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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

SENATE BILL 493 IMPLEMENTATION COMMITTEE

For the Meeting of February 25, 2015

Stan Weisser, RPh, Board President and Committee Chair
Amy Gutierrez, Pharm D
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SB 493 creates a number of new opportunities for pharmacists to provide direct care to patients. There are essentially two levels of additional services authorized – one for all pharmacists, the second to create a new licensure category of advanced practice pharmacist to provide additional duties.

The board has formed this committee to implement the multiple requirements of SB 493. This committee, called simply the Senate Bill 493 Implementation Committee, will work on components to implement the multiple provisions of this bill. The meetings where these deliberations will occur are public, and will be listed on the board's website. We invite interested individuals to attend. The recent enactment of AB 1535 (Bloom) has directed the board to develop a naloxone protocol through an emergency rulemaking process. For expediency, this task has been added to the agenda of this committee.

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a. <u>Update: Requirements for Licensure as Advanced Practice Pharmacists</u>

Attachment 1

At the January 2015 Board Meeting, the board approved and moved to initiate a regulation rulemaking that specifies the ways and supporting documentation needed to qualify for registration as an advance practice pharmacist. Additionally a fee of $300 was selected as the application and renewal fee for this license. Board staff will very soon be noticing this language to initiate the rulemaking process.

As a review:
California Business and Professions Code section 4210 provides that applicants to:

Satisfy any two of the following criteria:
(A) Earn certification in a relevant area of practice, including, but not limited to, ambulatory care, critical care, geriatric pharmacy, nuclear pharmacy, nutrition support pharmacy, oncology pharmacy, pediatric pharmacy, pharmacotherapy, or psychiatric pharmacy, from an organization recognized by the Accreditation Council for Pharmacy Education or another entity recognized by the board.

(B) Complete a postgraduate residency through an accredited postgraduate institution where at least 50 percent of the experience includes the provision of direct patient care services with interdisciplinary teams.
(C) Have provided clinical services to patients for at least one year under a collaborative practice agreement or protocol with a physician, advanced practice pharmacist, pharmacist practicing collaborative drug therapy management, or health system.

The board's proposed regulation to qualify for this license is provided in **Attachment 1.**

Since the language has not yet been released, during this meeting, the committee may wish to discuss questions with the language. Any modification would need to be returned to the board for its review – fortunately, this can be scheduled for Board of Pharmacy Board Meeting on March 9.

b. <u>Update on the Status of the Drafted Protocols:</u>

1. Protocol For Pharmacists Who Furnish Self-Administered Hormonal Contraceptives

Attachment 2

At the January Board Meeting, the board approved the proposed protocol for hormonal contraception. The board also moved to regulation hearing the approved protocol if the Medical Board of California approved the protocol during its meeting on January 30. The Medical Board did approve the protocol with a small change.

Attachment 2 contains the approved protocol with the Medical Board-suggested change indicated.

Meanwhile, the American Congress of Obstetricians and Gynecologists, who under SB 493 the board is required to consult in developing the protocol, appeared at the Medical Board meeting to request changes in the protocol. The Medical Board did not incorporate ACOG's recommendations into the protocol when it modified and approved the protocol. (Staff notes that since early summer 2014, board staff have been communicating with ACOG's representatives so they could participate in the development of the protocol. The first time the board learned of ACOG's concerns with the proposed protocol was during the Medical Board's meeting.)

At this meeting ACOG representatives have advised staff that they will appear to provide their recommended changes to the protocol. If additional changes are made to the protocol, the Board of Pharmacy and the Medical Board will both need to approve the modification.

2. Protocol for Pharmacists Who Furnish Nicotine Replacement Products

Attachment 3

At the January Board of Pharmacy Meeting, the board approved the proposed protocol for nicotine replacement products. The board also moved to initiate the rulemaking process if the Medical Board of California approved the protocol during its meeting on January 30.

The Medical Board did approve the protocol. The approved protocol is provided in **Attachment 3**, which will be noticed for public comment as a regulation in the near future.

3. Protocol for Pharmacists Who Furnish Naloxone

Attachment 4

At the January Board Meeting, the board approved the proposed protocol for pharmacists to provide naloxone. The Medical Board of California approved the protocol during its meeting on January 30.

The naloxone protocol was authorized by AB 1535 (Bloom, Chapter 346, Statutes of 2014). This bill contained a provision that specifies:

> 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).

The board is ready to file the protocol as an emergency regulation following this meeting. The approved protocol is provided in **Attachment 4.**

c. <u>Review and Discussion About the Factsheet on Naloxone</u>

Attachment 5

Staff have reviewed various factsheets for patients describing the use of naloxone. Recently, staff have identified a factsheet that provides information of value to consumers – at least those who have reviewed the factsheet support use of this specific document.

The factsheet was developed by Phillip O. Coffin, MD, MIA, Director of Substance Use Research, San Francisco Department of Public Health. We have been granted permission by Dr. Coffin to use this factsheet, which is provided in **Attachment 5.**

Since the naloxone protocol will be put into effect very soon, the committee's comments on this factsheet are desired at this meeting so the factsheet may be placed on the board's website for use by pharmacies.

d. Review and Discussion About the Factsheet on Self-Administered Hormonal Contraception

Attachment 6

The board has provided examples of factsheets on various forms of hormonal contraception in **Attachment 6.**

e. Review and Discussion About a Factsheet on Nicotine Replacement Products

Most of the patient care elements enacted by SB 493 require the development of a fact sheet. However, the provision of nicotine replacement products does not require such a document.

This agenda item was added simply to affirm that the committee does not wish to develop such a factsheet.

f. Discussion and Identification of Materials Where Board Guidance Is Envisioned, Discussion of the Requirements:

1. For Pharmacists Who Initiate and Administer Immunizations Pursuant to Recommended Immunization Schedules by the Federal Advisory Committee of Immunization Practices

Attachment 7

According to section 4052.8, immunizations may be provided by pharmacists who possess the required training to provide immunizations. Specifically, to initiate immunizations, a pharmacist must:

- complete an immunization training program endorsed by the CDC,
- be certified in basic life support,
- comply with all state and federal recordkeeping requirements,
- provide information to the patient's primary care physician and into the appropriate immunization registry designated by the immunization branch of the CDPH.

During this meeting, the committee needs to address certain issues, and determine if it wishes to create requirements for these components. If so, regulations will need to be drafted if the board desires the provisions to be enforceable.

Mandatory Reporting to an Immunization Registry

At prior committee meetings, the committee has discussed various aspects of immunizations, including required reporting into an immunization registry. At this

meeting, we believe we will again be fortunate enough to have someone from the Los Angeles Department of Public Health to provide information in this area.

The committee needs to identify whether it will make reporting of vaccinations into the CDPH Immunization Registry mandatory, and whether patients can opt out. If so, there are some issues to resolve, including:

- How long from the time of immunization must the pharmacy/pharmacist input the information into the registry?
- Will patients be provided with written information document the immunization(s) they receive?
- How long does the pharmacist have to provide immunization information to the primary care provider? In what form?
- What documentation must the pharmacist maintain?

Required Training for Those Providing Immunizations

The law (section 4052.8(b)(1) of the B&P Code) requires that a pharmacist complete an immunization training program endorsed by the CDC (this would seem to be the APhA Pharmacy-Based Immunization Delivery Program), that at a minimum includes hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines, and shall maintain that training.

Does the committee wish to be more specific in what it will require under this category (i.e., APHA's Pharmacy-Based Immunization Delivery Program)?

What does "shall maintain that training" mean – a certain number of CE hours?

Possession of Required Training

Future enforcement checks of practitioners who provide immunizations under this provision will require that the board be provided with evidence that a pharmacist possesses the required training. Part of the enforcement check will depend on the specificity the board requires for training. For example, some students in CA schools of pharmacy will have had training in immunizations provided as core instruction.

At prior committee meetings, there has been discussion about whether students who may have received this training in pharmacy school could use their training without retaking it somewhere else – how can they document they completed this training several years before? **Attachment 7** contains a chart developed by UCSF that displays the training provided by currently accredited CA schools of pharmacy in various patient services that were included in SB 493.

This information could facilitate identification by board staff monitoring to ensure the pharmacists possess the required training if the board chooses to accept such training.

Additional discussion items:

1. What information shall be placed in patient records regarding vaccinations?
2. What are the "required records" the statute refers to in 4052.8(b)(3)
   "Comply with all state and federal recordkeeping and reporting requirements, including providing documentation to the patient's primary care provider and entering information in the appropriate immunization registry designated by the immunization branch of the State Department of Public Health."
3. Is there a difference between "initiate" and "administer" as used in section 4052.8(a)
   "In addition to the authority provided in paragraph 11 of subdivision (a) of section 4052, a pharmacist may independently initiate and administer vaccines listed on the routine immunization schedules recommended from the Federal Advisory Committee on Immunization Practices . . . "

2. For Prescription Medications Not Requiring a Diagnosis that Are Recommended by the CDC for Travel Outside the US

Attachment 8

At this meeting, the committee will continue its discussions about the parameters for travel medications. The committee has indicated it may wish to establish regulations for some of the travel medication components.

At a prior meeting, the board discussed "not requiring a diagnosis." Dr. Goad has indicated that the CDC Yellow-book is the guidance document that the legislation references. He reported that there is a chapter in the CDC Yellow-book on self-treatable illnesses. Here is the link to the book and the specific chapter:

Book: http://wwwnc.cdc.gov/travel/page/yellowbook-home-2014
Self-treatable conditions: http://wwwnc.cdc.gov/travel/yellowbook/2014/chapter-2-the-pre-travel-consultation/self-treatable-conditions

Below is an excerpt from this reference:

> Despite providers' best efforts, some travelers will become ill while traveling. Obtaining reliable and timely medical care during travel can be problematic in many destinations. As a result, prescribing certain medications in advance can empower the traveler to self-diagnose and treat common health problems. With some activities in remote settings, such as trekking, the only alternative to self-treatment would be no treatment. Pre-travel counseling may actually result in a more accurate self-diagnosis and treatment than relying on local medical care in some developing countries. In addition, the increasing awareness of substandard and

counterfeit drugs in pharmacies in the developing world (as many as 50% of the drugs on the shelves) makes it more important for travelers to bring quality manufactured drugs with them from a reliable supplier in their own country (see *Perspectives*: Pharmaceutical Quality & Counterfeit Drugs later in this chapter).

Providing education and prescriptions is part of the pre-travel consultation. The key aspect of this strategy is to recognize the conditions for which the traveler may be at risk, given the travel itinerary, and to educate the traveler about the diagnosis and treatment of those particular conditions. The keys to successful self-treatment strategies are providing a simple disease or condition definition, providing one choice of treatment, and educating the traveler about the expected outcome of treatment. Using travelers' diarrhea as an example, a practitioner could provide the following advice:

- "Travelers' diarrhea" is the sudden onset of abnormally loose, frequent stools.
- The treatment is ciprofloxacin 500 mg, every 12 hours, for 1 day (2 doses).
- The traveler should feel better within 6–24 hours.
- If symptoms persist for 24–36 hours despite self-treatment, it may be necessary to seek medical attention.

Training Requirements

The committee has in the past discussed possible specifications for minimum training for pharmacists who provide travel medication and services. Below are some providers of travel medicine training. They differ greatly in their scope:

1. APhA has a training module of 20 hours for immunizations plus a second 10 hours for travel medication. A certificate is provided for this training.
    - Is this sufficient?
    - What would be a maintenance requirement for this training in the future?
2. The International Society of Travel Medicine **(**ISTM**)** has a ccertificate program.
    - This is a lengthy program
    - Requires an exam, which is given periodically somewhere in the world
    - Maintenance of the certification is via another exam, required every 10 Years
3. American Society of Tropical Medicine and Hygiene
    - This program was recommended as a potential certificate source. From its website: "The American Society of Tropical Medicine and Hygiene (ASTMH), founded in 1903, is a worldwide organization of scientists, clinicians and program professionals whose mission is to promote global health through the prevention and control of infectious and other diseases that disproportionately afflict the global poor. Research, health care and education are the central activities of ASTMH members, whose work bridges basic laboratory research to international field work and clinics to

countrywide programs. A page from their web site is provided as **Attachment 8.**

4. American Association for Professionals in Infection Control and Epidemiology
    - Has a certification program that was recommended as a possible type of training. A page from their website is provided as **Attachment 8.**

For whatever program selected, would there need to be a CE requirement to ensure maintenance of skills and recent updates, (e.g., 3 units of CE every two years)?

The diversity of countries to which a patient may travel would seemingly require use of the Yellow Book and/or specialized software to reference standard health and safety issues of travel to a particular region. Should the board require this?

Yellow fever is an issue in some parts of the world. Currently the CDPH provides a stamp to physicians who are trained to do this. Should pharmacists who complete the training be made eligible to provide this vaccine?

Should documentation from patients showing their travel itineraries be required?

Should "travel history forms" be required to enable review of where a patient has traveled? Sample travel history forms are provided in **Attachment 8**.

What is the time frame for and how should a patient's primary care provider be notified?

Should limits be placed on particular drugs (anti-infectives or prophylactics for Jet-lag)?

Should a patient's itinerary shall be retained by the pharmacy? For how long?

3. For Ordering and Interpreting Tests to Monitor and Manage Drug Therapies

Attachment 9

- *All pharmacists can:*
  Order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies. A pharmacist who orders and interprets tests pursuant to this paragraph shall ensure that the ordering of those tests is done in coordination with the patient's primary care provider or diagnosing prescription, as appropriate, including promptly transmitting written notification to the patient's diagnosing prescriber or enter the appropriate information in a patient record system shared with the prescriber, when available and as permitted by the prescriber. (CA B&P Code section 4052(a)(12)
- *APP licensed pharmacists can:*
  Order and interpret drug-therapy related tests, and initiate or modify therapy

This item is on the agenda so the committee and audience may discuss it.

At prior meetings, comments made on this topic include that during creation of the legislation, doctors stated that they wanted pharmacists to have the ability to order tests in order to make recommendations on the patient's care based on actual data.

The language in SB 493 states that pharmacists *may* order tests to improve patient safety and access to care. However, at a prior committee meeting it was noted that in the future, the standard of care could evolve to a point where a pharmacist *must* order a test prior to dispensing a certain medication.

CPhA drafted a guidance document for pharmacists ordering and managing tests. This document has been provided in **Attachment 9**.

g. General Discussion Concerning Implementation of SB 493

This item is to allow for general discussion about all things SB 493.

h. Public Comment for Items Not on the Agenda, Matters for Future Meetings*

**(Note: the committee may not discuss or take action on any matter raised during the public comment section that is not included on this agenda, except to decide to place the matter on the agenda of a future meeting. Government Code Sections 11125 and 11125.7(a))*

Attachment 1

Article 3.5
Advanced Practice Pharmacist

1730 Acceptable Certification Programs

The board recognizes the pharmacy patient care certification programs that are certified by the National Commission for Certification Agencies (NCCA) for purposes of satisfying the requirements in Business and Professions Code section 4210(a)(2)(A).

1730.1 Documentation Requirements for Advanced Practice Pharmacist Licensure

(a) Documentation of possession of a certification as specified in California Business and Professions Code section 4210(a)(2)(A) shall be via:
  (1) A notarized copy of the certification award that includes the name of the applicant pharmacist, the area of specialty and date of completion, or
  (2) A letter from the certification program attesting the award of the certification that includes the name of the applicant pharmacist, the area of specialty and the date of completion.

(b) Documentation of completion of a postgraduate residency earned through an accredited postgraduate institution as specified in California Business and Professions Code section 4210(a)(2)(B) shall be via either:
  1. A notarized copy of the residency certificate awarded by the postgraduate institution that includes the name of the applicant pharmacist, the area of specialty, and dates of participation and completion, or
  2. A letter of completion of a postgraduate residency signed by the dean or residency program director of the postgraduate institution and sent directly to the board from the postgraduate institution that lists the name of the applicant pharmacist, the dates of participation and completion, and areas of specialty.

(c) Documentation of experience earned under a collaborative practice agreement or protocol for at least one year with no fewer than 1,500 hours as specified in California Business and Professions Code section 4210(a)(2)(C) shall be via:
  (1) A copy of an agreement or protocol under which the applicant pharmacist has provided clinical services to patients, and
  (2) A letter from the supervising practitioner attesting under penalty of perjury that the applicant pharmacist has completed at least one year of the experience providing clinical services to patients.

Article 6. Fees

1749. Fee Schedule.

The fees for the issuance and renewal of licenses, certificates, and permits, and the penalties to be assessed for failure to renew in accordance with sections 163.5, 4110, 4127.5, 4196, and 4400 of the Business and Professions Code are hereby fixed as follows:

(a) The fee for the issuance of a pharmacy license is four hundred dollars ($400). The fee for the annual renewal of pharmacy license is two hundred fifty dollars ($250). The penalty for failure to renew is one hundred and twenty five dollars ($125).

(b) The fee for the issuance of a temporary license is two hundred fifty dollars ($250).

(c) The fee for the issuance of a pharmacy technician license shall be one hundred five dollars ($105). The fee for the biennial renewal of a pharmacy technician license shall be one hundred thirty dollars ($130). The penalty for failure to renew a pharmacy technician license is sixty-five dollars ($65).

(d) The fee for application and examination as a pharmacist is one hundred eighty-five dollars ($185).

(e) The fee for regrading an examination is eighty-five dollars ($85).

(f)**(1)** The fee for the issuance of an original pharmacist license is one hundred fifty dollars ($150).

(2) The fee for application and issuance of an advanced practice pharmacist license is three hundred dollars ($300).

(g)**(1)** The fee for the biennial renewal of a pharmacist's license is one hundred fifty dollars ($150). The penalty fee for failure to renew is seventy-five dollars ($75).

(2) The fee for the biennial renewal of an advanced practice pharmacist license is three hundred dollars ($300). The penalty fee for failure to renew is one hundred fifty dollars ($150).

(h) The fee for the issuance or renewal of a wholesaler's license is six hundred dollars ($600). The penalty for failure to renew is one hundred fifty dollars ($150).

(i) The fee for the issuance or renewal of a hypodermic license is one hundred twenty five dollars ($125). The penalty for failure to renew is sixty-two dollars and fifty cents ($62.50).

(j) The fee for the issuance of a license as a designated representative pursuant to Section 4053 of the Business and Professions Code shall be two hundred fifty dollars ($250). If the applicant is not issued a license as a designated representative, the board shall refund one hundred ten dollars ($110) of the fee. The fee for the annual renewal of a license as a designated representative shall be one hundred fifty dollars ($150). The penalty for failure to renew is seventy-five dollars ($75).

(k) The fee for the issuance or renewal of a license as a nonresident wholesaler is six hundred dollars ($600). The penalty for failure to renew is one hundred fifty dollars ($150).

(l) The fee for an intern pharmacist license is seventy-five dollars ($75). The fee for transfer of intern hours or verification of licensure to another state is twenty dollars ($20).

(m) The fee for the reissuance of any permit, license, or certificate, or renewal thereof, which must be reissued because of change in the information, other than name change, is one hundred dollars ($100).

(n) The fee for evaluation of continuing education courses for accreditation is forty dollars ($40) for each hour of accreditation requested.

(o) The fee for the issuance of a clinic license is four hundred dollars ($400). The fee for the annual renewal of a clinic license is two hundred fifty dollars ($250). The penalty for failure to renew is one hundred and twenty five dollars ($125).

(p) The fee for the issuance of a nongovernmental license, or renewal of a license, to compound sterile drug products is six hundred dollars ($600). The penalty for failure to renew is one hundred fifty dollars ($150).

(q) The fee for the issuance of a license as a designated representative for a veterinary food-animal drug retailer shall be two hundred fifty dollars ($250). If the applicant is not issued a license as a designated representative, the board shall refund one hundred fifty dollars ($150) of the fee. The fee for the annual renewal of a license as a designated representative shall be one hundred ten dollars ($110). The penalty for failure to renew is fifty-five dollars ($55).

(r) The fee for a veterinary food-animal drug retailer license is four hundred dollars ($400). The annual renewal fee for a veterinary food-animal drug retailer is two hundred and fifty dollars ($250). The fee for the issuance of a temporary license is two hundred and fifty dollars ($250)

(s) The fee for the issuance of a retired pharmacist license shall be thirty dollars ($30).

Authority cited: Sections 163.5 and 4005, Business and Professions Code. Reference: Sections 163.5, 4005, 4110, 4112(h), 4120, 4127.5, 4196, 4200,**4210** 4400, 4401 and 4403, Business and Professions Code.

Attachment 2

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 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 or health care facility for a period of at least three years from the date of dispense.

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 answer any questions the patient may have regarding self-administered hormonal contraception.

Pharmacists should provide the patient with a copy of a current consumer-friendly comprehensive birth control guide such as that created by the FDA, and a copy of an administration-specific factsheet; examples of appropriate guides and factsheets are available on the Board of Pharmacy's website.

(7) Follow-Up Care: Upon furnishing a self-administered hormonal contraceptive, or if 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 contraception 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 an appropriate health care professional of the patient's choice.

(9) Referrals and Supplies: If self-administered hormonal contraception services are not immediately available or the pharmacist declines to furnish pursuant to a conscience clause, the pharmacist shall refer the patient to another appropriate health care provider.

The pharmacist also shall comply with all state mandatory reporting laws, including sexual abuse laws.

(10) Product Selection: The pharmacist, in consultation with the patient, may select any hormonal contraceptive listed in the current version of the USMEC for individuals identified 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 or health care facility, and shall be available on the Board of Pharmacy's website.

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 or health care facility for a period of at least three years from the date of dispense. 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 or facility'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 2014 in an accredited 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 or health care facility shall operate under the pharmacy or facility'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 ☐	No ☐
	Did you ever experience a bad reaction to using hormonal birth control?	Yes ☐	No ☐
	Are you currently using birth control pills, or a birth control patch, ring, or shot/injection?	Yes ☐	No ☐
3	Have you ever been told by a medical professional not to take hormones?	Yes ☐	No ☐
4	Do you smoke cigarettes?	Yes ☐	No ☐
5	Do you think you might be pregnant now?	Yes ☐	No ☐
6	Have you given birth within the past 6 weeks?	Yes ☐	No ☐
7	Are you currently breastfeeding an infant who is less than 1 month of age?	Yes ☐	No ☐
8	Do you have diabetes?	Yes ☐	No ☐
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 ☐	No ☐
10	Do you have high blood pressure, hypertension, or high cholesterol?	Yes ☐	No ☐
11	Have you ever had a heart attack or stroke, or been told you had any heart disease?	Yes ☐	No ☐
12	Have you ever had a blood clot in your leg or in your lung?	Yes ☐	No ☐
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 ☐	No ☐
14	Have you had bariatric surgery or stomach reduction surgery?	Yes ☐	No ☐
15	Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?	Yes ☐	No ☐
16	Do you have or have you ever had breast cancer?	Yes ☐	No ☐
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 ☐	No ☐
18	Do you have lupus, rheumatoid arthritis, or any blood disorders?	Yes ☐	No ☐
19	Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)?	Yes ☐	No ☐
	If yes, list them here:		
20	Do you have any other medical problems or take regular medication?	Yes ☐	No ☐
	If yes, list them here:		

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

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.

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.

Attachment 3

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: Prescription nicotine replacement products approved by the federal Food and Drug Administration and provided by a pharmacist for smoking cessation are covered under this protocol. Pharmacists may continue to provide over-the-counter smoking cessation products without use of 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 become pregnant? (If yes, do not furnish and refer to an appropriate health care provider)
    - Have you had a 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)

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

- 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 answer any questions the patient may have regarding smoking cessation therapy and/or nicotine replacement products.

(5) Product Selection: The pharmacist, in consultation with the patient, 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 or health care facility, and shall be available on the Board of Pharmacy's website.

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 provided 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 or health care facility for a period of at least three years from the date of dispense. 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 or facility'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 an approved continuing education program specific to smoking cessation therapy and nicotine replacement therapy, or an equivalent curriculum-based training program completed within the last two years in an accredited California school of pharmacy.

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

(9) Patient Privacy: All pharmacists furnishing nicotine replacement products in a pharmacy or health care facility shall operate under the pharmacy or facility'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* 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
	Gum	**Lozenge**	**Patch**	**Nasal Spray**	**Inhaler**	
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 mcL 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	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Temporomandibular joint disease ▪ Pregnancy[3] and breastfeeding ▪ Adolescents (<18 years)	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Pregnancy[3] and breastfeeding ▪ Adolescents (<18 years)	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Pregnancy[3] (Rx formulations, category D) and breastfeeding ▪ Adolescents (<18 years)	▪ 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 ▪ Pregnancy[3] (category D) and breastfeeding ▪ Adolescents (<18 years)	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Bronchospastic disease ▪ Pregnancy[3] (category D) and breastfeeding ▪ Adolescents (<18 years)	▪ See precautions for individual agents
Dosing	*1st cigarette ≤30 minutes after waking:* 4 mg *1st cigarette >30 minutes after waking:* 2 mg Weeks 1–6: 1 piece q 1–2 hours Weeks 7–9: 1 piece q 2–4 hours Weeks 10–12: 1 piece q 4–8 hours ▪ 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	*1st cigarette ≤30 minutes after waking:* 4 mg *1st cigarette >30 minutes after waking:* 2 mg Weeks 1–6: 1 lozenge q 1–2 hours Weeks 7–9: 1 lozenge q 2–4 hours Weeks 10–12: 1 lozenge q 4–8 hours ▪ 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	*>10 cigarettes/day:* 21 mg/day x 4–6 weeks 14 mg/day x 2 weeks 7 mg/day x 2 weeks *≤10 cigarettes/day:* 14 mg/day x 6 weeks 7 mg/day x 2 weeks ▪ May wear patch for 16 hours if patient experiences sleep disturbances (remove at bedtime) ▪ Duration: 8–10 weeks	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 ▪ Maximum – 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	6–16 cartridges/day Individualize dosing; initially use 1 cartridge q 1–2 hours ▪ 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	*Reserve for patients smoking ≥10 cigarettes/day:* **Long-acting NRT**: to prevent onset of severe withdrawal symptoms ▪ **Nicotine patch** 21 mg/day x 4-6 weeks 14 mg/day x 2 weeks 7 mg/day x 2 weeks **PLUS** **Short-acting NRT**: used as needed to control breakthrough withdrawal symptoms and situational urges for tobacco ▪ **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	▪ Mouth/jaw soreness ▪ Hiccups ▪ Dyspepsia ▪ Hypersalivation ▪ Effects associated with incorrect chewing technique: – Lightheadedness – Nausea/vomiting – Throat and mouth irritation	▪ Nausea ▪ Hiccups ▪ Cough ▪ Heartburn ▪ Headache ▪ Flatulence ▪ Insomnia	▪ Local skin reactions (erythema, pruritus, burning) ▪ Headache ▪ Sleep disturbances (insomnia, abnormal/vivid dreams); associated with nocturnal nicotine absorption	▪ Nasal and/or throat irritation (hot, peppery, or burning sensation) ▪ Rhinitis ▪ Tearing ▪ Sneezing ▪ Cough ▪ Headache	▪ Mouth and/or throat irritation ▪ Cough ▪ Headache ▪ Rhinitis ▪ Dyspepsia ▪ Hiccups	▪ See adverse effects listed for individual agents
Advantages	▪ Might serve as an oral substitute for tobacco ▪ Might delay weight gain ▪ Can be titrated to manage withdrawal symptoms ▪ Can be used in combination with other agents to manage situational urges	▪ Might serve as an oral substitute for tobacco ▪ Might delay weight gain ▪ Can be titrated to manage withdrawal symptoms ▪ Can be used in combination with other agents to manage situational urges	▪ Once daily dosing associated with fewer adherence problems ▪ Of all NRT products, its use is least obvious to others Can be used in combination with other agents; delivers consistent nicotine levels over 24 hours	▪ Can be titrated to rapidly manage withdrawal symptoms ▪ Can be used in combination with other agents to manage situational urges	▪ Might serve as an oral substitute for tobacco ▪ Can be titrated to manage withdrawal symptoms ▪ Mimics hand-to-mouth ritual of smoking ▪ Can be used in combination with other agents to manage situational urges	▪ 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 single agent NRT ▪ Attractive option for patients who have previously failed treatment with monotherapy ▪ See advantages listed for individual agents
Disadvantages	▪ Need for frequent dosing can compromise adherence ▪ Might be problematic for patients with significant dental work ▪ Proper chewing technique is necessary for effectiveness and to minimize adverse effects ▪ Gum chewing might not be acceptable or desirable for some patients	▪ Need for frequent dosing can compromise adherence ▪ Gastrointestinal side effects (nausea, hiccups, heartburn) might be bothersome	▪ 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)	▪ Need for frequent dosing can compromise adherence ▪ 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	▪ Need for frequent dosing can compromise adherence ▪ Cartridges might be less effective in cold environments (≤60°F)	▪ Combination therapy is more costly than monotherapy ▪ 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.

Attachment 4

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 opioid[1] 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 recipient[3] currently uses or has a history of using illicit or prescription 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 (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.
    - The pharmacist shall provide the recipient with any informational resources on hand and/or referrals to appropriate resources if the

[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.

recipient indicates interest in addiction 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
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. Syringe 3ml 25G X 1" # 2 SIG: Use as directed for naloxone administration. Kit should contain 2 vials and 2 syringes.	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. Mucosal Atomization Device (MAD) # 2 SIG: Use as directed for naloxone administration. Kit should contain 2 prefilled needleless syringes and 2 atomizers.	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. Kit is commercially available as a twin pack with directions for administration included.

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 pharmacy or 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 pharmacy or 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 pharmacy or health care facility shall operate under the pharmacy or 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 comprehensives 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 contacts 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.

Attachment 5

What is an opioid overdose?

Opioids can cause bad reactions that make your breathing slow or even stop. This can happen if your body can't handle the opioids that you take that day.

TO AVOID AN ACCIDENTAL OPIOID OVERDOSE:

- Try not to mix your opioids with alcohol, benzodiazepines (Xanax, Ativan, Klonopin, Valium), or medicines that make you sleepy.
- Be extra careful if you miss or change doses, feel ill, or start new medications.

Now that you have naloxone…

Tell someone where it is and how to use it.

Common opioids include:

GENERIC	BRAND NAME
Hydrocodone	Vicodin, Lorcet, Lortab, Norco, Zohydro
Oxycodone	Percocet, OxyContin, Roxicodone, Percodan
Morphine	MSContin, Kadian, Embeda, Avinza
Codeine	Tylenol with Codeine, TyCo, Tylenol #3
Fentanyl	Duragesic
Hydromorphone	Dilaudid
Oxymorphone	Opana
Meperidine	Demerol
Methadone	Dolophine, Methadose
Buprenorphine	Suboxone, Subutex, Zubsolv, Bunavail, Butrans

* Heroin is also an opioid.

For patient education, videos and additional materials, please visit
www.prescribetoprevent.org

SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH

Opioid safety and how to use naloxone

A GUIDE FOR PATIENTS AND CAREGIVERS

SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH

How to identify an opioid overdose:

Look for these common signs:

- The person won't wake up even if you shake them or say their name
- Breathing slows or even stops
- Lips and fingernails turn blue or gray
- Skin gets pale, clammy

In case of overdose:

Call 911 and give naloxone

If no reaction in 3 minutes, give second naloxone dose

Do rescue breathing or chest compressions

Follow 911 dispatcher instructions

After naloxone

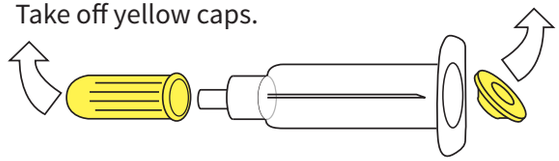
Stay with person for at least 3 hours or until help arrives

How to give naloxone:

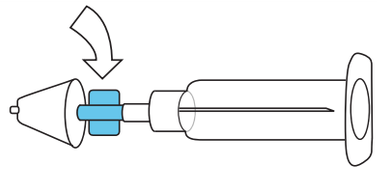
There are 3 ways to give naloxone. Follow the instructions for the type you have.

Nasal spray naloxone

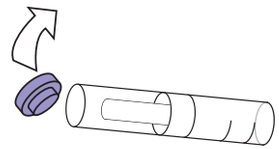
1 Take off yellow caps.

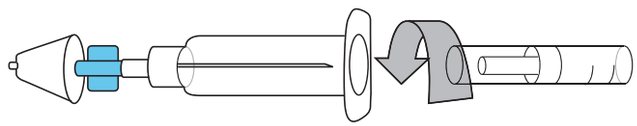


2 Screw on white cone.

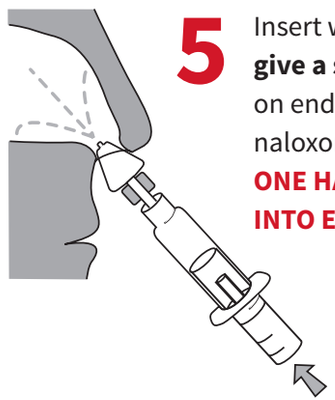


3 Take purple cap off capsule of naloxone.





4 Gently screw capsule of naloxone into barrel of syringe.



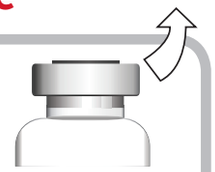
5 Insert white cone into nostril; **give a short, strong push** on end of capsule to spray naloxone into nose:
ONE HALF OF THE CAPSULE INTO EACH NOSTRIL.

Push to spray.

6 If no reaction in 3 minutes, give second dose.

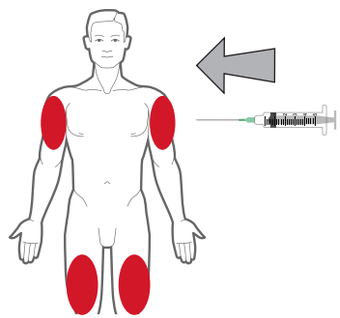
Injectable naloxone

1 Remove cap from naloxone vial and uncover the needle.



2 Insert needle through rubber plug with vial upside down. Pull back on plunger and take up 1 ml.

3 Inject 1 ml of naloxone into an upper arm or thigh muscle.



4 If no reaction in 3 minutes, give second dose.

Auto-injector

The naloxone auto-injector is FDA approved for use by anyone in the community. It contains a speaker that provides instructions to inject naloxone into the outer thigh, through clothing if needed.

Attachment 6

Medicines To Help You

BIRTH CONTROL GUIDE

Office of Women's Health

Most Effective

Methods	Number of pregnancies expected per 100 women*	Use	Some Risks
Sterilization Surgery for Women	less than **1**	Onetime procedure Permanent	• 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	• Mild to moderate pain after insertion • Ectopic (tubal) pregnancy
Sterilization Surgery for Men	less than **1**	Onetime procedure Waiting period before it works Permanent	• Pain • Bleeding • Infection
Implantable Rod	less than **1**	Inserted by a healthcare provider Lasts up to 3 years	• 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	• 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	• Irregular bleeding • No periods • Abdominal/pelvic pain • Ovarian cysts
Shot/Injection	**6**	Need a shot every 3 months	• Bone loss • Bleeding between periods • Weight gain • Nervousness • Abdominal discomfort • Headaches
Oral Contraceptives (Combined Pill) "The Pill"	**9**	Must swallow a pill every day	• Nausea • Breast Tenderness • Headache • Rare: high blood pressure, blood clots, heart attack, stroke
Oral Contraceptives (Progestin only) "The MiniPill"	**9**	Must swallow a pill every day	• Irregular bleeding • Headache • Breast tenderness • Nausea • Dizziness
Oral Contraceptives Extended/Continuous Use "The Pill"	**9**	Must swallow a pill every day.	• 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.	• 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.	• 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.	• Irritation • Allergic reactions • Urinary tract infection • Toxic shock
Sponge with Spermicide	**12-24**	Must use every time you have sex.	• Irritation • Allergic reactions • Hard time removing • Toxic shock
Cervical Cap with Spermicide	**17-23**	Must use every time you have sex.	• Irritation • Allergic reactions • Abnormal Pap test • Toxic shock
Male Condom	**18**	Must use every time you have sex. Except for abstinence, latex condoms are the best protection against HIV/AIDS and other STIs.	• Allergic reactions
Female Condom	**21**	Must use every time you have sex. May give some protection against STIs.	• Irritation • Allergic reactions
Spermicide Alone	**28**	Must use every time you have sex.	• Irritation • Allergic reactions • Urinary tract infection
Emergency Contraception — If your primary method of birth control fails			
Plan B 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.	• Nausea • Vomiting • Abdominal pain • Fatigue • Headache
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.	• Headache • Nausea • Abdominal pain • Menstrual pain • Tiredness • Dizziness

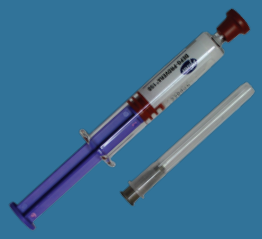
Least Effective

*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

FACT SHEET : THE SHOT/DEPO-PROVERA

Remember, Depo **does not protect you from Sexually Transmitted Infections or HIV.** Always use condoms to protect yourself!



HOW DOES DEPO WORK?

- Depo contains a hormone like the ones your body makes. This hormone stops your ovaries from releasing eggs. Without an egg, you cannot get pregnant.
- No method of birth control is 100% effective, but Depo is 99% effective if you get your shots on time.

HOW DO I USE DEPO?

- You get a Depo injection in the arm or in the buttocks.
- **Use condoms as back-up the first 7 days** after your first shot of Depo.
- You should get a shot every 3 months (every 12 weeks).

WHAT IF I AM LATE FOR THE NEXT SHOT?

- Depo works best if you get a new shot every 12 weeks.
- If your shot is more than 4 weeks late, you should get a pregnancy test before the next shot. You should **use condoms for the next 7 days**.

WHAT IF I AM LATE GETTING A SHOT AND HAD UNPROTECTED SEX?

- If your last shot was more than 16 weeks ago, take Emergency Contraception (EC) **right after** unprotected sex. EC can prevent pregnancy up to 5 days after sex, and it works better the sooner you take it.

HOW DOES DEPO HELP ME?

- Depo is safe & effective. It keeps you from getting pregnant for 3 months.
- The shot lowers your risk of cancer of the uterus.
- It is safe to breastfeed while on Depo.

HOW WILL I FEEL ON DEPO?

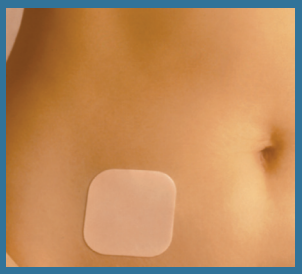
- You will most likely have spotting between periods. You may have weight gain, bloating, headaches and/or mood changes. Talk to your health care provider about treating any side effects.
- After the first 2-3 shots, you may have *no period at all*. This is normal.
- Your bones may become slightly weaker while you take Depo. Bone strength returns to normal once you stop getting the shot.
- After you stop Depo, it takes a few months for your fertility to return to normal. This means that it may take a while for you to get pregnant (even if you're trying) – but if you don't want to get pregnant, you need to use a new form of birth control after you stop Depo.

DOES DEPO HAVE RISKS?

- The shot is very safe. Severe problems are rare. If you have any of the symptoms below, call your doctor:
  - Severe headaches
  - Very heavy bleeding
- Your health care provider can help you find out if these symptoms are signs of a severe problem.

FACT SHEET : THE PATCH

Remember, the patch **does not protect you from Sexually Transmitted Infections or HIV.** Always use condoms to protect yourself!



HOW DOES THE PATCH WORK?

- The patch contains hormones like the ones your body makes. These hormones stop your ovaries from releasing eggs. Without an egg, you can't get pregnant.
- No method of birth control is 100% effective, but the patch is 99% effective if used correctly.

HOW DO I START THE PATCH?

- There are 2 ways to start the patch:
  - **Quick Start:** Put on your first patch as soon as you get the pack.
  - **Next period:** Put on your first patch soon after your next period begins.
- If you put on your first patch *up to 5 days after the start of your period*, you are protected against pregnancy **right away**.
- If you put on your first patch *more than 5 days after the start of your period*, you should **use condoms as back-up for the first 7 days**.

HOW DO I USE THE PATCH?

- The patch is like a sticker you wear on your skin for a week. You can wear the patch anywhere on your skin except your breasts, your genitals, palms of your hands or soles of your feet.
- Choose a spot on your body where you can see the patch if it falls off. Place the patch on a clean, dry area and make sure the edges stick well.
- You will use a new patch every week for 3 weeks and no patch for the 4th week.
- Expect your period during the patch-free week. (You may have a light period or no period at all.)
- Start a new box of patches at the end of the 4th week.

WHAT IF THE PATCH COMES OFF?

- If the patch comes off, put it back on right away. If it does not stick, use a new patch.
- If the patch falls of for more than a day, put on a new patch and **use condoms for the next 7 days**.
- Put on your next patch a week from the date of this new patch.

WHAT IF I FORGET TO CHANGE THE PATCH AFTER 7 DAYS?

- The patch has enough hormones for 9 days. If you leave the patch on for 9 days or less, just put on a new patch.
- If you leave the patch on for more than 9 days, put on a new patch and **use condoms for the next 7 days**.

WHAT IF I STOPPED USING THE PATCH AND HAD UNPROTECTED SEX?

- Take Emergency Contraception (EC) **right away**. EC can prevent pregnancy up to 5 days after sex, and it works better the sooner you take it.

HOW DOES THE PATCH HELP ME?

- The patch is safe and effective birth control. Your periods may be more regular, lighter, and shorter. You may have clearer skin.
- The patch lowers your risk of getting cancer of the uterus and ovaries.
- The patch has **no effect** on your ability to get pregnant in the future, after you stop using it.

HOW WILL I FEEL ON THE PATCH?

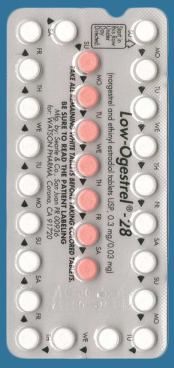
- You will feel about the same. During the first 2-3 months you may have nausea, bleeding between periods, weight change, and/or breast pain. These problems often go away after 2-3 months.

DOES THE PATCH HAVE RISKS?

- The patch is very safe. Serious problems are rare. If you have any of the symptoms below, call your health provider:
  - Leg pain, swelling, and redness
  - Weakness or numbness on 1 side of your body
  - Bad headache
  - Vision problems
  - Chest pain
- Your health provider can help you find out if these symptoms are signs of a serious problem.

FACT SHEET : THE PILL

Remember, the pill **does not protect you from Sexually Transmitted Infections or HIV.** Always use condoms to protect yourself!



HOW DO BIRTH CONTROL PILLS WORK?

- Birth control pills contain hormones like the ones your body makes. These hormones stop your ovaries from releasing eggs. Without an egg, you cannot get pregnant.
- No method of birth control is 100% effective, but birth control pills are 99% effective if you take them each day.

HOW DO I START THE PILL?

- There are 2 ways to start the pill:
  - **Quick Start:** Take your first pill as soon as you get the pack.
  - **Next period:** Take your first pill soon after your next period begins.
- If you take your first pill *up to 5 days after the start of your period*, you are protected against pregnancy **right away**.
- If you take your first pill *more than 5 days after the start of your period*, you should **use condoms as back-up for the first 7 days.**

HOW DO I USE THE PILL?

- **Once you start using the pill**, take 1 pill each day. Take your pill at the same time each day.
- After you finish a pack of pills, you should start a new pack the next day. You should have NO day without a pill.

WHAT IF I MISS PILLS?

- **I forgot ONE pill:** Take your pill as soon as you can.
- **I forgot TWO pills or more:** Take your pill as soon as you can. Take your next pill at the usual time. **Use condoms for 7 days. Use emergency contraception (EC) if you have unprotected sex.**

WHAT IF I STOPPED TAKING THE PILL AND HAD UNPROTECTED SEX?

- Take Emergency Contraception (EC) **right away**. EC can prevent pregnancy up to 5 days after sex, and it works better the sooner you take it.

HOW DOES THE PILL HELP ME?

- The pill is safe and effective birth control.
- Your periods may be more regular, lighter, and shorter. You may have clearer skin.
- The pill lowers your risk of getting cancer of the uterus and ovaries.
- The pill has **no effect** on your ability to get pregnant in the future, after you stop taking it.

HOW WILL I FEEL ON THE PILL?

- You will feel about the same. In the first 2-3 months you may have nausea, bleeding between periods, weight change, and/or breast pain. These problems often go away after 2-3 months.

DOES THE PILL HAVE RISKS?

- The pill is very safe. Serious problems are rare. If you have any of the symptoms below, call your health provider.
- Leg pain, swelling, and redness
- Weakness or numbness on 1 side of your body
- Bad headache
- Vision problems
- Chest pain
- Your health provider can help you find out if these symptoms are signs of a serious problem.

FACT SHEET : PROGESTIN-ONLY/ MINI-PILL

Remember, the mini-pill **does not protect you from Sexually Transmitted Infections or HIV.** Always use condoms to protect yourself!

HOW DOES THE MINI-PILL WORK?

- The mini-pill contains a hormone like the ones your body makes. It works by making the mucus in your cervix too thick for sperm to pass through. If sperm cannot reach the egg, you cannot get pregnant.
- No method of birth control is 100% effective, but birth control pills are 97-98% effective if you take them each day.

HOW DO I START THE MINI-PILL?

- There are 2 ways to start the pill:
  - **Quick Start:** Take your first pill as soon as you get the pack.
  - **Next period:** Take your first pill soon after your next period begins.
- If you take your first pill *up to 5 days after the start of your period*, you are protected against pregnancy **right away**.
- If you take your first pill *more than 5 days after the start of your period*, you should **use condoms as back-up for the first 7 days**.

HOW DO I USE THE MINI-PILL?

- **Once you start using the pill**, take 1 pill each day. Take your pill at the same time each day.
- After you finish a pack of pills, you should start a new pack the next day. You should have NO day without a pill.

WHAT IF I MISS MINI-PILLS?

- **I forgot ONE pill:** Take your pill as soon as you can. If you take your pill more than 3 hours late, **use condoms for the next 7 days.**
- **I forgot TWO pills or more:** Take your pill as soon as you can. Take your next pill at the usual time. **Use condoms for the next 7 days. Use emergency contraception (EC) if you have unprotected sex.**

WHAT IF I STOPPED TAKING THE MINI-PILL AND HAD UNPROTECTED SEX?

- Take Emergency Contraception (EC) **right away**. EC can prevent pregnancy up to 5 days after sex, and it works better the sooner you take it.

HOW DOES THE MINI-PILL HELP ME?

- The mini-pill is safe & effective birth control. The mini-pill is safe for you to use while breastfeeding.
- The mini-pill has **no effect** on your ability to get pregnant in the future, after you stop taking it.

HOW WILL I FEEL ON THE MINI-PILL?

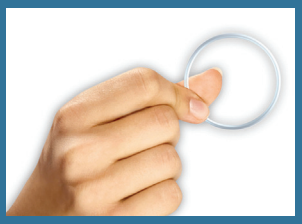
- You will feel about the same. Most women notice changes in their periods. You may have spotting or no period at all. This is normal. You may have nausea, spotting, weight change, and/or breast pain. These problems often go away after 2-3 months.

DOES THE MINI-PILL HAVE RISKS?

- The mini-pill is very safe.

FACT SHEET : THE RING

Remember, the ring **does not protect you from Sexually Transmitted Infections or HIV.** Always use condoms to protect yourself!



HOW DOES THE RING WORK?

- The ring contains hormones like the ones your body makes. These hormones stop your ovaries from releasing eggs. Without an egg, you cannot get pregnant.
- No method of birth control is 100% effective, but the ring is 99% effective if used the right way.

HOW DO I START THE RING?

- There are 2 ways to start the ring:
  - **Quick Start:** put in your first ring as soon as you get the pack.
  - **Next period:** put in your first ring soon after your next period begins.
- If you put your first ring in *up to 5 days after the start of your period*, you are protected against pregnancy **right away**.
- If you put your first ring in *more than 5 days after the start of your period*, you should **use condoms as back-up for the first 7 days**.

HOW DO I USE THE RING?

- The ring is a small, bendable, plastic circle that you insert into your vagina.
- You leave the ring in your vagina for 3 weeks, and remove it for the 4th week.
- Remove the ring by hooking a finger under the rim and pulling it out.
- Most women get their period during the ring-free week.
- Insert a new ring at the end of the 4th week.
- You can store the ring at room temperature up to four months. In the refrigerator, the ring lasts much longer.

DO I HAVE TO GET A PERIOD?

- Because the ring has enough hormones to last 35 days, you can leave it in for more than 3 weeks. You can change the ring on the same day of each month (for instance, March 1st, April 1st, May 1st, etc.). If you remove the old ring and insert the new ring on the same day, you may not get a period. This is ok.

WHAT IF THE RING COMES OUT?

- The ring may slip out during sex or when you use the bathroom. The ring can stay out of your body for up to 3 hours and still prevent pregnancy. If the ring is out of your body for more than 3 hours, you should put it back into your vagina and **use condoms for the next 7 days**.

WHAT IF I STOPPED USING THE RING AND HAD UNPROTECTED SEX?

- Take Emergency Contraception (EC) **right away**. EC can prevent pregnancy up to 5 days after sex, and it works better the sooner you take it.

HOW DOES THE RING HELP ME?

- The ring is safe and effective birth control. Your periods may be more regular, lighter, and shorter. You may have clearer skin. The ring lowers your risk of getting cancer of the uterus and ovaries. The ring has **no effect** on your ability to get pregnant in the future, after you stop using it.

HOW WILL I FEEL ON THE RING?

- You will feel about the same. In the first few months you may have nausea, bleeding between periods, weight change, and/or breast pain. These problems often go away after 2-3 months.

DOES THE RING HAVE RISKS?

- The ring is very safe. Serious problems are rare. If you have any of the symptoms below, call your health provider:
  - Leg pain, swelling, and redness
  - Weakness or numbness on 1 side of your body
  - Bad headache
  - Vision problems
  - Chest pain
- Your health provider can help you find out if these symptoms are signs of a serious problem.

Attachment 7

Patient Care Services in the Core Curricula (and year of implementation) in California Colleges and Schools of Pharmacy *(January 2015)*

	CNU[A]		LLU[B]		TU[C]		UCSD[D]		UCSF[E]		UOP[F]		USC[G]		WU[H]	
	Yes/ No	Year	Yes/ No	Year	Yes/ No	Year	Yes/ No	Year	Yes/ No	Year	Yes/ No	Year	Yes/ No	Year	Yes/ No	Year
Smoking cessation/NRT	**Y**	2008	**Y**	2004	**Y**	2007	**Y**	2005	**Y**	2000	**Y**	2000	**Y**	2000	**Y**	2000
Immunizations	**Y**	2009	**Y**	2004	**Y**	2007	**Y**	2006	**Y**	2005	**Y**	2001	**Y**	2003	**Y**	Pre-2000
Hormonal contraception	**Y**	2010	**Y**	2004	**Y**	2006	**Y**	2009	**Y**	Pre-2000	**Y**	2014	**Y**	2011	**Y**	2008
Emergency contraception	**Y**	2008	**Y**	2004	**Y**	2006	**Y**	2009	**Y**	2005	**Y**	2010	**Y**	2004	**Y**	2007
Ordering tests	**Y**	2009	**Y**	2004	**Y**	2006	**Y**	2006	**Y**	Pre-2000	**Y**	Pre-2000	**Y**	Pre-2000	**Y**	Pre-2000
Naloxone HCl	**Y**	2011	**Y**	2004	**Y**	2015	**N***	Plan 2015	**N***	Plan 2015	**Y**	2015	**N***	Plan 2015	**Y**	2014
Travel medications	**N**	—	**N#**	—	**Y**	2014	**N***	Plan 2015	**N**	—	**Y**	2014	**N#**	—	**Y**	2006

Abbreviations: [A]California Northstate University College of Pharmacy; [B]Loma Linda University, School of Pharmacy; [C]Touro University College of Pharmacy; [D]University of California—San Diego School of Pharmacy; [E]University of California—San Francisco School of Pharmacy; [F]University of the Pacific School of Pharmacy; [G]University of Southern California School of Pharmacy; [H]Western University of Health Sciences College of Pharmacy.

*Not currently in core curricula—plans to incorporate in 2015
Currently offered as an elective course

Sources of information:
CNU—Parto Khansari & Heather Schumann (Department Chairs/Chair of the Curriculum Committee); LLU—Rashid Mosavin (Executive Associate Dean); TUC—Eric Ip (Chair, Department of Pharmacy Practice); UCSD—David Adler, (Associate Dean for Academic Affairs); UCSF—Sharon Youmans, (Vice Dean); UOP—Eric Boyce (Associate Dean for Academic Affairs); USC—Kathleen Besinque (Assistant Dean, Curriculum and Assessment); WU—Eunice Chung (Assistant Dean for Curricular Affairs)

Description of curricular content with the school/college of pharmacy curricula

Smoking Cessation/Nicotine Replacement Therapy

1.	Assist patients with tobacco cessation using patient specific interventions, including referral to quitlines and other resources in the community.
2.	Select an appropriate smoking cessation medication regimen, including nicotine replacement therapy, after evaluation of patient-specific factors including precautions and contraindications for medication therapy.
3.	Counsel patients on the appropriate use of smoking cessation medications (e.g., dosing, administration and adverse effects).

Immunizations

1.	Evaluate a patient for indications and contraindications for vaccines listed on the routine immunization schedules recommended by ACIP and the CDC for persons 3 years of age and older.
2.	Demonstrate appropriate administration of vaccines using hands-on technique.
3.	Recognize and treat emergency reactions to vaccines.

Hormonal Contraception

1.	Evaluate a patient for indications and contraindications for self-administered hormonal contraception using United States Medical Eligibility Criteria (USMEC) for Contraceptive Use developed by the CDC.
2.	Counsel patients on the appropriate use of self-administered hormonal contraception (e.g., dosing, administration and adverse effects).

Emergency Contraception

1.	Evaluate a patient for indications and contraindications for emergency contraception.
2.	Counsel patients on the appropriate use of emergency contraception (e.g., dosing, administration and adverse effects).

Ordering Tests

1.	Evaluate a patient for necessary and appropriate tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies.
2.	Order and interpret tests to monitor the efficacy and toxicity of drug therapies.

Naloxone Hydrochloride

1.	Evaluate a patient for whom the distribution of an opioid antagonist for the treatment of an opioid overdose would be appropriate (i.e., determined to be at risk of an opioid-related overdose).
2.	Counsel patients on the appropriate use of naloxone hydrochloride (e.g., dosing, safe administration and adverse effects; opioid overdose prevention, recognition and response; seeking emergency medical care; availability of drug treatment programs).

Travel Medications

1.	Evaluate a patient for indications and contraindications for prescription medications not requiring a diagnosis that are recommended by the CDC for individuals traveling outside of the United States.
2.	Counsel patients on the appropriate use of travel medications (e.g., dosing, administration and adverse effects).

Attachment 8

Who We Are

The American Society of Tropical Medicine and Hygiene (ASTMH), founded in 1903, is a worldwide organization of scientists, clinicians and program professionals whose mission is to promote global health through the prevention and control of infectious and other diseases that disproportionately afflict the global poor. Research, health care and education are the central activities of ASTMH members, whose work bridges basic laboratory research to international field work and clinics to countrywide programs.

Specific ASTMH goals include:

- **Improving the health** of people worldwide
- **Advancing research** in tropical diseases
- **Fostering international scientific collaboration**
- **Supporting career development** in tropical medicine and global health
- **Educating medical professionals, policymakers and the public** about tropical medicine and global health
- **Promoting science-based policy** regarding tropical medicine and global health
- **Recognizing exceptional achievement** in tropical medicine and global health

American Journal of Tropical Medicine and Hygiene 2013 Member Directory

- Geographical Distribution of Members
- Awards and Honors
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American Journal of Tropical Medicine and Hygiene 2012 Member Directory

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American Journal of Tropical Medicine and Hygiene 2011 Member Directory

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History of ASTMH

The ASTMH has a long and distinguished history. The current organization was formed in 1951 with the amalgamation of the American Society of Tropical Medicine, founded in 1903, and the National Malaria Society, founded in 1940.

View the 2003 ASTMH Centennial Celebration Address (2003) (PDF)

Presidential Addresses

2013
After Malaria is Controlled, What's Next?
David H. Walker, MD

2012
Evolution and "Near" Future of the American Society of Tropical Medicine and Hygiene Circa 2012

American Committee on Clinical Tropical Medicine and Travelers' Health (ACCTMTH)

The American Committee on Clinical Tropical Medicine and Travelers' Health (ACCTMTH) is the clinicians' group within ASTMH, and includes civilian, military and governmental experts in travelers' health, tropical infection and tropical disease.

2014 Clinical Group Symposium Reference List

Question of the Month!

What are the differences and similarities between the qualifications of an Infectious Disease Specialist and a Tropical Infectious Disease Specialist?

In the United States, an Infectious Diseases Specialist would be a physician who has completed training in either Internal Medicine or Pediatrics, and then 2-3 more years of subspecialty training in Infectious Diseases, and has passed a Board Certification exam in Infectious Diseases from either the American Board of Internal Medicine or the American Board of Pediatrics, both under the supervision of the American Board of Medical Specialties.

There is no equivalent Certification in Tropical Medicine available from the ABMS. In the United States, one can demonstrate a recognized level of training in tropical medicine via several pathways:

There are a very few educational institutions in the United States which offer an established degree program in clinical tropical medicine focusing on clinical expertise. For example, Tulane University has long offered a Masters in Public Health and Tropical Medicine, which is open only to clinicians and is designed to prepare them for the practice of tropical medicine.

A number of institutions, listed on the ASTMH website, offer Diploma or Certificate courses in clinical tropical medicine. Individuals who have taken one of these courses, or who have demonstrated significant practice experience in tropical medicine, are eligible to take the examination offered by ASTMH and to be awarded the Certificate of Knowledge in Clinical Tropical Medicine and Traveler's Health- CTropMed® from the ASTMH. Although this is not an ABMS recognized certification, it does reflect a standardized level of knowledge sanctioned by the primary society for clinical tropical medicine in the United States. Persons who have achieved this certificate are recognized by ASTMH and can use the CTropMed® designation.

The International Society of Travel Medicine offers a Certificate in Travel Medicine (CTM) which requires passing an examination offered by that Society. The CTM body of knowledge is more specific to travel, in particular pre-travel preparation, and does not as intensively focus on practice in the tropics.

Other medical practitioners may have an interest in or have received advance training in tropical medicine but not fulfilled the above criteria. They are not prohibited from advertising as specialists in tropical medicine.

In Europe, there is a body similar to the ABMS, which is the UNION EUROPÉENNE DES MÉDECINS SPÉCIALISTES (EUROPEAN UNION OF MEDICAL SPECIALISTS, or UEMS). They also do not have a recognized certification for tropical medicine. In Europe however there are somewhat more institutions which offer well established degree programs for clinicians in tropical medicine; some of these also confer eligibility to sit for the ASTMH exam.

Other countries may have specific programs in tropical medicine which vary as to requirements, but the ASTMH Certificate of Knowledge in Clinical Tropical Medicine and Traveler's Health- CTropMed® is one of the few nationally standardized programs to recognize a certain level of competency in clinical tropical medicine.

Intensive Update Course

2015 Intensive Update Course
Date and location will be provided in Feb/March 2015

This course provides a broad overview of the core topics in clinical tropical medicine and travelers' health. Presented in a two-day condensed format, it is an excellent review for health care professionals.

Download Course Brochure

CTropMed® - Certificate of Knowledge in Clinical Tropical Medicine and Travelers' Health

The Society fosters professional development in the fields of clinical tropical medicine and travelers' health. The Society has advocated and facilitated the development of new training programs in these fields and has established a mechanism for accrediting them. In addition, ASTMH has prepared an examination to assess and recognize individual excellence in training and knowledge. Passing this examination leads to a CTropMed®. Certificate of Knowledge in Clinical Tropical Medicine and Travelers' Health.

The next exam will be held November 12, 2016 in Atlanta, GA. Click here for details.

ACCTMTH Member Benefits

Clinical Consultants Directory
Any ACCTMTH member in good standing can list in a standardized format details of their clinical practice in the directory, which is available to the public on the ASTMH web site.

View the directory.

To be listed, contact Buffy Finn, Member Services Administrator at bfinn@astmh.org or at 111 Deer Lake Road, Suite 100, Deerfield, IL 60015, or fax +1-847-480-9282.

2013 Clinical Group Business Meeting Minutes

Awards and Scholarships

Benjamin H. Kean Traveling Fellowship in Tropical Medicine
The American Society of Tropical Medicine and Hygiene has established a fellowship in Dr. Kean's name, administered by the American Committee on Clinical Tropical Medicine and Traveler's Health (ACCTMTH), that will provide travel expenses for medical students who arrange clinical or research electives in tropical areas. Round-trip airfare (best-price ticketing) and up to $1,000 for living expenses will be provided. Kean Fellows will be required to prepare and present reports describing their activities. View the application guidelines.

Elsevier-ASTMH Clinical Research Award
Clinically oriented abstracts submitted by students (including residents and fellows) will be judged based on the quality and impact of the work. The three top abstracts will receive a book award provided by Elsevier at the annual meeting by the ASTMH Clinical Group (American Committee on Clinical Tropical Medicine and Travelers' Health – ACCTMTH). This award recognizes excellence in clinically oriented research presented by a student at the annual meeting. All students and persons in training, including undergraduate, graduate (Masters and PhD) as well as medical students, residents and fellows are eligible.

Elsevier Clinical Research Award Recipients

Paul Griffin, 2014
Junxiong Pang, 2014
Luis Marcos, 2014
Remko Schats, 2013
Sarah-Blythe Ballard, 2013
Samuel Tassi Yunga, 2013
Else Bijker, 2012
Grace Chan, 2012
Jesica Christensen, 2012
Andrew Brent, 2011
Elizabeth Schlaudecker, 2011
Luther Bartelt, 2011
Paul Krezanoski, 2010
Kevin Esch, 2010
Jennifer Downs, 2010

Marcolongo Lecture
A graduate of the medical school at the University of Rome, Italy, Vincenzo Marcolongo did his post-graduate training at McGill University in Montreal, Canada, and obtained his doctorate in tropical medicine back at the University of Rome. In his late 30s, while practicing in his native Rome, and with the advent of mass travel, he realized that an international effort of cooperation was needed to assist ill travelers all over the world. He realized that travelers needed to be educated about health risks and tropical diseases they would encounter on trips to ever more exotic destinations. Of

particular interest to him was malaria, and the prevention of the unnecessary morbidity and mortality it causes among travelers. So in 1960 he founded the International Association for Medical Assistance to Travellers (IAMAT), a non-profit foundation, and organized physicians from all over the world into a network assisting travelers.

In his own words: “Distinguished physicians and respected medical institutions, with a sense of solidarity which makes them like one family, are now working in harmony to assist the traveler who may require medical assistance on his journey...The need for peace and understanding between the peoples of the world has never been as great as now. Peace can come only with understanding, and travel is an important means of acquiring it. It is, however, only through the full consciousness of ‘the essence of the human’ that we shall be able to open the difficult paths of international relationships. As a traveler you have an excellent opportunity to serve your country and the world in creating ties of friendship. To you, therefore, we bring this message, a message sparked with beauty all its own: ‘The search for the human’.”

Through his foundation and numerous publications he worked tirelessly to inform and educate the public. Every year tens of thousands of travelers rely on the advice and information provided by IAMAT. Vincenzo Marcolongo died at age 66 in February 1988. His foresight, compassion and generosity serve as inspiration for the continuation of his work through the Foundation.

The Marcolongo Lecture was instituted in 1990; the list of speakers follows.

2014	Paraccocidiodomycosis: A Neglected Mycosis of Latin America	Carlos Seas
2013	Management of Tegumentary Leishmaniasis: Lessons from Studies on Pathogenesis of Leishmania braziliensis Infection	Edgar Carvalho
2012	Gallbladder Carriage of Salmonella: From Chile to Nepal	Buddha Basnyat
2011	Prevention of Mother To Child Transmission of HIV Infection and HIV Free Survival: Perspectives From Resource Limited Settings	Frederick Sawe
2010	Neonatal Infections- A Global Perspective	Anita K.M. Zaidi
2009	Paradigm Shifts in Tuberculosis Drug Susceptibility Testing: New Dos and Don'ts	David Moore
2008	Understanding Neurocysticercosis: Advances in the Last 50 Years	Raul Isturiz
2007	Human African Trypanosomiasis: A Neglected Diseasse with Low Prevalence but High Impact	Christian Burri
2006	Severe Malaria: a Moving Target?	Kevin Marsh
2005	Cystic Echinococcosis: to Treat or not to Treat?	Enrico Brunetti
2004	Human African Trypanosomiasis: The Past Explains the Present and is the Key to the Future	Jacques Pepin
2003	Japanese Encephalitis: West Nile's Ugly Sister	Tom Solomon
2002	Melioidosis: The Peril in the Paddy Fields	David Dance
2001	Leishmaniasis in the Sudan	Edward Zijlstra
2000	Leptospirosis, the Hide and Seek Disease	Solly Faine
1999	Malaria Prophylaxis: A New Approach	Eli Schwartz
1998	Puerto Rico Meeting Canceled (Hurricane)	
1997	Clinical Features & Epidemiology of Tick-Borne Encephalitis in Central and Eastern Europe	M. Roggendorg
1996	An Infectious Disease Specialist in Hait: AIDS, Typhoid Fever and Civil Unrest	Jean Pape
1995	Tuberculosis: Developments in Epidemiology, Diagnosis, Treatment and Prevention	JJ Ellner
1994	Management of Severe and Complicated Malaria	Nick White
1993	Human Rabies: Clinical Features, Pathogenesis and Potential Treatment	Thiravat Hemauchuda
1992	HIV and Opportunistic Infections in Northeastern Brazil	Anastacio de Queiroz Sousa
1991	Tropical Dermatology	Anthony Bryceson
1990	Radiological Aspects of Tropical and Parasitic Disease	Michael Reeder

Clinical Sessions at ASTMH Annual Meeting

Three or four half-day sessions, which are purely clinical in nature, are organized by ACCTMTH as well as an annual pre-meeting course. For the 2010 Annual Meeting, efforts were made to group the clinical content into the first two days of the conference (which follows the Clinical Pre-Meeting Course). The annual business meeting is preceded by the Marcolongo Lecture, an invited speaker of international stature, and a travelers' health and malaria update by CDC.

Clinical and Educational Resources

Only open access, non-profit, quality sites will be posted here. If you are aware of sites that would be useful to the members of the clinical group please contact the Clinical Group President with a request to have posted.

Images in Tropical Medicine Quiz: http://www.astmh.org//Content/NavigationMenu/Education/ClinicalImagesQuiz/CIQ_2.htm

Creepy Dreadful Wonderful Parasites: http://parasitewonders.blogspot.com/

Gorgas Clinical Cases: http://gorgas.dom.uab.edu/2010cases/100809.html

ASTMH-accredited Courses: www.astmh.org/Approved_Diploma_Courses/2543.htm

CDC Travelers Heath: www.cdc.gov/travel

Zaiman Tropical Medicine Slides: www.astmh.org/Zaiman_Slides.htm

CDC: DPDx (Laboratory identification of Parasites of Public Health Concern): http://www.dpd.cdc.gov/dpdx/Default.htm

Join ACCTMTH

To join ACCTMTH (you must also join the parent society, ASTMH) contact:

Buffy Finn
Member Services Administrator
American Society of Tropical Medicine and Hygiene
111 Deer Lake Road, Suite 100
Deerfield, IL 60015
Phone: +1-847-480-9592
Fax: +1-847-480-9282
E-mail: bfinn@astmh.org

ACCTMTH Executive Council Members

Position	Member	Term Expires
President	Susan McLellan	2015
President Elect	Duane Hospenthal	2015
Past President	Richard Oberhelman	2015
Secretary/Treasurer	Beth Kirkpatrick	2015
Councilor	Brett Hendel-Paterson	2015
Councilor	Walter (Ted) Kuhn	2016
Councilor	Frederique Jacquerioz	2017

MENU

APIC Spreading knowledge. Preventing infection.
Association for Professionals in Infection Control and Epidemiology

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About

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About APIC

A A A 7

The Association for Professionals in Infection Control and Epidemiology (APIC) is the leading professional association for infection preventionists (IPs) with more than 15,000 members. Our mission is to create a safer world through the prevention of infection. This is achieved by the provision of better care to promote better health at a lower cost.

Most APIC members are nurses, physicians, public health professionals, epidemiologists, microbiologists, or medical technologists who:

- Collect, analyze, and interpret health data in order to track infection trends, plan appropriate interventions, measure success, and report relevant data to public health agencies.
- Establish scientifically based infection prevention practices and collaborate with the healthcare team to assure implementation.
- Work to prevent healthcare-associated infections (HAIs) in healthcare facilities by isolating sources of infections and limiting their transmission.
- Educate healthcare personnel and the public about infectious diseases and how to limit their spread.

Many IPs are employed within healthcare institutions and also serve as educators, researchers, consultants, and clinical scientists. The majority of APIC members are affiliated with acute care settings. An increasing number practice in ambulatory and outpatient services where they direct programs that protect patients and personnel from HAIs. Members are also involved in long-term care, home health, and other practice settings where infection prevention and control is an increasing area of responsibility for nurses and other healthcare personnel.

2014 APIC Annual Business Meeting Material – includes agenda and info on submitting questions, reports, and financial statements.

2014 Proposed Bylaws Changes Packet – includes detailed spreadsheet with explanation for each proposed bylaws change, a copy of the "redlined" Bylaws and Articles of Amendment for the Articles of Incorporation.

APIC's educational programs, products, and services support the infection prevention activities of the many patient safety stakeholders. APIC collaborates with other professional associations, consumer groups, and thought leaders, as well as regulatory and accrediting bodies, to maximize the synergy of shared interests and resources with the goal of improving patient outcomes.

Watch a video and find out what forty years of growth and progress has meant to members.

MENU

APIC Spreading knowledge. Preventing infection.
Association for Professionals in Infection Control and Epidemiology

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Education & Certification

- Overview
- CIC Certification
- Event calendar
- Annual Conference 2015
- EPI Intensive
- Infection Prevention Academy
- Online learning
- Webinars

Home> Education & Certification> CIC Certification

Ready to certify? APIC is here to help. A A A

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A growing number of employers expect candidates to have or be working toward their Certification in Infection Prevention and Control, or CIC®, credential. Take the next step in your career by becoming certified in infection prevention and control!

The CIC® credential identifies healthcare professionals who have shown mastery in knowledge of infection prevention and control by sitting for and passing the certification exam. The CIC® credential shows a commitment to best practices in infection prevention and control and improved patient care and signals to your employer and colleagues that you are committed to your professional growth.

Listen to an audio recording for inspiration about receiving your CIC®.

More than 2,000 infection preventionists and other health professionals certify or re-certify each year. Learn more and join this growing group of professionals.

CAA 2014 Application Deadline 7/31/14
The deadline for application has passed. We encourage and look forward to receiving your application next year. Please be sure to watch for announcements about the CAA application process in 2015.Thank you for your interest in the CAA program!

How can I get started toward CIC® certification?

The CIC® credential is awarded by the Certification Board of Infection Control and Epidemiology, Inc. (CBIC). The CBIC website contains a wealth of resources including Frequently Asked Questions, eligibility requirements, and information about re-certification.

Though APIC does not certify, we work closely with CBIC to provide the best materials to prepare you for certification. APIC has a number of educational resources and member networks available to assist members, whether sitting for the exam for the first time or recertifying. Visit the APIC Store to view books and manuals to help you prepare for the exam. Take the IP Competency Review online course to test your knowledge in the latest infection prevention practices. Or, connect with a local chapter to find a convenient study group.

Certification matters!

To meet the demands of the rapidly expanding field of infection prevention, and equip professionals for the challenges of the future, APIC has created the infection preventionist (IP) competency model. The model outlines the skills needed to advance the infection prevention field and was created to help direct the IP's professional development at all career stages. Certification is a critical stage in the model.

Watch a short video about certification.

A growing body of evidence demonstrates the benefits of certification:

- Certification is key in preventing infections, advancing careers, Infection Control Today, 2/9/2015
- A study published in the February 2013 issue of the *American Journal of Infection Control* by Sanjay Saint, MD, MPH bolsters support for the CIC® credential. Read the study, and the press release.
- A study in the March 2012 issue of the *American Journal of Infection Control* found that hospitals whose infection prevention and control programs are led by CIC® have significantly lower rates of methicillin-resistant *Staphylococcus aureus* (MRSA) bloodstream infections than those that are not led by a certified professional. Read the press release about the study.
- Read personal accounts about why certification matters.

For more information about certification, visit CBIC's website at www.cbic.org.

INTERNATIONAL TRAVEL MEDICAL HISTORY FORM

Your Name:_____ Date of birth:_____ Age:_____ Gender: M F

Address:_____City:_____ZIP_____Phone:_____

Your Pharmacy:_____Address:_____Phone:_____

Your medical doctor:_____ Address:_____Phone:_____

MEDICAL HISTORY: Please circle "yes" or "no" to the following questions **(attach additional pages if necessary):**

1. Have you ever had severe reactions to immunizations/vaccinations? Yes No If yes, please describe:_____
2. Are you being treated for leukemia, lymphoma, cancer or any other malignant disease: Yes No
3. Do you have a history of deficiency of the immune system? Yes No
4. Do you had medical treatment for any blood disorder? Yes No
5. Do you have any existing medical condition such as diabetes, heart disease or pulmonary disease? Yes No If yes, please list /:describe:_____

_____

6. Do you have a history of kidney disease? Yes No
7. Do you have a history of psychiatric disorder? Yes No OR Severe Depression? Yes No
8. Do you have a history of seizures? Yes No
9. Are you pregnant; suspect you may be pregnant or trying to become pregnant? Yes No
10. Are you breastfeeding? Yes No

---

11. Do you have any allergies to the following? (Circle all that apply)

Eggs Neomycin Antibiotics Mercury (thinerosal) Bee Stings Streptomycin Polymyxin B

If yes, please describe the reaction:_____

12. Are there any other drugs to which you have had an allergic reaction? Yes No If yes, please list and describe:_____

_____

13. List all of the medications you are currently taking. Include medications for allergies and skin problems. _____

_____

14. **TRAVEL INFORMATION**: Departure date: _____ Return date:_____

15. Please indicate the countries you will be visiting (attach additional pages if necessary):

Destination	Where will you stay	Length of stay:	Rural Travel or camping
			Yes No
			Yes No
			Yes No
			Yes No

16. Please mark all the vaccines you have had including the date of vaccination:

	Date		Date		Date
❑ Typhoid injection		❑ Yellow Fever		❑ Japanese Encephalitis	
❑ Typhoid oral		❑ Meningococcal		❑ Measles/Mumps/Rubella	
❑ Hepatitis A		❑ Immune Globulin		❑ Tetanus Diphtheria	
❑ Hepatitis B		❑ Polio		❑ Rabies	
❑ Malaria drug (name of drug)				❑ Varicella (Chicken Pox	

Client Signature: _____ ***Reviewed by:*** _____ ***Date:*** _____

Travel History Form (Please complete this form in its entirety and fax it to (310) 385-3577 or call (310) 385-3534)

Name_____**Date of Birth** _____ / _____ /_____

Primary Care Physician _____ **Insurance**_____ **Member ID**_____

Sex: ☐ M ☐ F **Phone** (_____)_____ **Country of Birth**_____

Purpose of Trip: ☐ Business ☐ Pleasure ☐ School-related Study or Work

Country AND Cities in Order of Visit (include return visits)	Arrival Date	Departure Date

Will you be:	**Yes**	**No**
Visiting ONLY urban areas?	☐	☐
Staying ONLY in hotels?	☐	☐
Working with exposure to animals?	☐	☐
Working in the medical or dental field with exposure to blood?	☐	☐
Ascending to high altitudes (greater than 7,000 feet)	☐	☐
Potentially having sexual contact with new partners?	☐	☐
Requiring precise manual dexterity, precise thinking/perception or skilled physical activity (such as mountain climbing or piloting)?	☐	☐

Have you had an allergic reaction to any of the following? (Check all that apply.)

☐ Antibiotics (tetracyclines or neomycin) ☐ Lactose ☐ Sulfa Drugs
☐ Bee stings ☐ Pyrimethamine ☐ Thimerosal
☐ Chrysanthemums ☐ Quinines ☐ Yeast
☐ Eggs ☐ Soy ☐ Other allergies:_____

Have you completed the following immunizations?

Hepatitis A	☐ Yes	☐ No	If yes, when? _____
Hepatitis B	☐ Yes	☐ No	If yes, when? _____
Influenza	☐ Yes	☐ No	If yes, when? _____
Meningococcal	☐ Yes	☐ No	If yes, when? _____
MMR (measles, mumps, rubella)	☐ Yes	☐ No	If yes, when? _____
Polio	☐ Yes	☐ No	If yes, when? _____
Tetanus/Diphtheria/Pertussis	☐ Yes	☐ No	If yes, when? _____
Typhoid Fever	☐ Yes	☐ No	If yes, when? _____
Yellow Fever	☐ Yes	☐ No	If yes, when? _____

Past AND Current Medical Problems	ALL Current Medications (Prescription and Nonprescription)

For Women Only:

When was your last normal menstrual period?_____

Are you or could you possibly be pregnant? ☐ Yes ☐ No Are you breastfeeding an infant? ☐ Yes ☐ No

CEDARS-SINAI MEDICAL GROUP

Insert organization logo/letterhead

Student ID:_____
Date:_____

Travel History Form

Name:_____ DOB:_____ Sex (circle): M F

Telephone: Home: _____ Work: _____ Mobile:_____

Home Address:_____

City:_____ State:_____ ZIP:_____ Email: _____

Who is your primary care physician?_____ Telephone: _____

Student ID#: _____ Primary Insurance: _____

Does your insurance cover: Health care overseas? ❑ Yes ❑ No ❑ Not sure Medical evacuation? ❑ Yes ❑ No ❑ Not sure

Travel Plans

(list additional information on back of form if needed)

Purpose of Trip (check all that apply): ❑ Vacation ❑ Business ❑ Study ❑ Other: _____

Planned activities: _____

Will you be:	Yes	No	
	❑	❑	Visiting ONLY urban areas? If no, explain:_____
	❑	❑	Visiting friends and/or family?
	❑	❑	Ascending to high altitudes (8,000 feet or higher)?
	❑	❑	Working with potential exposure to bodily fluids (e.g., medical or dental work)?
	❑	❑	Working with exposure to animals?
	❑	❑	Potentially having new sexual partners?

Countries and Cities in order of visit	Arrival Date	Departure Date

Accommodations: (Check all that apply.)
_____Resorts or large hotels ____Small hotels ____Cruise Ship ____Private Home ____Camp ____Dormitory
____Youth Hostel _____Other (list)_____

Have you traveled outside the United States before? ❑ Yes ❑ No
If yes, when and where? _____

Health History

Medical Conditions (such as heart disease, stroke, cancer, arthritis, diabetes, hypertension, psychiatric illnesses, etc) _____

_____

Surgical History:

Allergies (include medications, foods (incl. eggs), environmental allergens such as ragweed):_____
_____

Intolerances or other reactions (include side effects from previous medications, such as nausea, constipation, sleepiness, dizziness, stomach upset, etc.):_____
_____

Insert organization logo/letterhead

Student ID:_____
Date:_____

Vaccination History

Were you born in the United States? ❑ Yes ❑No If no, where? _____

Have you received the following immunizations?

Hepatitis A	❑ Yes	When? _____	❑ No	❑ Not sure
Hepatitis B	❑ Yes	When? _____	❑ No	❑ Not sure
Meningococcal Meningitis	❑ Yes	When? _____	❑ No	❑ Not sure
Measles/Mumps/Rubella	❑ Yes	When? _____	❑ No	❑ Not sure
Polio	❑ Yes	When? _____	❑ No	❑ Not sure
Tetanus	❑ Yes	When? _____	❑ No	❑ Not sure
Typhoid	❑ Yes	When? _____	❑ No	❑ Not sure
Yellow Fever	❑ Yes	When? _____	❑ No	❑ Not sure
Japanese Encephalitis	❑ Yes	When? _____	❑ No	❑ Not sure
Influenza	❑ Yes	When? _____	❑ No	❑ Not sure

Other: _____

Have you ever had an adverse reaction to an immunization? ❑ Yes Explain: _____ ❑ No

Medications

Are you currently using corticosteroids, receiving cancer treatment, or other immunosuppressive therapy? ❑ Yes ❑ No

Prescription medications: List all current prescription medications and condition treated. (include birth control pills):

Prescription Medication	Reason for Use/Medical Condition

Nonprescription products: List all over-the-counter, herbal, homeopathic products, vitamins, supplements etc.)

Nonprescription medications	Reason for Use/Medical Condition

Women Only

Are you pregnant now, or do you suspect that you might be pregnant? ❑ Yes ❑ No
Do you have plans to become pregnant in the next 3 months ❑ Yes ❑ No
Date of your last menstrual period: _____

Questions/Concerns:

List any additional questions or concerns you have about your travel: _____
_____
_____

PROGRESS NOTE ***INTERNATIONAL TRAVEL HEALTH CLINIC***

PT NAME (*last, first*):				**DOB:**		**MRN:**
BP:	**P:**	**WT:**	**HT:**	**TEMP:**	**SEX:**	**ALLERGIES:**

SUBJECTIVE/OBJECTIVE:

Destination:

_____ Departure Date (from U.S.) _____ Return Date_____

Details of Itinerary:_____

_____

_____

Past Medical History: _____

Medications:_____

Immunization hx (date completed): Hep A_____ Hep B_____ Td/Tdap _____ Polio_____ Other: _____

ASSESSMENT: *Per patient's itinerary, at risk for…*

PLAN:

✓	Vaccine	Recommended by: (Date)	Administered on: (Date)	Administration Details (Vaccine Name; Manufacturer; Lot number; Expiration Date; VIS; Dose; Route; Location)	Administered by:
	Hepatitis A # 1 , 2				
	Hepatitis B # 1, 2, 3				
	Hepatitis A + B combo # 1, 2, 3				
	Influenza (Inactivated)				
	Influenza (Live Intranasal)				
	Japanese Encephalitis				
	Meningococcal				
	Pneumococcal				
	Polio (IPV)				
	Rabies				
	TD or Tdap (circle one)				
	Typhoid Injection / PO				
	Yellow Fever				
	Int'l Certificate of Immunization				

✓		Date
	General Advice (Including: Accident and Risk Awareness)	
	Food/Water Precautions	
	Traveller's Diarrhea (written information provided), Loperamide & BSS use	
	Vector Borne Disease Precautions	
	HIV / Hepatitis B / Hepatitis C Precautions: □ Sexual Activity □ Risk Avoidance □ Contraceptive Foam & Condoms from USA	
	Malaria Prophylaxis (written information provided), DEET & permethrin use	
	Rabies: Animal Bites and Scratches	

✓	Medications	QTY
	Ciprofloxacin 500 mg Sig: Take 1 tablet BID x 3 days for traveler's diarrhea Take 2 tabs one time for traveler's diarrhea. May repeat dose.	
	Levofloxacin 500 mg Sig: Take 1 tablet QD x 3 days for traveler's diarrhea	
	Azithromycin 500 mg Sig: □ Take 1 tab QD x 3 days for traveler's diarrhea □ Take 2 tabs one time for traveler's diarrhea **Alternate dosing: Azithromycin** _____	
	Chloroquine phosphate 500 mg (eq 300mg base) Sig: Take 1 table weekly starting 1 week before entering malarious area, continue weekly during the stay and continue for 4 weeks after leaving area. Take with food.	
	Mefloquine 250 mg Sig: take one tablet weekly starting 1 week before entering malarious area, continue weekly during the stay and continue for 4 weeks after leaving area.	
	Doxycycline 100 mg Sig: Take 1 tab QD starting 1 day before entering malarious area, during stay, and for 4 weeks after leaving area.	
	Malarone (atovaquone-proguanil) 250 mg / 100 mg Sig: Take 1 tab QD 1 day before arrival in malarious area, take 1 tab QD while there, then take 1 tablet daily for 7 days after leaving area. Take with food.	
	Malarone (atovaquone-proguanil) 250 mg / 100 mg ~ SELF TREATMENT~ Sig: Take 4 tab daily as a single dose for 3 days for treatment of malaria.	**12**
	Acetazolamide 125 mg BID Sig: Take 1 tablet BID the day before ascent, then take 1 tablet BID during ascent, and then 1 tablet BID for 2 days while at altitude	
	Transderm Scop (Scopolamine) 0.5 mg/24hr. patch Sig: Apply 1 disc (0.5 mg delivered over 3 days) to skin behind the ear 4 hours before antiemetic effect is needed. The disc may be left in place for three days.	
	Typhoid Vaccine Live Oral Ty21a Sig: Take 1 capsule PO once daily for 4 alternate days (days 1, 3, 5 and 7), taken 1 hour before meals with cold or lukewarm water.	**4**

Additional Notes: _____

_____

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_____

Pharmacist Name and Signature:_____ Date: _____

Attachment 9

v

Guidelines for Pharmacists Ordering and Managing Tests to Ensure Safe and Appropriate Medication Therapy (Version 5)

Last Updated: May 19, 2014

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I. Purpose and Objectives

The purpose of this guideline is to identify the professional standards pharmacists should follow when ordering and interpreting tests for the purpose of monitoring the efficacy and safety or drug therapy. Specific objectives are as follows:

1. Establish best practices for pharmacists ordering and managing tests in the course of monitoring and managing the efficacy and safety of medication therapy in collaboration with the patient's primary care provider, diagnosing prescriber, medical home, etc. The priority of these best practices is to ensure that test ordering by pharmacists is performed only when necessary and that results are managed appropriately and promptly. These best practices are based on research, government reports, and decades of combined experience from California and other states.
2. Provide resources to educate other healthcare professionals, testing organizations, health plans, and other third party payers about the role of pharmacists in ordering and managing tests in coordination with primary care providers and other members of the healthcare team.
3. Describe payment models for test ordering by pharmacists.

II. Background / Rationale

With the signing of Senate Bill 493 by Governor Brown in 2013, California licensed pharmacists are now recognized as healthcare providers and are granted certain authorities in all practice settings that had previously been limited to inpatient settings or integrated systems. One of these authorities is ordering and interpreting tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies. Specifically, the section of SB 493 that describes this authority is as follows:[1]

> *4052.(a)(12) Order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies. A pharmacist who orders and interprets tests pursuant to this paragraph shall ensure that the ordering of those tests is done in coordination with the patient's primary care provider or diagnosing prescriber, as appropriate, including promptly transmitting written notification to the patient's diagnosing prescriber or entering the appropriate information in a patient record system shared with the prescriber, when available and as permitted by that prescriber*

The basis for this authorization includes decades of published experience and evidence demonstrating that granting pharmacists the clinical privilege to order medication-related tests is associated with improvements in healthcare quality measures, medication safety, and overall healthcare costs. The literature containing this information is best summarized by the

1: Official California Legislation Information, available at: http://www.leginfo.ca.gov/pub/13-14/bill/sen/sb_0451-0500/sb_493_bill_20131001_chaptered.pdf

U.S. Public Health Service.[2] In addition, the importance of these clinical privileges on patient and health system outcomes is emphasized by many government and interdisciplinary national healthcare organizations such as HRSA, CDC, and the Patient Center Primary Care Collaborative.[3,4,5] In fact, the services outlined in SB 493, including ordering tests, are already performed by pharmacists in California health system settings working collaboratively in accordance with physician-endorsed policies and procedures and evidence-based practice guidelines s as well as in other states. For over five decades, pharmacists have been engaged as primary care providers in team-based federal health care models such as the Indian Health Service, Department of Veterans Affairs and Department of Defense. Kaiser Permanente has similarly integrated pharmacists into their medical practices for over 30 years. The California Right Care Initiative, from the California Department of Managed Healthcare, recognizes pharmacists with clinical privileges as a key to improving health outcomes and is supporting efforts to help health plans and medical groups identify methods for initiating or expanding clinical pharmacy programs.[6] Ultimately, a pharmacist's responsibility as a member of the healthcare team is to consider all relevant information when determining the appropriateness, safety, and effectiveness of medication therapy, and oftentimes test results are essential to make such a determination. Examples include individualizing dosing for drugs with narrow therapeutic windows or requiring dosage adjustment in renal or hepatic impairment, ruling out an adverse drug reaction, monitoring a chemistry panel for patients receiving medications that can alter electrolytes or renal function markers, or screening patients for untreated medical conditions that may prompt further follow-up with the assigned primary care provider.

III. Guidelines for Test Ordering, Interpretation, and Management by Pharmacists

Key principles for test ordering, interpretation, and management by pharmacists are:

- Testing should be for ensuring safe and effective medication therapy in coordination with the patient's primary care provider or diagnosing prescriber.
- Tests must only be ordered when necessary.
- Test results must be managed appropriately and promptly;
- Patients should receive feedback on their tests in a timely manner.
- Quality assurance should be integrated into the test ordering, interpretation, and management process.

2: Giberson S, Yoder S, Lee MP. Improving patient and health system outcomes through advanced pharmacy practice. A report to the U.S. Surgeon General. Washington, DC: Office of the Chief Pharmacist, U.S. Public Health Service; 2011.

3: HRSA Patient Safety and Clinical Pharmacy Services Collaborative (PSPC), Available at: http://www.hrsa.gov/publichealth/clinical/patientsafety/

4: The Centers for Disease Control. A Program Guide for Public Health: Partnering with Pharmacists in the Prevention and Control of Chronic Diseases (2012). National Center for Chronic Disease Prevention and Health Promotion. Available at: http://www.cdc.gov/dhdsp/programs/nhdsp_program/docs/pharmacist_guide.pdf

5: The Patient-Centered Primary Care Collaborative. Integrating Comprehensive Medication Management to Optimize Patient Outcomes, Second Edition. June 2012. Available at: http://www.pcpcc.net/files/medmanagement.pdf

6: The California Right Care Initiative. Available at: http://www.dmhc.ca.gov/healthplans/gen/gen_rci.aspx

A. Responsibility[7]

Pharmacists are individually responsible for personal competence in ordering tests and interpreting results. Variables that may impact test results must be considered by pharmacists when interpreting results including timing of testing, medications, renal or hepatic function, fluid status, lab error, etc. The Advanced Pharmacist Practitioner designation as described in SB493 is designed to establish a minimum level of competence. Pharmacists are expected to maintain competency demonstrated with ongoing education, training, and experience. Specific institutions or third party payers may apply their own credentialing and privileging requirements, to enhance requirements for specific needs, within their organizations.

B. Using test results

In situations where tests could impact medication therapy decisions or medication therapy might alter testing results, pharmacists should review relevant tests that are required to make this determination. If required tests are not available, e.g., tests that are mandated in current treatment guidelines, FDA recommendations, or medication prescribing information, then the pharmacist should consider ordering or facilitating the ordering of these tests in collaboration with the relevant medical entity (see section III.C.) Examples where a review of test results is indicated include but are not limited to:

1. Individualizing drug dosing
    a. Serum drug levels for medications with narrow therapeutic indexes (e.g., lithium, antipsychotics, anticonvulsants)
    b. INR for warfarin patients
    c. Renal and hepatic function tests for medications requiring dose adjustment in renal or hepatic impairment.
    d. Culture and sensitivity results for antibiotic therapy

2. Selection of appropriate drug therapy (Note per section III.D. that the pharmacist is not necessarily the individual who will interpret the test results, depending on expertise and training.)
    a. Patient with unspecified heart failure (e.g., no echo report, PCP and other members of healthcare team unaware of ejection fraction and other information relevant to treatment).
    b. Adult patient diagnosed with new onset asthma with vague symptoms and no history of spirometry testing.
    c. Patient with diagnosis of Type 2 diabetes and no response to oral diabetes medications or very widely fluctuating glucose levels with

7 : Guidelines for Pharmacists Ordering Laboratory Tests and Using Laboratory Data. Alberta College of Pharmacists. Available at: https://pharmacists.ab.ca/Content_Files/Files/GuidelinesForOrderingLabTests.pdf

minor changes in insulin doses, no history of insulin antibody and C-peptide testing.
    d. Chest X-ray to screen for long-term adverse drug effects (e.g., amiodarone)

3. Attainment of patient specific treatment goals outlined in established guidelines and government standards
    a. A1c for diabetes treatments
    b. Thyroid function tests for thyroid replacement therapy
    c. Uric acid for gout therapy

4. Medication safety and monitoring, as mandated by guidelines and government standards
    a. INR for change in medications/diet/ health that may affect warfarin therapy
    b. Chemistry panel for patients with recent changes in doses of diuretics, ACE-inhibitors, ARBs, etc., particularly those at risk for renally-related adverse effects (e.g., heart failure, renal impairment).
    c. Liver function tests for Tb treatment, methotrexate therapy, etc.
    d. Urine drug test screening
    e. EKG for QT interval screening
    f. Pregnancy testing for risk evaluation and mitigation programs (urine beta-HCG)
    g. Lab monitoring for alcohol use disorders (AST, ALT, MCV, GGT)

5. Recognition of untreated health conditions: screen patients at risk of developing various health conditions
    a. Bone density test for individuals at risk for osteoporosis
    b. Patient with Type 2 diabetes for several years and no history of UACR testing
    c. Metabolic panel and weight gain monitoring with antipsychotics
    d. Patient assessment with PHQ-9 for depression

C. Ordering tests

1. If specific tests are important for determining the appropriateness, efficacy, or safety of medication therapy and test results have not been previously ordered or are out of date then pharmacists should order the tests or follow the procedure within their collaborative practice to ensure that the appropriate test is ordered.

2. Pharmacists must pursue all reasonable approaches to ensuring that tests are not duplicative prior to ordering, e.g., review of the electronic health record, contact with test technician if such a line of communication is available. An exception is when a result is questionable and warrants a repeat test (e.g., abnormal potassium level and suspected hemolysis of blood sample based on previous test results).

3. Pharmacists should only order those tests that they are personally competent to order; otherwise, an appropriate authority should be consulted.

4. Tests must be necessary (e.g., per treatment guidelines, government mandates, prescribing information; clinical evaluation requirement) and limited to patients under the care of the pharmacist / pharmacy service.

D. Interpretation of test results

1. Pharmacists should only order tests that they are experienced in interpreting. An exception is when a test is necessary and, in a pre-arranged collaboration, the test is ordered but planned for interpretation by a qualified healthcare professional.

2. Pharmacist must use professional judgment and consider all variables when interpreting test results. For example, tests can be influenced by multiple variables including lab error, gender, other drugs, pregnancy, diet, organ function, genetics, or incorrect timing of tests.

E. Following-up on test results

1. Pharmacists who order tests must have a procedure established to ensure that results are followed-up appropriately. Pharmacists should either be available at any time of the day every day or establish an alternative plan for responding to critical test results, e.g., on-call groups, agreements with medical home providers, etc.

2. Patients should be informed of what to expect by having the pharmacist order tests, e.g., who will follow-up and how soon. The timeliness of follow up will depend on multiple variables such as the urgency of the test or the availability of the patient; in some cases (e.g., homeless or transient patients), the next appointment may acceptable for follow up.

   It may be reasonable to involve capable patients in following up on their own test results after an appropriate time interval. This does not relieve the pharmacist of their duty to follow up, but add a level of safety to the test follow-up process while engaging patients in their own care.

3. If tests are necessary for treatment decisions and results are not available in a timely manner, it is the pharmacist's responsibility to follow-up with either the testing organization or patient to determine the status of the test and whether rescheduling / reordering is necessary.

4. Pharmacists must take appropriate action if the result of a lab test ordered is a critical value, defined as, "A laboratory test result that represents a pathophysiologic state at such variance with normal as to be life-threatening unless something is done promptly and for which some corrective action could

be taken".[8] No national standard exists for critical value thresholds; these values are best defined by healthcare organizations utilizing the literature, local and national peer institutions or networks, and input from medical service groups or healthcare leadership committees.

5. At minimum, a pharmacist who receives a critical value should contact the physician responsible for the care of the patient at the time of notification (e.g., PCP, MOD). Examples of other actions taken by the pharmacist include, but are not limited to:
   - Repeat the test if the value does not seem plausible based on other subjective and objective findings or consult with the testing organization about the abnormal finding.
   - Discuss the results with the patient in an attempt to correlate results with clinical presentation
   - Consult with other members of the healthcare team, in particular informing the assigned primary care provider regardless of the action(s) taken
   - If the test relates to an existing diagnosis, modify drug therapy or (depending on collaborative practice agreement) recommend modifying drug therapy to the primary care provider in accordance with test results.
   - If the test suggests a new medical problem, refer the patient to the appropriate member of the healthcare team.

F. Standards for documentation

1. As required by SB 493, all actions related to test ordering, interpretation, and management (including subsequent medication therapy changes and altered treatment or monitoring plans) must be documented within 24 hours in a system readily accessible to all involved healthcare team members involved. The documentation system of choice, the electronic health record, should be made available to pharmacists who are part of the care team regardless of location / care venue (e.g., integrated into medical home, community pharmacies, remote telehealth clinical pharmacy services). In addition to supporting real-time communication, EHR access will reduce the likelihood of unnecessary or duplicative testing.

2. Documentation of pharmacist decisions involving test results should include:
   - Interpretation of the result
   - Rationale for the decision based on the result and any other patient-related information

8: Lundberg GD. When to panic over abnormal values. MLO Med Lab Obs. 1972;4:47-54.

- What was communicated to the patient and other healthcare team members involved in the patient's care

G. Quality Assurance of Testing Management

1. A quality assurance program is essential for ensuring the reliability of the testing process used by any healthcare professional. It is recommended that pharmacists work with collaborating healthcare organizations to determine the most effective and efficient method of integrating a quality assurance process. One approach may be to include pharmacists in the organization's existing peer review process.

2. Tools are available to examine how tests are being managed, from ordering to patient notification of results and any decisions made as a result of the tests. A recent quality assurance resource for testing from AHRQ requires the following elements for adoption:[9]
   - A commitment to improvement
   - Senior leadership support for quality and safety improvement
   - Teamwork and an acceptance that everyone is responsible for the success of the process
   - Commitment to honest and open communication.
   - Regular peer review and sharing of perfo/./rmance results among staff.
   - A focus on systems / processes instead of blame on individuals.

IV. Information and Resources for Other Stakeholders / Partners Regarding Pharmacists Ordering, Interpreting, and Managing Tests

Every stakeholder and partner involved with patient care needs to understand the pharmacist's role in ordering, interpreting, and managing tests under SB 493. Information shared should include background about provider status under SB 493 and reference to language in the bill regarding test ordering and interpretation by pharmacists. Other clarifying information may include the rationale for pharmacists ordering tests, procedures used to ensure that test results are managed appropriately and in a timely manner, methods of communication / documentation, and quality assurance of the testing process. A sample 1-page (double-sided) Q&A information sheet is attached in Appendix A that may be appropriate for healthcare professionals, third party payers, and testing organizations.

9: Improving Your Office Testing Process: A Toolkit for Rapid-Cycle Patient Safety and Quality Improvement. Available at: http://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/office-testing-toolkit/

V. Reimbursement for Tests Ordered and Managed by Pharmacists

Section 4052.(a)(12) of SB493 states that pharmacists are able to, "*Order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies*." Furthermore, the section clarifies that the ordering of tests by pharmacists must be, *"…done in coordination with the patient's primary care provider or diagnosing prescriber..."* As a result, reimbursement for tests ordered and managed by pharmacists is achieved through agreements between the pharmacist / pharmacy, primary care provider or diagnosing prescribers, and third party payers. Third party payers need to understand the role of pharmacists in ordering and managing tests to ensure that tests ordered by pharmacists in collaboration with the appropriate care provider are accepted and processed. The nature of reimbursement will vary, ranging from negotiated fees for specific tests to shared payments under value-based reimbursement contracts.

In other states where pharmacists have provider status, test ordering by pharmacists in and of itself is not directly reimbursed. For example, test ordering by pharmacists in North Carolina is facilitated through collaborative practice agreements, signed by supervising physicians, that list "approved tests". Some but not all institutions have pharmacists undergo credentialing and privileging. The benefits to institutions from allowing pharmacists to order and manage tests include finances to the institution through billing for tests (fee for service) and improvement in healthcare quality and safety through improved monitoring and attainment of treatment goals, as well as increased physician access as patients requiring greater time and resources for monitoring are managed by the pharmacist (value-based).

Appendix A: Information about pharmacists ordering and managing tests

In October of 2013 Governor Brown signed Senate Bill 493, making California the 4th state in the nation to recognize pharmacists as healthcare providers. A primary driver behind the Governor's decision to sign the bill is the proven impact pharmacists have on improving healthcare quality and safety while reducing healthcare costs. To accomplish this, pharmacists must consider all information relevant to the safety and efficacy of medication therapy, including tests results. As a result, one of the authorities granted to pharmacists in SB493 is ordering and interpreting tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies, in coordination with the patient's primary care provider or diagnosing prescriber.[10]

Q: What qualifies pharmacists to order tests?

A: All pharmacy schools today confer the Doctor of Pharmacy degree to graduates, requiring didactic and experiential training in comprehensive management of medication therapy including testing relevant to medication efficacy and safety. In addition, residency training for pharmacists provides in-depth experience with direct management of patient drug therapy, and board certification for pharmacists provides ongoing assessment to achieve a high level of clinical knowledge that includes appropriate use of tests. Every healthcare institution or third party payer should apply credentialing standards for pharmacists that are similar to other healthcare providers.

Q: Won't pharmacists ordering tests lead to duplication and wasted resources?

A: Pharmacists review all sources of test results before ordering any test, and tests ordered by pharmacists should be for the purpose of, "…monitoring and managing the efficacy and toxicity of drug therapy."[8]

Q: Who interprets tests ordered by pharmacists?

A: Pharmacists only order tests that they are experienced in interpreting UNLESS a pre-arranged collaboration is established for a qualified individual to interpret the test result. Pharmacist are trained to use professional judgment and consider all relevant variables when interpreting test results including lab error, gender, other drugs, pregnancy, diet, organ function, genetics, or incorrectly timing of tests.

Q: Who is responsible for following-up and managing tests ordered by pharmacists?

A: Pharmacists who order tests will have a procedure established to ensure that results are followed-up appropriately. Pharmacists should either be available at any time of the day every day or establish an alternative plan for responding to critical test results, e.g., on-call groups, agreements with medical home providers, etc. Patients will be informed of what to expect by having the pharmacist order the test, e.g., who will follow-up and how soon. If tests are necessary for treatment decisions and results are not available in a timely manner, it is the pharmacist's responsibility to follow-up with either the testing organization or patient to determine the status of the test and whether rescheduling / reordering is necessary.

10: Official California Legislation Information, available at: http://www.leginfo.ca.gov/pub/13-14/bill/sen/sb_0451-0500/sb_493_bill_20131001_chaptered.pdf

Q: How will pharmacists manage highly abnormal test results ("critical values")?

A: Pharmacists must take appropriate action if the results of a lab test that ordered is highly abnormal and exceeds critical value limits established by the collaborating healthcare organization. . Examples of such actions, established in agreement with the appropriate primary care provider or prescriber, include:

- Repeat the test if the value does not seem plausible based on other subjective and objective findings or consult with the testing organization about the abnormal finding.
- Discuss the results with the patient in an attempt to correlate results with clinical presentation
- Consult with other members of the healthcare team, in particular informing the assigned primary care provider regardless of the action(s) taken
- If the test relates to an existing diagnosis, modify drug therapy or (depending on collaborative practice agreement) recommend modifying drug therapy to the primary care provider in accordance with test results.
- If the test suggests a new medical problem, refer the patient to the appropriate member of the healthcare team.

Q: How will pharmacists communicate their decisions and actions to other members of the healthcare team?

A: All actions related to test ordering, interpretation, and management (including subsequent medication therapy changes and altered treatment or monitoring plans) will be documented within 24 hours in a system readily accessible to all involved healthcare team members involved. The documentation system of choice, the electronic health record, should be made available to pharmacists who are part of the care team regardless of location / care venue (e.g., integrated into medical home, community pharmacies, remote telehealth clinical pharmacy services). In addition to supporting real-time communication, EHR access will reduce the likelihood of unnecessary or duplicative testing. Documentation of pharmacist decisions involving test results should include:

- Interpretation of the result
- Rationale for the decision based on the result and any other patient-related information
- What was communicated to the patient and other healthcare team members involved in the patient's care

Q: How will pharmacists ensure that the process used to order and managed tests remains safe, appropriate, and effective?

A: Pharmacists are responsible for ensuring that a quality assurance assurance is in place for verifying that the testing process is safe, appropriate, and effective. In many instances, collaborating healthcare organizations can integrate pharmacists into their internal peer review process for test ordering and other quality measures. Tools such as the AHRQ Toolkit for Rapid-Cycle Patient Safety and Quality Improvement for Testing (http://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/office-testing-toolkit/) can be utilized for this purpose.