- Para obtener el anillo necesitas visitar a tu proveedor de atención a la salud por una receta.
- Algunas mujeres pueden tener efectos secundarios al usar el anillo. Algunos de los efectos secundarios más comunes generalmente desaparecen a los dos o tres meses. Estos incluyen, sangrado entre menstruaciones, sensibilidad en los pechos y náusea y vómitos. El anillo también puede aumentar el flujo vaginal.
- Puede ser difícil recordar retirar el anillo después de las tres semanas e insertar un anillo nuevo después de la semana de descanso. Para ayudarte a recordar, puedes programar la alarma en tu teléfono celular y marcar la "fecha de cambio" en tu calendario.

- Mujeres con ciertas condiciones de salud no deberían usar el anillo. Tu proveedor de atención a la salud te puede ayudar a decidir si el anillo es apropiado para ti.
- Algunas drogas pueden interactuar con el anillo y hacerlo menos efectivo para prevenir el embarazo. Habla con tu proveedor de atención a la salud sobre cualquier medicina, con o sin receta, que estés tomando.

¿Dónde puedo obtener el anillo vaginal?

Tu proveedor de atención a la salud te mostrará como colocar y extraer el anillo y te dará una receta para reemplazos mensuales. Tú puedes comprar el anillo con una receta en una farmacia, un centro de salud o una clínica.

¿Dónde puedo obtener más información?

Para mayor información sobre el anillo vaginal, habla con tu proveedor de atención a la salud.

Compara el anillo vaginal con otras opciones anticonceptivas y ve un corto video sobre cada método, en inglés o en español, en Method Match de ARHP (www.arhp.org/MethodMatch).

HEALTH MATTERS

Vaginal Ring

www.arhp.org/healthmatters

What is the vaginal ring?

The vaginal ring is a small, flexible ring that you put into your vagina once a month to prevent pregnancy. The ring is easy to put in and one size fits most women. The ring contains hormones called estrogen and progestin. These are the same hormones that are in most birth control pills.

How effective is the vaginal ring?

If always used correctly, less than 1 out of 100 women will get pregnant each year using the ring. If not always used correctly, 8 out of 100 women will get pregnant each year using the ring.

When you first start using the ring, it takes several days to begin working. Be sure to use backup birth control (like a condom) for the first seven days.

How does it work?

The hormones in the vaginal ring keep your ovaries from releasing eggs and thicken your cervical mucus to block sperm from getting into the uterus.

Insert the ring into your vagina. The ring stays in place for three weeks straight. You take it out the fourth week and you have your period. After the week off, you simply insert a new ring and start the cycle again.

If you want to, you can skip the one week break and keep the ring in for four weeks straight. This will eventually make your period very light or disappear totally. This is called continuous-use contraception. If you are interested in this option, talk to your health care provider.

The ring can sometimes fall out of the vagina when removing a tampon, going to the bathroom, or having sex. Most women wear the ring during sex with no problems and without their partners feeling it. If the ring falls out or you remove it, rinse it with warm water and put it back in within three hours.

What are the benefits of using the vaginal ring?

- The vaginal ring is safe, convenient, and very effective.
- If you use the ring, you don't have to think about birth control every day or every time you have sex.
- Many women who use the ring have lighter, shorter, and more regular periods.
- Most women can get pregnant quickly after they stop using the ring.
- The hormones in the ring offer health benefits. The ring can offer some protection against acne, non-cancerous breast growths, ectopic pregnancy, endometrial and ovarian cancers, iron deficiency anemia, ovarian cysts, pelvic inflammatory disease, PMS symptoms, and menstrually-related migraine headaches.

What are the downsides of using the vaginal ring?

- The vaginal ring does not protect against sexually transmitted infections (STIs).
- Getting the ring requires a visit to a health care provider for a prescription.
- Some women may have side effects while using the ring. Some of the most common side effects usually go away after two or three months. They include bleeding between periods, breast tenderness, and nausea and vomiting. The ring may also increase vaginal discharge.
- It can be challenging to remember to remove the ring after three weeks and then insert a new ring after the one-week break. To help you remember, you may want to set the alarm on your cell phone and mark the "change date" on your calendar.
- Women with certain health conditions should not use the ring. Your healthcare provider will help you decide if the ring is right for you.
- Certain drugs may interact with the ring to make it less effective in preventing pregnancy. Talk with your health care provider about any over the counter or prescription medications you are taking

Where can I get the vaginal ring?

Your health care provider will show you how to insert and remove the ring and give you a prescription for monthly refills. You can purchase the ring at a drugstore, health center, or clinic with a prescription.

Where can I get more information?

For more information on the vaginal ring, talk to your health care provider.

Compare the ring to other birth control options using ARHP's Method Match at www.arhp.org/MethodMatch.

Attachment 2

Protocol for Pharmacists Furnishing Nicotine Replacement Products

(a) A pharmacist furnishing nicotine replacement products pursuant to Section 4052.9 of the Business and Professions code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Nicotine Replacement Products

(1) Authority: Section 4052.9(a) of the California Business and Professions code authorizes a pharmacist to furnish nicotine replacement products approved by the federal Food and Drug Administration for use by prescription-only in accordance with a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol in this section satisfies that requirement.

(2) Purpose: To provide timely access to nicotine replacement products and to ensure that the patient receives information to appropriately initiate smoking cessation medication therapy.

(3) Explanation of Products Covered: Nicotine replacement products approved by the federal Food and Drug Administration and prescribed by a pharmacist for smoking cessation are covered under this protocol.

(4) Procedure: When a patient requests nicotine replacement therapy or other smoking cessation medication, or when a pharmacist in his or her professional judgment decides to initiate smoking cessation treatment and counseling, the pharmacist shall complete the following steps:

- Review the patient's current tobacco use and past quit attempts.
- Ask the patient the following screening questions:
 - Are you pregnant or plan to be pregnant? (If yes, do not furnish and refer to an appropriate health care provider)
 - Have you had a recent heart attack within the last 2 weeks? (If yes, furnish with caution and refer to an appropriate health care provider)
 - Do you have any history of heart palpitations, irregular heartbeats, or have you been diagnosed with a serious arrhythmia? (If yes, furnish with caution and refer to an appropriate health care provider)
 - Do you currently experience frequent chest pain or have you been diagnosed with unstable angina? (If yes, furnish with caution and refer to an appropriate health care provider)
 - Do you have any history of allergic rhinitis (e.g., nasal allergies)? (If yes, avoid nasal spray)
 - Have you been diagnosed with temporal mandibular joint (TMJ) dysfunction? (If yes, avoid nicotine gum)
- When a nicotine replacement product is furnished:

- The pharmacist shall review the instructions for use with every patient using a nicotine replacement product.
- Pharmacists should recommend the patient seek additional assistance for behavior change, including but not limited to the California Smokers' Helpline (1-800-NO-BUTTS), web-based programs (e.g., <http://smokefree.gov>), apps, and local cessation programs.
- The pharmacist shall review any questions the patient may have regarding smoking cessation therapy and/or nicotine replacement products.

(5) Product Selection: Based on the information gathered from the patient during the Procedure outlined above, the pharmacist may select any nicotine replacement product (alone or in combination) from the list of therapies specified in this protocol in the Table "Nicotine Replacement Therapy Medications for Smoking Cessation." This list shall be kept current and maintained in the pharmacy. Furthermore, generic equivalent products may be furnished.

(6) Notifications: The pharmacist shall notify the patient's primary care provider of any prescription drug(s) and/or device(s) furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with a written record of the prescription drug(s) and/or device(s) furnished and advise the patient to consult an appropriate health care provider of the patient's choice.

(7) Documentation: Each nicotine replacement product prescribed for smoking cessation and furnished by a pharmacist pursuant to this protocol shall be documented in a patient medication record and securely stored within the originating pharmacy for a period of at least three years from the date when the last nicotine replacement product was furnished. A patient medication record shall be maintained in an automated data processing or manual record mode such that the required information under title 16, sections 1717 and 1707.1 of the California Code of Regulations is readily retrievable during the pharmacy's normal operating hours.

(8) Training: Prior to furnishing prescription nicotine replacement products, pharmacists who participate in this protocol must have completed a minimum of two hours of a Board-approved continuing education program specific to smoking cessation therapy and nicotine replacement therapy, or an equivalent curriculum-based training program completed on or after the year 2000 in a California School of Pharmacy.

Additionally, pharmacists who participate in this protocol must complete ongoing continuing education focused on smoking cessation therapy from a Board-approved provider once every two years.

(9) Patient Privacy: All pharmacists furnishing nicotine replacement products in a pharmacy shall operate under the pharmacy's policies and procedures to ensure that patient confidentiality and privacy are maintained.

10) Nicotine Replacement Therapy Medications for Smoking Cessation

Insert chart

Note: Authority cited: Section 4052.9, Business and Professions Code. Reference: Section 4052(a)(10), Business and Professions Code.

Protocol Sources

Centers for Disease Control and Prevention, "Quitting Smoking," *available at* http://www.cdc.gov/tobacco/data_statistics/fact_sheets/cessation/quitting/index.htm.
This resource describes the methods of quitting smoking and their effectiveness.

CPhA/CSHP, "Pharmacists Protocol for Dispensing Nicotine Replacement Products."
This draft protocol was consulted in development of the Board's recommended protocol.

Frank Vitale, "Brief Intervention Protocol for Assisting Patients with Tobacco Cessation," 64 AM. J. HEALTH-SYST PHARM. 2583 (2007).
This commentary provides important resources and specific dialogue for a pharmacists' procedure for assisting patients with tobacco cessation.

Nicole Van Hoey, "Opportunities for Smoking Cessation Services in Emerging Models of Care," *America's Pharmacist* (Oct. 2014).
This Continuing Education provided helpful referral resources, especially smartphone resources.

University of California, San Francisco, "Smoking Cessation Leadership Center," <http://smokingcessationleadership.ucsf.edu/>.
This site offers evidence-based resources for providers as well as continuing education opportunities in smoking cessation for CME and CEU credit.

University of California, San Francisco, "Rx for Change," <http://rxforchange.ucsf.edu/>.
This site offers evidence-based resources for providers and non-providers.

Accreditation Council for Pharmacy Education, "Basic Tobacco Intervention Workshop," P.L.A.N. Search Detail, *available at* <https://www.acpe-accredit.org/pwtool/plan/DetailResultsPLAN.aspx?progtype=1&id=267501&cosp=289079&fromdate=10/27/2014>.
This website shows ACPE-approved education involving smoking cessation.

Agency for Healthcare Research and Quality, "Treating Tobacco Use and Dependence: 2008—Clinical Practice Guideline," *available at*

December 16, 2014

<http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/tobacco/clinicians/index.html>.

This site provides tobacco reference materials and guides for health care providers.



NICOTINE REPLACEMENT THERAPY MEDICATIONS FOR SMOKING CESSATION

NICOTINE REPLACEMENT THERAPY (NRT) FORMULATIONS USED AS MONOTHERAPY						COMBINATION NRT
G		L	P	N S	I	
PRODUCT	Nicorette ¹ , Generic OTC 2 mg, 4 mg original, cinnamon, fruit, mint	Nicorette Lozenge, ¹ Nicorette Mini Lozenge, ¹ Generic OTC 2 mg, 4 mg cherry, mint	NicoDerm CQ ¹ , Generic OTC (NicoDerm CQ, generic) Rx (generic) 7 mg, 14 mg, 21 mg (24-hour release)	Nicotrol NS ² Rx Metered spray 0.5 mg nicotine in 50 mL aqueous nicotine solution	Nicotrol Inhaler ² Rx 10 mg cartridge delivers 4 mg inhaled nicotine vapor	Combinations with demonstrated efficacy Nicotine patch + nicotine gum Nicotine patch + nicotine lozenge Nicotine patch + nicotine nasal spray Nicotine patch + nicotine oral inhaler
PRECAUTIONS	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Temporomandibular joint disease Pregnancy³ and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Pregnancy³ and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Pregnancy³ (Rx formulations, category D) and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Underlying chronic nasal disorders (rhinitis, nasal polyps, sinusitis) Severe reactive airway disease Pregnancy³ (category D) and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Bronchospastic disease Pregnancy³ (category D) and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> See precautions for individual agents
DOSING	<p>1st cigarette ≤ 30 minutes after waking: 4 mg</p> <p>1st cigarette >30 minutes after waking: 2 mg</p> <p>Weeks 1–6: 1 piece q 1–2 hours</p> <p>Weeks 7–9: 1 piece q 2–4 hours</p> <p>Weeks 10–12: 1 piece q 4–8 hours</p> <ul style="list-style-type: none"> Maximum, 24 pieces/day Chew each piece slowly Park between cheek and gum when peppery or tingling sensation appears (~15–30 chews) Resume chewing when tingle fades Repeat chew/park steps until most of the nicotine is gone (tingle does not return; generally 30 min) Park in different areas of mouth No food or beverages 15 minutes before or during use Duration: up to 12 weeks 	<p>1st cigarette ≤ 30 minutes after waking: 4 mg</p> <p>1st cigarette >30 minutes after waking: 2 mg</p> <p>Weeks 1–6: 1 lozenge q 1–2 hours</p> <p>Weeks 7–9: 1 lozenge q 2–4 hours</p> <p>Weeks 10–12: 1 lozenge q 4–8 hours</p> <ul style="list-style-type: none"> Maximum, 20 lozenges/day Allow to dissolve slowly (20–30 minutes for standard; 10 minutes for mini) Nicotine release may cause a warm, tingling sensation Do not chew or swallow Occasionally rotate to different areas of the mouth No food or beverages 15 minutes before or during use Duration: up to 12 weeks 	<p>≥ 10 cigarettes/day: 21 mg/day x 4–6 weeks 14 mg/day x 2 weeks 7 mg/day x 2 weeks</p> <p>≤ 10 cigarettes/day: 14 mg/day x 6 weeks 7 mg/day x 2 weeks</p> <ul style="list-style-type: none"> May wear patch for 16 hours if patient experiences sleep disturbances (remove at bedtime) Duration: 8–10 weeks 	<p>1–2 doses/hour (8–40 doses/day) One dose = 2 sprays (one in each nostril); each spray delivers 0.5 mg of nicotine to the nasal mucosa</p> <ul style="list-style-type: none"> Maximum <ul style="list-style-type: none"> 5 doses/hour or 40 doses/day For best results, initially use at least 8 doses/day Do not sniff, swallow, or inhale through the nose as the spray is being administered Duration: 3–6 months 	<p>6–16 cartridges/day Individualize dosing: initially use 1 cartridge q 1–2 hours</p> <ul style="list-style-type: none"> Best effects with continuous puffing for 20 minutes Initially use at least 6 cartridges/day Nicotine in cartridge is depleted after 20 minutes of active puffing Inhale into back of throat or puff in short breaths Do NOT inhale into the lungs (like a cigarette) but “puff” as if lighting a pipe Open cartridge retains potency for 24 hours No food or beverages 15 minutes before or during use Duration: 3–6 months 	<p><u>Reserve for patients smoking ≥ 10 cigarettes/day:</u></p> <p>Long-acting NRT: to prevent onset of severe withdrawal symptoms</p> <ul style="list-style-type: none"> Nicotine patch 21 mg/day x 4–6 weeks 14 mg/day x 2 weeks 7 mg/day x 2 weeks <p>PLUS</p> <p>Short-acting NRT: used as needed to control breakthrough withdrawal symptoms and situational urges for tobacco</p> <ul style="list-style-type: none"> Nicotine gum (2 mg) 1 piece q 1–2 hours as needed OR Nicotine lozenge (2 mg) 1 lozenge q 1–2 hours as needed OR Nicotine nasal spray 1 spray in each nostril q 1–2 hours as needed OR Nicotine inhaler 1 cartridge q 1–2 hours as needed

	NICOTINE REPLACEMENT THERAPY (NRT) FORMULATIONS USED AS MONOTHERAPY					COMBINATION NRT
	GUM	LOZENGE	PATCH	NASAL SPRAY	INHALER	
ADVERSE EFFECTS	<ul style="list-style-type: none">▪ Mouth/jaw soreness▪ Hiccups▪ Dyspepsia▪ Hypersalivation▪ Effects associated with incorrect chewing technique:<ul style="list-style-type: none">– Lightheadedness– Nausea/vomiting– Throat and mouth irritation	<ul style="list-style-type: none">▪ Nausea▪ Hiccups▪ Cough▪ Heartburn▪ Headache▪ Flatulence▪ Insomnia	<ul style="list-style-type: none">▪ Local skin reactions (erythema, pruritus, burning)▪ Headache▪ Sleep disturbances (insomnia, abnormal/vivid dreams); associated with nocturnal nicotine absorption	<ul style="list-style-type: none">▪ Nasal and/or throat irritation (hot, peppery, or burning sensation)▪ Rhinitis▪ Tearing▪ Sneezing▪ Cough▪ Headache	<ul style="list-style-type: none">▪ Mouth and/or throat irritation▪ Cough▪ Headache▪ Rhinitis▪ Dyspepsia▪ Hiccups	<ul style="list-style-type: none">▪ See adverse effects listed for individual agents
ADVANTAGES	<ul style="list-style-type: none">▪ Might satisfy oral cravings▪ Might delay weight gain▪ Patients can titrate therapy to manage withdrawal symptoms▪ Variety of flavors are available	<ul style="list-style-type: none">▪ Might satisfy oral cravings▪ Might delay weight gain▪ Easy to use and conceal▪ Patients can titrate therapy to manage withdrawal symptoms▪ Variety of flavors are available	<ul style="list-style-type: none">▪ Provides consistent nicotine levels over 24 hours▪ Easy to use and conceal▪ Once daily dosing associated with fewer compliance problems▪ FDA-approved for use in combination with bupropion SR	<ul style="list-style-type: none">▪ Patients can titrate therapy to rapidly manage withdrawal symptoms	<ul style="list-style-type: none">▪ Patients can titrate therapy to manage withdrawal symptoms▪ Mimics hand-to-mouth ritual of smoking (could also be perceived as a disadvantage)	<ul style="list-style-type: none">▪ Provides consistent nicotine levels over 24 hours and patients can titrate therapy to manage withdrawal symptoms and situational urges for tobacco▪ Research studies suggest combination therapy provides a small, but meaningful increase in success rates compared to NRT monotherapy▪ Attractive option for patients who have previously failed treatment with NRT monotherapy▪ See advantages listed for individual agents
	<ul style="list-style-type: none">▪ Need for frequent dosing can compromise compliance▪ Might be problematic for patients with significant dental work▪ Proper chewing technique is necessary for effectiveness and to minimize adverse effects▪ Gum chewing may not be acceptable or desirable for some patients	<ul style="list-style-type: none">▪ Need for frequent dosing can compromise compliance▪ Gastrointestinal side effects (nausea, hiccups, heartburn) might be bothersome	<ul style="list-style-type: none">▪ When used as monotherapy, cannot be titrated to acutely manage withdrawal symptoms▪ Not recommended for use by patients with dermatologic conditions (e.g., psoriasis, eczema, atopic dermatitis)	<ul style="list-style-type: none">▪ Need for frequent dosing can compromise compliance▪ Nasal administration might not be acceptable or desirable for some patients; nasal irritation often problematic▪ Not recommended for use by patients with chronic nasal disorders or severe reactive airway disease	<ul style="list-style-type: none">▪ Need for frequent dosing can compromise compliance▪ Cartridges might be less effective in cold environments (≤60°F)	<ul style="list-style-type: none">▪ Increased cost of therapy▪ See disadvantages listed for individual agents

¹ Marketed by GlaxoSmithKline.

² Marketed by Pfizer.

³ The U.S. Clinical Practice Guideline states that pregnant smokers should be encouraged to quit without medication based on insufficient evidence of effectiveness and theoretical concerns with safety. Pregnant smokers should be offered behavioral counseling interventions that exceed minimal advice to quit.

Abbreviations: NRT, nicotine replacement therapy; OTC, over-the-counter (non-prescription product); Rx, prescription product.

For complete prescribing information, please refer to the manufacturers' package inserts.

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Attachment 3

Protocol for Pharmacists Furnishing Naloxone Hydrochloride

(a) A pharmacist furnishing naloxone hydrochloride pursuant to Section 4052.01 of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Naloxone Hydrochloride

(1) Authority: Section 4052.01(a) of the California Business and Professions Code authorizes a pharmacist to furnish naloxone hydrochloride in accordance with a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol in this section satisfies that requirement.

(2) Purpose: To provide access to naloxone hydrochloride via standardized procedures so that pharmacists may educate about and furnish naloxone hydrochloride to decrease harm from opioid¹ overdose.

(3) Procedure: When someone requests naloxone hydrochloride, or when a pharmacist in his or her professional judgment decides to advise of the availability and appropriateness of naloxone hydrochloride, the pharmacist shall complete the following steps:

- Screen for the following conditions:²
 - i. Whether the potential recipient³ currently uses or has a history of using illicit or prescription opioids—especially long acting or extended release opioids (If yes, skip question ii and continue with Procedure);
 - ii. Whether the potential recipient is in contact with anyone who uses or has a history of using illicit or prescription opioids—especially long acting or extended release opioids (If yes, continue with Procedure);
 - iii. Whether the person to whom the naloxone hydrochloride would be administered has a known hypersensitivity to naloxone? (If yes, do not furnish).
- Provide training in opioid overdose prevention, recognition, response, and administration of the antidote naloxone.
- When naloxone hydrochloride is furnished:
 - The pharmacist shall provide the recipient with appropriate counseling and information on the product furnished, including dosing, effectiveness, adverse effects, storage conditions, shelf-life, and safety. The recipient is not permitted to waive the required consultation.

¹ For purposes of this protocol, “opioid” is used generally to cover both naturally derived opiates and synthetic and semi-synthetic opioids.

² These screening questions shall be made available in alternate languages for patients whose primary language is not English.

³ For purposes of this protocol, “recipient” means the person to whom naloxone hydrochloride is furnished.

- The pharmacist shall provide the recipient with any informational resources on hand and/or referrals to appropriate resources if the recipient indicates interest in chemical dependency treatment, recovery services, or medication disposal resources at this time.
- The pharmacist shall answer any questions the recipient may have regarding naloxone hydrochloride.

(4) Product Selection: Naloxone hydrochloride may be supplied as an intramuscular injection, intranasal spray, and auto-injector. Other FDA approved products may be used. Those administering naloxone should choose the route of administration based on the formulation available, how well they can administer it, the setting, and local context.

(5) Suggested Kit Labeling:

Intramuscular	Intranasal	Auto-Injector
<p>Naloxone 0.4mg/1ml single dose vial, # 2 vials SIG: Inject 1 ml intramuscularly upon signs of opioid overdose. Call 911. May repeat x 1.</p> <p>Syringe 3ml 25G X 1” # 2 SIG: Use as directed for naloxone administration.</p> <p>Kit should contain 2 vials and 2 syringes.</p>	<p>2ml needleless syringe prefilled with naloxone (1mg/1ml concentration), # 2 syringes SIG: Spray one-half (1ml) of the naloxone into each nostril upon signs of opioid overdose. Call 911. May repeat x 1.</p> <p>Mucosal Atomization Device (MAD) # 2 SIG: Use as directed for naloxone administration.</p> <p>Kit should contain 2 prefilled needleless syringes and 2 atomizers.</p>	<p>Naloxone 0.4 mg/0.4 ml #1 twin pack SIG: Use one auto-injector upon signs of opioid overdose. Call 911. May repeat x 1.</p> <p>Kit is commercially available as a twin pack with directions for administration included.</p>

Optional items for the kits include alcohol pads, rescue breathing masks, and rubber gloves.

Kit labels shall include an expiration date for the naloxone hydrochloride furnished. An example of appropriate labeling is available on the Board of Pharmacy website.

(6) Fact Sheet: The pharmacist shall provide the recipient a copy of the current naloxone fact sheet approved by the Board of Pharmacy. This fact sheet shall be made available in alternate languages for patients whose primary language is not English.

(7) Notifications: If the recipient of the naloxone hydrochloride is also the person to whom the naloxone hydrochloride would be administered, then the naloxone recipient is considered a patient for purposes of this protocol and notification may be required under this section.

If the patient gives verbal or written consent, then the pharmacist shall notify the patient's primary care provider of any drug(s) and/or device(s) furnished, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the patient and that primary care provider.

If the patient does not have a primary care provider, or chooses not to give notification consent, then the pharmacist shall provide a written record of the drug(s) and/or device(s) furnished and advise the patient to consult an appropriate health care provider of the patient's choice.

(8) Documentation: Each naloxone hydrochloride product furnished by a pharmacist pursuant to this protocol shall be documented in a medication record for the naloxone recipient, and securely stored within the originating health care facility for a period of at least three years from the date of dispense. The medication record shall be maintained in an automated data processing or manual record mode such that the required information under title 16, sections 1717 and 1707.1 of the California Code of Regulations is readily retrievable during the facility's normal operating hours.

(9) Training: Prior to furnishing naloxone hydrochloride, pharmacists who participate in this protocol must have successfully completed a minimum of one hour of an approved continuing education program specific to the use of naloxone hydrochloride, or an equivalent curriculum-based training program completed in a board recognized school of pharmacy.

(10) Privacy: All pharmacists furnishing naloxone hydrochloride in a health care facility shall operate under the facility's policies and procedures to ensure that recipient confidentiality and privacy are maintained.

Note: Authority cited: Section 4052.01, Business and Professions Code.

Protocol Sources

Scott Burris, et al., "Stopping an Invisible Epidemic: Legal Issues in the Provision of Naloxone To Prevent Opioid Overdose," DREXEL L. REV. 1(2):273-339, 326 (2009).

This law review article recommends fostering naloxone distribution through pharmacies, and using EC statutes as a model.

Substance Abuse and Mental Health Services Administration, "Opioid Overdose Toolkit," available at <http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit-Updated-2014/SMA14-4742>.

This resource provides materials to develop policies to prevent opioid overdose.

The Network for Public Health Law, "Legal Interventions To Reduce Overdose Mortality: Naloxone Access and Overdose Good Samaritan Laws" (Aug. 2014), available at https://www.networkforphl.org/_asset/qz5pvn/naloxone-_FINAL.pdf.

This article describes naloxone access nationwide.

Harm Reduction Coalition, "Guide to Developing and Managing Overdose Prevention and Take-Home Naloxone Projects" (2012), available at <http://harmreduction.org/issues/overdose-prevention/tools-best-practices/manuals-best-practice/od-manual/>.

This manual outlines the process of developing an overdose prevention program, including with a take-home naloxone component.

Northeast Behavioral Health, "Opioid Overdose Prevention and Reversal via Peer-Administered Narcan" (2012), available at <http://harmreduction.org/wp-content/uploads/2012/02/od-train-the-trainer-parents.pdf>.

This PowerPoint presentation provides information to educate peers on opioid prevention and reversal.

CA Department of Health Care Services, "Pharmacist Protocol for Furnishing Naloxone for the Prevention of Opioid Overdose" (last updated Oct. 29, 2014).

This draft protocol was consulted in development of the Board's recommended protocol.

World Health Organization, "Community Management of Opioid Overdose" (2014).

This resource provides materials to develop policies to prevent opioid overdose.

Drug Policy Alliance, "What Is Naloxone?" (Aug. 2014), available at <http://www.drugpolicy.org/resource/what-naloxone>.

This fact sheet provides comprehensive information on naloxone.

Massachusetts Department of Health and Human Services, "Dispensing of Naloxone by Standing Order" (2014), available at <http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/dhpl/pharmacy/dispensing-of-naloxone-by-standing-order-.html>.

This site contains a pamphlet recommended as the base for the Board's factsheet.

N. Zaller, et al., "The Feasibility of Pharmacy-Based Naloxone Distribution Interventions: A Qualitative Study with Injection Drug Users and Pharmacy Staff in Rhode Island," 48 SUBST. USE MISUSE 8 (2013).

This research supports pharmacy-based naloxone intervention, but notes barriers including misinformation and costs.

Traci C. Green, et al., "Responding to Opioid Overdose in Rhode Island: Where the Medical Community Has Gone and Where We Need To Go," R.I. MED. J. 29-33 (Oct. 2014), *available at* <http://www.rimed.org/rimedicaljournal/2014/10/2014-10-29-dadt-green.pdf>.

This article gives an overview of opioid overdose, provides guidance resources, and emphasizes the importance of Good Samaritan Laws.