



**California State Board of Pharmacy**

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STATE AND CONSUMERS AFFAIRS AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

ARNOLD SCHWARZENEGGER, GOVERNOR

**Licensing Committee  
Report**

**And Report of the Meeting of May 30, 2007**

Members:

Ruth Conroy, PharmD, Chairperson, Board Vice President

Robert Graul, RPh,

Clarence Hiura, PharmD

Susan Ravnan, PharmD

Minutes of the Licensing Committee Meeting held May 30, 2007, appear at the end of this tab section under **Attachment A**.

**FOR ACTION:**

**ITEM 1: FOR DISCUSSION AND APPROVAL: Proposed Regulation  
Requirements for Pharmacies that Compound**

Since January, the board has been refining regulation requirements for pharmacies that compound. Initially developed during the meetings of the Work Group on Compounding held throughout 2004, refinements to the regulations have been made at the March and May 2007 Licensing Committee Meetings.

At the May Licensing Committee Meeting, the committee walked through the regulations, section by section. Comments submitted in writing or made during this review session were considered. Following the meeting, Deputy Attorney Joshua Room, Supervising Inspectors Robert Ratcliff, Judi Nurse and I worked through the sections and the comments. We have prepared the version of the regulations provided in **Attachment 1**, which we present for board consideration as a final draft.

We believe the regulation requirements provide a balance of consumer protection with the need for pharmacies to compound medication for patients, either pursuant to a prescription or based upon the need for future furnishing. Records, labeling and quality assurance are needed for any product a pharmacy compounds, even if the pharmacy does it only rarely. The level of record keeping and quality assurance required as specified in these regulations does depend on the frequency and volume of medicine compounded. The pharmacy that rarely compounds medicine or does so to a limited extent may provide much of the record keeping on the prescription document itself. When larger volumes of medicine are compounded, the board expects more record

keeping and higher quality assurance. We believe that the regulations distinguish between these two levels.

Some of the comments made submitted included beyond use vs. expiration dates, a definition of unit dose containers, why require downloading of certificates, what is a master formula, must compounding occur in a pharmacy, use of the term compounded preparation vs. compounded drug product. There were also comments expressing concern that any requirements on pharmacies that compound would be overly burdensome and prevent pharmacies from compounding.

Staff also believes that there is no need to specify requirements for pharmacies that perform only sterile compounding as being exempt from these compounding requirements or to specifically state that compounding pharmacies are exempt from the requirements of sterile compounding regulations. Both are in separate sections and relate to the products that are being compounded.

Finally, existing regulations (sections 1716.1 and 1716.2) for pharmacies that compound in anticipation of future furnishing or for prescriber office use have been included into the new sections.

*Note: to take action to move the draft language to formal public notice, the board will need a motion and a second.*

**ITEM 2: RECOMMENDATION: Approve a legislative proposal for establishment of a state protocol for immunizations by seeking amendment to Business and Professions Code section 4052(a)(9) to add:  
Administer immunizations pursuant to a protocol with a prescriber or pursuant to the recommendations of the Advisory Committee on Immunization Practices (ACIP) of the federal Centers for Disease Control and Prevention.**

At the April Board Meeting, the board voted to propose a statutory modification to California Pharmacy Law to allow pharmacists to administer immunizations pursuant to a state-adopted protocol. The language above is the statutory language developed by staff. The amendment is inserted into the full text of section 4052 in **Attachment 2**.

Forty-four states allow pharmacists to provide immunizations under some type of arrangement. In California pharmacists can currently provide immunizations under protocols with a physician under the authority of section 4052 of the Business and Professions Code. According to testimony provided at prior meetings, physicians are reluctant to accept the liability for this action, even though the practice has wide support.

Since the April Board Meeting, staff has developed a proposal for a statutory modification, based in part on Health and Safety Code section 1261.3, that allows a pharmacist to administer influenza and pneumococcal immunizations for a certain patient population in skilled nursing facilities pursuant to standing orders.

Also since the May 30 Licensing Committee Meeting, Board Member Ravnan has worked with staff and Dr. Jeff Goad of USC's School of Pharmacy to refine limits on the protocols and what kind of training would be required of pharmacists before they could provide immunizations under the proposed amendment. This information will be provided to the Licensing Committee at the next meeting.

Specific suggestions would limit the types of immunizations to those specified in the Immunization Schedules for Adults and Adolescents identified by the National Immunization Program consistent with the General Recommendations by the Advisory Committee on Immunization Practices.

Additionally, the language will also specify training requirements - - completion of the APHA certificate program within the last four years and CE requirements - - 2.5 hours annually specifically in the area of immunizations and administration.

## FOR INFORMATION

### **ITEM 3: California Schools of Pharmacy Proposal to Identify the Professional Competencies that Should Be Achieved by the End of Basic Intern Experience**

From January through April, the board participated in a joint project of California's pharmacy schools to develop and assess the competencies that pharmacy students should achieve by the end of the introductory pharmacy experience of 300 hours. This is part of changes to intern experience objectives made by the Accreditation Council for Pharmacy Education, which accredits US schools of pharmacy. Board Member Susan Ravnan, and Virginia Herold and Anne Sodergren have attended the three work sessions held for this purpose since the beginning of the year.

In **Attachment 3** is the copy of the proposed competencies developed by the workgroup. This phase of the project is now over.

The next phase of the project will be done by the pharmacy schools and will involve developing an exam to assess student achievement of the basic competencies. The first meeting to do this was held in mid-June, and additional work sessions will be needed to complete this portion of the project. The workgroup hopes to complete the process in time for incorporation during the 2007-08 academic year.

## ITEM 4: FOR INFORMATION: Emergency Preparedness Planning for California

Disaster or emergency preparedness continues to be an important initiative of the Schwarzenegger Administration. The committee reviewed the following items at its May 30 meeting.

### 1. Surge Response Planning

In late February, the state began working with PriceWaterhouseCoopers to develop a response plan for the surge response following a serious emergency event or emergency events. The goal is to prepare state agencies for an effective and less chaotic surge response. Board staff and Board Member Conroy collectively have attended at least 12 days of these meetings since February.

The board's emergency response plan has been highly promoted during these meetings. However, one downside has been to minimize the need for pharmacists during emergency surge because "the board is going to waive any requirements." However, repeated clarification from board staff about what the meaning of waiving requirements means have helped to reshape the thinking of developing disaster planning with respect to needing pharmacists.

The committee reviewed a preliminary report of the "Development of Standards and Guidelines for Healthcare Surge During Emergencies, Supplies, Pharmaceuticals and Equipment." A copy of this draft is included in **Attachment 4**.

### **UPDATE:**

In addition, on July 11, the Center for Medicare and Medicaid Services has established an Emergency Prescription Assistance Program (EPAP) that will use "the existing supply chain infrastructure as the distribution mechanism for future emergency responses." This is outlined in an announcement released by CMS (provided at the front of **Attachment 4**).

The announcement states:

In the event of disaster of national significance, the Federal Emergency Management Administration (FEMA) will identify individuals or groups of individuals who may be eligible for the (EPAP and that information will be communicated to pharmacies through Argus. Upon activation of the EPAP system, disaster victims may present at any network pharmacy to fill a prescription written for a covered medication to treat an acute condition, to replace maintenance drugs that the individual may have lost in the emergency or to obtain certain covered DME. Pharmacies will be required to check for existing coverage at the point of sale prior to billing the EPAP. If the disaster victim does not have private third party prescription drug coverage or other federal or state

prescription drug coverage (e.g., Medicaid) they will be eligible for EPAP coverage.

## 2. NABP Recommendations for Disaster Response

The committee reviewed information published in the May 2007 NABP Newsletter on guidelines for boards to use in preparing for disaster response (**Attachment 5**). Chairperson Conroy was one of the members of the NABP task force that developed the NABP recommendations.

The board has already accomplished or is working on most of the 11 recommendations.

The committee also reviewed other NABP-prepared materials including the "Emergency and Disaster Preparedness and Response: Roles of Federal, State and Local Governments." Discussion at the meeting included concern that in the initial federal disaster plan, pharmacists were not listed as a critical health care provider, as were physicians, nurses and EMTs.

Pharmacists need to become trained in disaster response so that the public health can be better served with respect to appropriate drug therapy during disasters.

The July *The Script* contains another article on disaster preparedness and the need for pharmacists to preregister for training for disaster response so they can be "first responders."

Additionally board staff has served on panel to select the vendor to do the preregistration of health care responders (ESAR-VHPs).

## 3. County of San Diego's Request for Dispensing Doxycycline or Ciprofloxacin

The board received a request from San Diego County to provide an unspecified number of up to 500,000 bottles of a 7-14 day dosing regimen of doxycycline or ciprofloxacin to first responders, that would be stored in their homes for their and their families use, with the remainder being stored somewhere (unmentioned) else. The county seeks an exemption from patient specific labeling because "it would be difficult, if not impossible" to label these containers (**Attachment 6**).

However, the San Diego County staff missed the meeting and was not in attendance.

Discussion at the meeting included: while the board could exempt such labeling after an emergency had been declared, the board has no authority to exempt labeling requirements in advance of a disaster unless the board promulgates a regulation or obtained statutory authority to authorize this.

At least one county has provided labeled medication to first responders.

Since no one from San Diego County was in attendance at the meeting, the committee took no additional action.

### **ITEM 5: FOR INFORMATION: Request to Add the Exam for the Certification of Pharmacy of Pharmacy Technicians**

In October 2006, the board voted to review the ExCPT exam, which is a competing examination to the PTCB exam, both of which assess the knowledge of pharmacy technicians. In California the PTCB exam has been specified in law as one way to qualify for licensure as a pharmacy technician. The other methods are:

- Possessing an associate's degree in pharmacy technology
- Completing a course of training specified by the board in regulations (accredited by ASHP, provided by the armed forces or at least 240 hours of instruction covering specific topics)
- Graduating from a school of pharmacy accredited by the board.

Since October 2006 the board has sought a psychometric evaluation of the ExCPT examination to assure this exam fits the requirements of Business and Professions Code section 139 for job relatedness. The board had hoped to use the Office of Examination Resources in the Department of Consumer Affairs to perform this function. However, since October, the department's Office of Examination Resources has been without staff that possesses PhDs in psychometric evaluation disciplines. Recruitment for such a position has been difficult, and the positions are still not filled.

In late April, Executive Officer Herold began a solicitation for an independent contractor to review materials for the ExCPT and PTCB exams to assure both are job related.

At this time, the board is developing a process by which the two exam vendors would pay for the evaluation of the respective exams and the reports come to the board.

To use the ExCPT exam as a qualifying method for pharmacy technician licensure, either a statutory or a regulation amendment needs to be adopted.

Additionally, CSHP and CPhA are initiating a study of intern qualifications and experience, and whether current requirements are sufficient to adequately prepare pharmacy technicians for the responsibilities of working in a pharmacy.

### **ITEM 6: INFORMATION ONLY: Mobile Community Clinics and Licensing by the Board of Pharmacy**

The committee held a discussion at the request of Paul Drogichen, PharmD, Director of Pharmaceutical Services, in which he requested that the Board of Pharmacy alter its

licensing requirements to issue clinic permits to mobile clinics, and not just to the brick and mortar administrative office.

Dr. Drogichen stated he was concerned with the differing licensing policies of the board and the Department of Health Services (now the Department of Public Health), since the DHPS will issue a unique clinic license to a mobile clinic, and the board will not.

Board staff explained that the board only issues a permit to a clinic at a brick and mortar location. Such a location can have multiple mobile clinics, but the main location, typically the main and administrative office, is what actually holds the board's license. There should be no problem with a mobile clinic having the benefits of a board license so long as a brick and mortar address is used as the licensed location.

## **ITEM 7: Competency Committee Report**

On June 1, the board began using the new test administrator for the CPJE. The transition has not been wholly smooth, and there are issues the board is working to resolve with the new vendor and the Department of Consumer Affairs (which is the board's intermediary to the vendor). However, staff hopes that the transition to the new vendor will be invisible to candidates.

Here is a quick overview:

- Board-eligible candidates have been able to take the exam since June 2.
- The board's Web site materials have been updated to reflect the new exam.
- A new Candidates' Guide has been mailed to all CPJE eligible candidates. This volume describes how to sign up for the exam, how to study for it, procedural items, what to expect at the test site, sample questions, etc.
- The board initiated a quality assurance review on June 1. This is where the board holds the results of the examination until approximately 400 individuals take the CPJE.
- Between 6/1/07 and 7/1/07, only 99 candidates took the CPJE.

Meanwhile, board staff did a tremendous job in getting 400 California school graduates of 2007 qualified in a two week period so they could take the examination from the prior vendor (on or before May 31, 2007). One school did not have students graduate early enough to qualify under B&P Code section's 4200 requirement that an applicant "be a graduate of a school of pharmacy."

## **ITEM 8: LICENSING STATISTICS, 7/1/06- 6/30/07**

Attachment 7 contains licensing statistics describing the Licensing Unit's processing activities throughout the prior fiscal year.

# Attachment 1

*Proposed Regulation Requirements  
for Pharmacies that Compound*

### **§1716.1. Compounding Unapproved Drugs for Prescriber Office Use.**

As used in Business and Professions Code Section 4052(a)(1), the following terms have the indicated meaning concerning the compounding of unapproved drugs for prescriber office use:

- (a) "Reasonable quantity" means that quantity of an unapproved drug which:
  - (1) is sufficient for that prescriber's office use consistent with the expiration date of the product as set forth in section 1716.2(a)(3); and
  - (2) is reasonable considering the intended use of the compounded medication and nature of the prescriber's practice; and
  - (3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality and purity of the compounded medication.
- (b) "Compounded medication" means medications actually compounded by the pharmacy supplying them to a prescriber.
- (c) "Prescriber office use" means application or administration in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients as estimated by the prescriber.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4027, 4033, 4050, 4051, 4052, 4059, 4170 and 4171, Business and Professions Code.

### **§1716.2. Record Requirements—Compounding for Future Furnishing.**

(a) For the purpose of compounding in quantities larger than required for immediate dispensing by a prescriber or for future dispensing upon prescription, a pharmacy shall maintain records that include, but are not limited to:

- (1) The date of preparation.
- (2) The lot numbers. These may be the manufacturer's lot numbers or new numbers assigned by the pharmacy. If the lot number is assigned by the pharmacy, the pharmacy must also record the original manufacturer's lot numbers and expiration dates, if known. If the original manufacturer's lot numbers and expiration dates are not known, the pharmacy shall record the source and acquisition date of the components.
- (3) The expiration date of the finished product. This date must not exceed 180 days or the shortest expiration date of any component in the finished product unless a longer date is supported by stability studies in the same type of packaging as furnished to the prescriber. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.
- (4) The signature or initials of the pharmacist performing the compounding.
- (5) A formula for the compounded product. The formula must be maintained in a readily retrievable form.
- (6) The name(s) of the manufacturer(s) of the raw materials.
- (7) The quantity in units of finished products or grams of raw materials.
- (8) The package size and the number of units prepared.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4051, 4059, 4081 and 4332, Business and Professions Code.

## **Article 4.5 General Compounding**

### **§1735. Compounding in Licensed Pharmacies**

- (a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:
  - (1) Altering the dosage form or delivery system of a drug
  - (2) Altering the strength of a drug
  - (3) Combining components or active ingredients
  - (4) Preparing a drug product from chemicals or bulk drug substances

- (b) “Compounding” does not include reconstitution of a drug pursuant to a manufacturer’s direction(s) for oral, rectal topical, or injectable administration, nor does it include the addition of flavoring agent(s) to enhance palatability.
- (c) “Compounding” does not include, except in small quantities under limited circumstances as justified by a specific, documented, medical need, preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug product that is commercially available in the marketplace.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, and 4052, Business and Professions Code.

### **§1735.1. Compounding Definitions**

- (a) “Integrity” means retention of potency until the expiration date noted on the label.
- (b) “Potency” means active ingredient strength within +/- 10% of the labeled amount.
- (c) “Quality” means the absence of harmful contaminants, filth, putrid, or decomposed substances, and absence of any active ingredients other than those noted on the label.
- (d) “Strength” means amount of active ingredient per unit of a compounded drug product.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, and 4052, Business and Professions Code.

### **§1735.2. Compounding Limitations and Requirements**

- (a) Except as specified in (b) and (c), no drug product shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug product either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.
- (b) A pharmacy may prepare and store a limited quantity of a compounded drug product in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population. ~~A quantity “necessary to ensure continuity of care” is that amount that might reasonably be expected to be prescribed for the identified patient population on any given day.~~
- (c) Pursuant to Business and Professions Code section 4052(a)(1), a “reasonable quantity” of compounded drug product may be furnished to a prescriber for office use upon prescriber order, where “reasonable quantity” is that amount of compounded drug product that:
  - (1) is sufficient for administration or application to patients in the prescriber’s office, or for distribution of not more than a 72-hour supply to the prescriber’s patients, as estimated by the prescriber;
  - (2) is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice; and
  - (3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product.<sup>1</sup>
- (d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:

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<sup>1</sup> Moved from 1716.1

- (1) Active ingredients to be used.
  - (2) Inactive ingredients to be used.
  - (3) Process and/or procedure used to prepare the drug.
  - (4) Quality reviews required at each step in preparation of the drug.
  - (5) Post-compounding process or procedures required, if any.
  - (6) Expiration dating requirements.
- (e) Where a pharmacy does not routinely compound a particular drug product, the master formula record for that product specified in subdivision (d) may be recorded on the prescription document itself.
  - (f) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product until it is dispensed.
  - (g) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendial and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.
  - (h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.
  - (i) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product.
  - (j) Prior to allowing any drug to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment form for compounding pharmacies developed by the board (form XXXXX). The self assessment shall subsequently be performed before July 1 of each year, within 30 days of the designation of a new pharmacist-in-charge, or within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, and 4052, Business and Professions Code.

### **§1735.3. Records of Compounded Drug Products**

- (a) For each compounded drug product, the pharmacy records shall include: ~~a record shall be made and kept that includes at least:~~
  - (1) The ~~information required for a~~ master formula record.
  - (2) The date the drug product was compounded.
  - (3) The identity of the pharmacy personnel who compounded the drug product.
  - (4) The identity of the pharmacist reviewing the final drug product.
  - (5) The quantity of each component used in compounding the drug product.
  - (6) The ~~supplier~~ manufacturer and lot number of each component.
  - (7) The equipment used in compounding the drug product.
  - (8) A pharmacy assigned ~~The internal~~ reference or lot (~~lot~~) number for the compounded drug product.
  - (9) The expiration date of the final compounded drug product.

- (10) The quantity or amount of drug product compounded.<sup>2</sup>
- (b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.
  - (c) Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, drug products, and components used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the Food and Drug Administration.
  - (d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, and 4052, Business and Professions Code.

#### **§1735.4. Labeling of Compounded Drug Products**

- (a) In addition to the labeling information required under Business and Professions Code Section 4076, the label of a compounded drug product shall contain the generic name(s) of the principal active ingredient(s).
- (b) A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient.
- (c) Drug products compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a) and (b) shall be labeled with at least the name(s) of the active ingredient(s), concentration or strength, volume or weight, pharmacy reference or lot number, and expiration date.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, and 4052, Business and Professions Code.

#### **§1735.5. Compounding Policies and Procedures**

- (a) Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.
- (b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented.
- (c) The policy and procedure manual shall include procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedure manual.
- (d) The policy and procedure manual shall include documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product.
- (e) The policy and procedure manual shall include the procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.

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<sup>2</sup> Imported in modified form from 1716.2

- (f) The policy and procedure manual shall include documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.
- (g) The policy and procedure manual shall include documentation of the methodology used to determine appropriate expiration dates for compounded drug products.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, and 4052, Business and Professions Code.

#### **§1735.6. Compounding Facilities and Equipment**

- (a) Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug products. Where applicable, this shall include records of certification(s) of facilities or equipment.
- (b) Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specifications.
- (c) Any equipment used to compound drug products shall be calibrated prior to use to ensure accuracy. Documentation of each such calibration shall be recorded in writing and these records of calibration shall be maintained and retained in the pharmacy.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, and 4052, Business and Professions Code.

#### **§1735.7. Training of Compounding Staff**

- (a) Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.
- (b) The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.
- (c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug product.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, and 4052, Business and Professions Code.

#### **§1735.8. Compounding Quality Assurance**

- (a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products.
- (b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.
- (c) The quality assurance plan shall include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated with the compounding record and master formula.

- (d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug product is ever discovered to be below minimum standards for integrity, potency, quality, or labeled strength.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, and 4052, Business and Professions Code.

**§1751.3. Recordkeeping Requirements.**

- (a) Pharmacies compounding sterile injectable products for future use pursuant to section ~~1716.1~~ 1735.2 shall, in addition to those records required by section ~~1716.2~~ 1735.3, have records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.
- (b) In addition to the records required by subdivisions (a), for sterile products compounded from one or more non-sterile ingredients the following records must be maintained for at least three years:
- (1) The training and competency evaluation of employees in sterile product procedures.
  - (2) Refrigerator and freezer temperatures.
  - (3) Certification of the sterile compounding environment.
  - (4) Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).
  - (5) Inspection for expired or recalled pharmaceutical products or raw ingredients.
  - (6) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.
- (c) Pharmacies shall maintain records of validation processes as required by Section 1751.7 (b) for three years.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.

From NACDS 5/29/07

Concerns in shaded areas.

March 2, 2007

Ms. Virginia Herold  
Executive Officer  
California Board of Pharmacy  
1625 N. Market Blvd. N219  
Sacramento, CA 95834

Dear Ms. Herold:

*Re: Article 4.5 General Compounding*

On behalf of the approximately 2,914 chain pharmacies that operate in the state of California, the National Association of Chain Drug Stores (NACDS) thanks the California Board of Pharmacy ("Board") for the opportunity to comment on the proposed rule amendments affecting the compounding of prescription drugs.

We are concerned that many of the proposed requirements would prevent most pharmacies from engaging in "nonsterile basic" compounding. The Pharmacy Compounding Accreditation Board (PCAB) defines "nonsterile basic" compounding as "compounding which involves the preparation of a formulation containing two or more nonsterile commercially available products employing basic pharmacy training skill sets, as well as, defined policy, procedures and processes necessary to ensure quality and consistency of the completed compounded preparation."<sup>1</sup> We believe that many of the proposed rules' requirements would place unnecessary burdens on pharmacies that engage only in this type of compounding on an occasional basis, pursuant to a prescription. Consequently, these pharmacies would no longer engage in compounding of any products for patients. We fear that patients' health and well-being may be negatively impacted if their local pharmacies are not able to provide nonsterile, basic compounded products.

We ask the Board to distinguish "nonsterile basic" compounding from other types of compounding, as defined by PCAB. We believe that many of the requirements for complex and sterile compounding are not appropriate for nonsterile basic compounding. As recognized by PCAB's definition, such compounding includes nonsterile products that are already commercially available, and requires only basic pharmacy training skill sets. With this in mind, we ask the Board to reconsider the following rules as they would apply to nonsterile basic compounding:

- 1735.1(b) – We believe that it would be unnecessarily burdensome for pharmacies to have to create a written master formula to engage in common nonsterile basic compounding, such as combining two commercially-available topical

<sup>1</sup> PCAB Standards with Compliance Indicators, p. 27, located at [www.pcab.info](http://www.pcab.info).

preparations, mixing together commercially-available liquids, or mixing a commercially-available injectable drug into a commercially-available topical preparation, all pursuant to a specific prescription order. For these products, the formula is the prescription order. We ask the Board not to require a written master formula for nonsterile basic compounding, or in the alternative, to allow such information to be recorded electronically.

- 1735.1(h) – For many of the same reasons, we believe the self-assessment requirement is not appropriate for nonsterile basic compounding. Since by its definition this type of compounding employs only basic pharmacy training skill sets, any licensed pharmacist should be able to engage in this type of compounding without additional oversight by a pharmacist-in-charge.
- 1735.4 – We ask the Board to clarify that the policy and procedure manual may recognize that many of the policies and procedures that apply to complex and sterile compounding would not apply to nonsterile basic compounding, such as procurement procedures, compounding and formulation methodologies, and quantitative/qualitative analysis reports.
- 1735.6 – We ask the Board to reconsider for nonsterile basic compounding the requirement of written documentation that pharmacy personnel have the skills and training required to correctly perform their assigned responsibilities relating to compounding. Nonsterile basic compounding employs basic pharmacy skill sets that any licensed pharmacist should readily possess. Similarly, we ask the Board amend the ongoing competency requirement such that pharmacists that engage only in nonsterile basic compounding would be encouraged to attend continuing education courses on this type of compounding, and that no additional ongoing competency would be required.

We ask the Board to consider our concerns so that all pharmacies may continue to engage in nonsterile basic compounding. We fear that if the proposed rules were adopted as currently written, most pharmacies would choose not to engage in any compounding due to the unnecessarily burdensome nature of the rules as they relate to nonsterile basic compounded products. We understand the Board must consider all factors that might affect public health and safety; we urge the Board to consider the difficulty consumers would face in obtaining nonsterile, basic, compounded products as a factor in your deliberation.

Under proposed Section 1735.1(a), the Board would require a dispensing pharmacist to establish a professional relationship with both a prescriber and a patient prior to compounding a drug. We ask that the Board require the dispensing pharmacist to establish a professional relationship only with the prescriber prior to compounding the drug, and with the patient prior to dispensing the compounded drug.

Some prescribers frequently prescribe the same compounded drug or drugs over time. For these prescribers, it is helpful for the prescriber, pharmacist, and patients for the pharmacist to be able to compound such drugs ahead of time based upon the prescriber's

routine prescribing habits. This way compounded products can be readily available for patients.

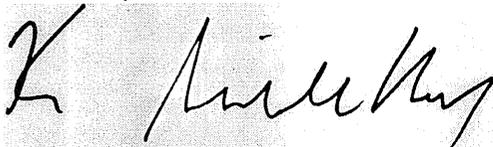
Compounding drugs can be a time-consuming process. Pharmacists may not have time to compound drugs during busy days, and may need to delay compounding a drug to another day, or perhaps over a weekend, when prescription volumes are lower. Allowing a pharmacist to compound ahead of time based on routine prescribing habits would allow pharmacists to plan ahead, rather than have to make patients wait hours or days for their compounded drugs. With demands on pharmacies ever increasing, pharmacies find it helpful to have available for patients compounded drugs that are commonly prescribed.

Under proposed rule 1735.2(b), we ask the Board to allow pharmacies to maintain in readily-retrievable centralized records information on the acquisition, storage, and proper destruction of chemicals, drugs, and components used in compounding. Many pharmacies presently maintain this information in this manner, and we ask the Board to clarify that pharmacies may continue to do so.

Finally, we ask the Board to clarify that adding a flavoring agent to a commercially-available product is not considered "compounding." Many patients prefer to have the flavor of an oral liquid medication changed to better suit their tastes; pharmacists oblige, recognizing that doing so will increase patient adherence to their medication therapy. Please clarify that merely changing the flavor of a medication is not considered "compounding," as doing so does not change the therapeutic effect of the medication and can positively affect patient adherence. Considering this service to be compounding would only act as a deterrent for pharmacists to provide this service, as having to comply with compounding requirements would be unnecessary burdens.

We thank the Board for considering our comments. Please do not hesitate to contact us if we can further assist you.

Sincerely,

A handwritten signature in black ink, appearing to read "Kevin Nicholson", written over a light gray rectangular background.

Kevin Nicholson, R.Ph., J.D.  
Vice President  
Pharmacy Regulatory Affairs



# californiapharmacistsassociation

## Comments on Proposed Compounding Regulations Licensing Committee

May 30, 2007

Submitted by the California Pharmacists Association

### Comments with General Applicability:

1. Our prior comments regarding consistent use of “expiration date” have been incorporated. We think the approach used in §1735.2(f) is acceptable. Likewise, our comment regarding incorporation of “readily retrievable” for much of the required documentation has been incorporated into the language.
2. In the memo that accompanied the original language and this amended language, the Board makes note of its review of “the federal bill associated with Senator Kennedy” This bill has never been introduced and appears to have lost much of its support. Any language in this proposed text that has been influenced by the legislative draft circulated at the federal level should be reconsidered.
3. There are some errors in numbering in the draft document – we noticed that there are two sections numbered §1735.2, and within the first §1735.2 there are two subsection (d)’s.

### Specific sections:

#### 1735 Compounding in Licensed Pharmacies

The problem of defining “compounding” has been a problem for many years. Although the language here has been used for some time, CPhA believes the language has considerable flaws and needs to be considered more carefully before being finalized – for instance, “altering the dosage form or delivery system of a drug” or “altering the strength of a drug” could place tablet splitting within the definition of “compounding.” In addition, the language in the definition that limits “compounding” to “activities occurring in a licensed pharmacy or under the supervision of a licensed pharmacist” would exclude similar activities either on a hospital floor or a physician’s office. It seems impossible to meet the public safety goals this regulation intends to accomplish without including all sites where compounding activity occurs.

#### §1735.1. Compounding Definitions

Reflects our recommendation to shift certain provisions into separate sections. Along with the addition of the definition of “Potency” and the revised definition of “Quality,” this is an improvement over the prior version.

#### §1735.2 Compounding Limitations and Requirements

In general, this section is much improved from the prior version, better reflects the Board’s intent and generally provides a more cohesive approach to the issues.



CPhA does have some comments with regard to Subsection (b):

- Overall, the language may be too restrictive (i.e. narrow) for practical purposes. The apparent requirement for a “documented history of prescriptions for [an identified population of patients]” which is used to establish “solely” the “quantity as is necessary” that may be compounded in advance sets an overly strict standard for estimating typical or historical usage. How could a pharmacy ever comply with this requirement? What sort of documentation would a pharmacy need to produce to support its advance compounding? What guidelines and flexibility will Board Inspectors have to gauge compliance with this section? Pharmacies should be allowed to justify advance compounding based on reasonable estimates of projected need.
- As it relates to defining a “quantity necessary to ensure continuity of care” the language used could be interpreted to establish a one day’s supply as the quantity of a product that can reasonably be compounded in advance of receipt of a prescription. If this is the intent of this language, CPhA feels it is inappropriate. If not, the language should be revised for clarity. Pharmacies should be allowed to compound in advance batch sizes that would be larger than the amount used in a single day.

Subsection (d)(4): we continue to believe the language should be changed to: “Quality reviews required at appropriate steps in the preparation of the compounded preparation.” Not all steps in the compounding process require quality review.

Subsection (f) We renew our prior comment: Eliminate the word “stability” before “studies” in the third line. The expense of a formal “stability study” is not an appropriate requirement; what is needed is some form of study that supports an extended beyond use date for a compounded drug product.

## **§1735.2 Records of Compounded Drug Products**

We renew our prior comments:

(a)(7) More detail is needed on what “equipment used” really should include.

(c) Change the last sentence to: “Certificates of purity or analysis are not required for *components used in compounding* that are approved by the Federal Food and Drug Administration.” An important consideration here is to either include or exempt foods, food colorings, flavorings or other components that are not subject to the drug approval process.

## **§1735.4 Compounding Policies and Procedures**

CPhA continues to think this section is drafted in a less than optimal way. We believe our previous suggestion continues to be clearer:



Change to:

Pharmacies must maintain a readily retrievable policy and procedure manual for compounding activities that includes at least:

- (a) Procurement procedures for components used in compounding;
- (b) Methods for the determining formulations and compounding processes for drug products;
- (c) Requirements for general cleaning and maintenance of facilities and equipment;
- (d) Standard operating procedures for the pharmacy;
- (e) Procedures for recalling dispensed compounded products;
- (f) Procedures for maintenance, storage, calibration, cleaning and disinfecting equipment used in compounding drug products;
- (g) Steps used to ensure that compounded drugs products have their labeled strength, consistent with standards for the profession;
- (h) Methods to notify the staff assigned to compounding duties of any changes in the policy and procedure manual.

The policy and procedure manual shall be reviewed annually by the pharmacist-in-charge.

#### **§1735.5 Compounding Facilities and Equipment**

Little has been done to address our previous concern. The use of the word “documentation” here is confusing. What needs to be documented or what sort of documentation is needed?

#### **§1735.6 Training of Compounding Staff**

We renew our previous comment that the section should add at the end of subsection (b): “The ongoing training and competency evaluation process shall include the procedures for maintenance, storage, calibration, cleaning and disinfecting of equipment used in compounding drug products.” Although the Board may feel that its language adequately addresses this issue, we feel this language will improve the clarity of the section.

#### **§1735.7 Compounding Quality Assurance**

The new language incorporates our prior comment.

May 25, 2007

Virginia Herold  
Licensing Committee  
California State Board of Pharmacy  
1625 North Market Blvd., Suite N219  
Sacramento, CA 95834



Dear Ms. Herold,

We recommend changing section 1735.4 of the proposed regulation requirements for Pharmacies that Compound Medication that are scheduled to be presented at the Licensing Committee on May 30, 2007. That change is in section 1735.4. Recommended changes are in bold and underlined.

Section 1735.3 Labeling of Compounded Drug Products

(a) In addition to the labeling information required under Business and Professions Code Section 4076, the label of a compounded drug product shall contain the generic name(s) of the principal active ingredients(s).

(b) A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient.

(c) Drug products compounded into unit-dose containers shall be labeled with the name(s) of the active ingredients(s), concentration or strength, volume or weight, lot or control number, name of pharmacy, and expiration date. If the unit-dose container is too small or is otherwise unable to accommodate a label with sufficient space to bear all of this information, the information shall appear on the outer container or the information shall appear on a leaflet within the package with the unit-doses.

Very best wishes,

McGuff Compounding Pharmacy Services, Inc.

A handwritten signature in cursive script that reads 'William J. Blair'.

William J. Blair, Pharm. D., MBA  
Director of Pharmacy Services

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June 8, 2007

Virginia Herold  
Executive Officer, California Board of Pharmacy  
1625 N. Market Blvd N219  
Sacramento, California 95834

**Re: Proposed Regulations - Article 4.5 General Compounding**

Dear Executive Officer Herold:

The California Society of Health-System Pharmacists (CSHP) is in support of regulations on **non-sterile** compounding. We agree that this area of pharmacy practice needs specific regulation to protect the safety of our patients. Upon further review of these regulations, it has come to our attention that minor technical changes are needed.

We recommend that **sterile** and **non-sterile** compounding be maintained in separate regulations. Current California regulations, Article 7 Section 1751 (Sterile Injectable Compounding) and Business & Professions Code Section 4127 (Injectable Sterile Drug Products) cover the issues related to **sterile** compounding. These current regulations contain the required elements (e.g., facility and equipment standards, policies and procedures, labeling and recordkeeping requirements, training and quality assurance processes) for the safe practice of **sterile** compounding and requirement of additional licensure or accreditation to perform the functions of **sterile** compounding.

The requirements for the safe preparation of **sterile** and **non-sterile** compounds are distinctly different. The United States Pharmacopeia (USP) regulates these processes separately in 2 distinct chapters. USP 797 deals with Pharmaceutical Compounding – Sterile Preparations and USP 795 deals with Pharmaceutical Compounding – Nonsterile Preparations.

Therefore we recommend the following changes to the proposed regulation to assure there is no confusion and that the regulations are clear as to the intent and requirements of both **sterile** and **non-sterile** compounding:

- Section 1735 Add  
(d) This section does not apply to Sterile Injectable Compounding as defined and regulated under Article 7, Section 1751 and Business & Professions Code Section 4127.
- Since Section 1716 is proposed to be deleted, the following change is needed in Section 1751 to update references on anticipatory compounding and recordkeeping in **sterile** compounding.  
**§1751.3. Recordkeeping Requirements.**  
(a) Pharmacies compounding sterile injectable products for future use pursuant to section ~~1716.1~~1735.2 shall, in addition to those records required by section ~~1716.2~~



1735.2, have records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.

- To correct the numbering error in the regulations as proposed in Sections 1735.2-1735.7, where 2 sections have the same number.

Founded in 1962, CSHP represents nearly 4,000 pharmacists and associates who serve patients and the public through the promotion of wellness and rational drug therapy. CSHP members practice in a variety of organized healthcare settings, including, but not limited to, hospitals, integrated healthcare systems, clinics, home healthcare and ambulatory care settings.

If you have any questions, please do not hesitate to contact me at (916) 447-1033 or CSHP's Legislative Advocate, Bryce W.A. Docherty at (916) 446-4343.

Respectfully,

Dawn Benton  
Interim, Executive Vice President

cc. Bryce Docherty

### **§1716.1. Compounding Unapproved Drugs for Prescriber Office Use.**

As used in Business and Professions Code Section 4052(a)(1), the following terms have the indicated meaning concerning the compounding of unapproved drugs for prescriber office use:

- (a) "Reasonable quantity" means that quantity of an unapproved drug which:
  - (1) is sufficient for that prescriber's office use consistent with the expiration date of the product as set forth in section 1716.2(a)(3); and
  - (2) is reasonable considering the intended use of the compounded medication and nature of the prescriber's practice; and
  - (3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality and purity of the compounded medication.
- (b) "Compounded medication" means medications actually compounded by the pharmacy supplying them to a prescriber.
- (c) "Prescriber office use" means application or administration in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients as estimated by the prescriber.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4027, 4033, 4050, 4051, 4052, 4059, 4170 and 4171, Business and Professions Code.

### **§1716.2. Record Requirements—Compounding for Future Furnishing.**

(a) For the purpose of compounding in quantities larger than required for immediate dispensing by a prescriber or for future dispensing upon prescription, a pharmacy shall maintain records that include, but are not limited to:

- (1) The date of preparation.
- (2) The lot numbers. These may be the manufacturer's lot numbers or new numbers assigned by the pharmacy. If the lot number is assigned by the pharmacy, the pharmacy must also record the original manufacturer's lot numbers and expiration dates, if known. If the original manufacturer's lot numbers and expiration dates are not known, the pharmacy shall record the source and acquisition date of the components.
- (3) The expiration date of the finished product. This date must not exceed 180 days or the shortest expiration date of any component in the finished product unless a longer date is supported by stability studies in the same type of packaging as furnished to the prescriber. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.
- (4) The signature or initials of the pharmacist performing the compounding.
- (5) A formula for the compounded product. The formula must be maintained in a readily retrievable form.
- (6) The name(s) of the manufacturer(s) of the raw materials.
- (7) The quantity in units of finished products or grams of raw materials.
- (8) The package size and the number of units prepared.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4051, 4059, 4081 and 4332, Business and Professions Code.

## **Article 4.5 General Compounding**

### **§1735. Compounding in Licensed Pharmacies**

- (a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:
  - (1) Altering the dosage form or delivery system of a drug
  - (2) Altering the strength of a drug
  - (3) Combining components or active ingredients
  - (4) Preparing a drug product from chemicals or bulk drug substances

- (b) “Compounding” does not include reconstitution of a drug pursuant to a manufacturer’s direction(s) for oral, rectal topical, or injectable administration, nor does it include the addition of flavoring agent(s) to enhance palatability.
- (c) “Compounding” does not include, except in small quantities under limited circumstances as justified by a specific, documented, medical need, preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug product that is commercially available in the marketplace.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, and 4052, Business and Professions Code.

### **§1735.1. Compounding Definitions**

- (a) “Integrity” means retention of potency until the expiration date noted on the label.
- (b) “Potency” means active ingredient strength within +/- 10% of the labeled amount.
- (c) “Quality” means the absence of harmful contaminants, filth, putrid, or decomposed substances, and absence of any active ingredients other than those noted on the label.
- (d) “Strength” means amount of active ingredient per unit of a compounded drug product.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, and 4052, Business and Professions Code.

### **§1735.2. Compounding Limitations and Requirements**

- (a) Except as specified in (b) and (c), no drug product shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug product either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.
- (b) A pharmacy may prepare and store a limited quantity of a compounded drug product in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population. ~~A quantity “necessary to ensure continuity of care” is that amount that might reasonably be expected to be prescribed for the identified patient population on any given day.~~
- (c) Pursuant to Business and Professions Code section 4052(a)(1), a “reasonable quantity” of compounded drug product may be furnished to a prescriber for office use upon prescriber order, where “reasonable quantity” is that amount of compounded drug product that:
  - (1) is sufficient for administration or application to patients in the prescriber’s office, or for distribution of not more than a 72-hour supply to the prescriber’s patients, as estimated by the prescriber;
  - (2) is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice; and
  - (3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product.<sup>1</sup>
- (d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:

<sup>1</sup> Moved from 1716.1

- (1) Active ingredients to be used.
  - (2) Inactive ingredients to be used.
  - (3) Process and/or procedure used to prepare the drug.
  - (4) Quality reviews required at each step in preparation of the drug.
  - (5) Post-compounding process or procedures required, if any.
  - (6) Expiration dating requirements.
- (e) Where a pharmacy does not routinely compound a particular drug product, the master formula record for that product specified in subdivision (d) may be recorded on the prescription document itself.
  - (f) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product until it is dispensed.
  - (g) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendial and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.
  - (h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.
  - (i) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product.
  - (j) Prior to allowing any drug to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment form for compounding pharmacies developed by the board (form XXXXX). The self assessment shall subsequently be performed before July 1 of each year, within 30 days of the designation of a new pharmacist-in-charge, or within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, and 4052, Business and Professions Code.

### **§1735.3. Records of Compounded Drug Products**

- (a) For each compounded drug product, the pharmacy records shall include: ~~a record shall be made and kept that includes at least:~~
  - (1) The information required for a master formula record.
  - (2) The date the drug product was compounded.
  - (3) The identity of the pharmacy personnel who compounded the drug product.
  - (4) The identity of the pharmacist reviewing the final drug product.
  - (5) The quantity of each component used in compounding the drug product.
  - (6) The ~~supplier~~ manufacturer and lot number of each component.
  - (7) The equipment used in compounding the drug product.
  - (8) A pharmacy assigned ~~The internal~~ reference or lot (~~lot~~) number for the compounded drug product.
  - (9) The expiration date of the final compounded drug product.

(10) The quantity or amount of drug product compounded.<sup>2</sup>

- (b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.
- (c) Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, drug products, and components used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the Food and Drug Administration.
- (d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, and 4052, Business and Professions Code.

#### **§1735.4. Labeling of Compounded Drug Products**

- (a) In addition to the labeling information required under Business and Professions Code Section 4076, the label of a compounded drug product shall contain the generic name(s) of the principal active ingredient(s).
- (b) A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient.
- (c) Drug products compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a) and (b) shall be labeled with at least the name(s) of the active ingredient(s), concentration or strength, volume or weight, pharmacy reference or lot number, and expiration date.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, and 4052, Business and Professions Code.

#### **§1735.5. Compounding Policies and Procedures**

- (a) Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.
- (b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented.
- (c) The policy and procedure manual shall include procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedure manual.
- (d) The policy and procedure manual shall include documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product.
- (e) The policy and procedure manual shall include the procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.

<sup>2</sup> Imported in modified form from 1716.2

- (f) The policy and procedure manual shall include documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.
- (g) The policy and procedure manual shall include documentation of the methodology used to determine appropriate expiration dates for compounded drug products.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, and 4052, Business and Professions Code.

#### **§1735.6. Compounding Facilities and Equipment**

- (a) Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug products. Where applicable, this shall include records of certification(s) of facilities or equipment.
- (b) Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specifications.
- (c) Any equipment used to compound drug products shall be calibrated prior to use to ensure accuracy. Documentation of each such calibration shall be recorded in writing and these records of calibration shall be maintained and retained in the pharmacy.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, and 4052, Business and Professions Code.

#### **§1735.7. Training of Compounding Staff**

- (a) Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.
- (b) The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.
- (c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug product.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, and 4052, Business and Professions Code.

#### **§1735.8. Compounding Quality Assurance**

- (a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products.
- (b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.
- (c) The quality assurance plan shall include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated with the compounding record and master formula.

- (d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug product is ever discovered to be below minimum standards for integrity, potency, quality, or labeled strength.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, and 4052, Business and Professions Code.

**§1751.3. Recordkeeping Requirements.**

- (a) Pharmacies compounding sterile injectable products for future use pursuant to section ~~1716.1~~ 1735.2 shall, in addition to those records required by section ~~1716.2~~ 1735.3, have records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.
- (b) In addition to the records required by subdivisions (a), for sterile products compounded from one or more non-sterile ingredients the following records must be maintained for at least three years:
- (1) The training and competency evaluation of employees in sterile product procedures.
  - (2) Refrigerator and freezer temperatures.
  - (3) Certification of the sterile compounding environment.
  - (4) Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).
  - (5) Inspection for expired or recalled pharmaceutical products or raw ingredients.
  - (6) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.
- (c) Pharmacies shall maintain records of validation processes as required by Section 1751.7 (b) for three years.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.

From NACDS 5/29/07

Concerns in shaded areas.

March 2, 2007

Ms. Virginia Herold  
Executive Officer  
California Board of Pharmacy  
1625 N. Market Blvd. N219  
Sacramento, CA 95834

Dear Ms. Herold:

*Re: Article 4.5 General Compounding*

On behalf of the approximately 2,914 chain pharmacies that operate in the state of California, the National Association of Chain Drug Stores (NACDS) thanks the California Board of Pharmacy ("Board") for the opportunity to comment on the proposed rule amendments affecting the compounding of prescription drugs.

We are concerned that many of the proposed requirements would prevent most pharmacies from engaging in "nonsterile basic" compounding. The Pharmacy Compounding Accreditation Board (PCAB) defines "nonsterile basic" compounding as "compounding which involves the preparation of a formulation containing two or more nonsterile commercially available products employing basic pharmacy training skill sets, as well as, defined policy, procedures and processes necessary to ensure quality and consistency of the completed compounded preparation."<sup>1</sup> We believe that many of the proposed rules' requirements would place unnecessary burdens on pharmacies that engage only in this type of compounding on an occasional basis, pursuant to a prescription. Consequently, these pharmacies would no longer engage in compounding of any products for patients. We fear that patients' health and well-being may be negatively impacted if their local pharmacies are not able to provide nonsterile, basic compounded products.

We ask the Board to distinguish "nonsterile basic" compounding from other types of compounding, as defined by PCAB. We believe that many of the requirements for complex and sterile compounding are not appropriate for nonsterile basic compounding. As recognized by PCAB's definition, such compounding includes nonsterile products that are already commercially available, and requires only basic pharmacy training skill sets. With this in mind, we ask the Board to reconsider the following rules as they would apply to nonsterile basic compounding:

- 1735.1(b) – We believe that it would be unnecessarily burdensome for pharmacies to have to create a written master formula to engage in common nonsterile basic compounding, such as combining two commercially-available topical

<sup>1</sup> PCAB Standards with Compliance Indicators, p. 27, located at [www.pcab.info](http://www.pcab.info).

preparations, mixing together commercially-available liquids, or mixing a commercially-available injectable drug into a commercially-available topical preparation, all pursuant to a specific prescription order. For these products, the formula is the prescription order. We ask the Board not to require a written master formula for nonsterile basic compounding, or in the alternative, to allow such information to be recorded electronically.

- 1735.1(h) – For many of the same reasons, we believe the self-assessment requirement is not appropriate for nonsterile basic compounding. Since by its definition this type of compounding employs only basic pharmacy training skill sets, any licensed pharmacist should be able to engage in this type of compounding without additional oversight by a pharmacist-in-charge.
- 1735.4 – We ask the Board to clarify that the policy and procedure manual may recognize that many of the policies and procedures that apply to complex and sterile compounding would not apply to nonsterile basic compounding, such as procurement procedures, compounding and formulation methodologies, and quantitative/qualitative analysis reports.
- 1735.6 – We ask the Board to reconsider for nonsterile basic compounding the requirement of written documentation that pharmacy personnel have the skills and training required to correctly perform their assigned responsibilities relating to compounding. Nonsterile basic compounding employs basic pharmacy skill sets that any licensed pharmacist should readily possess. Similarly, we ask the Board amend the ongoing competency requirement such that pharmacists that engage only in nonsterile basic compounding would be encouraged to attend continuing education courses on this type of compounding, and that no additional ongoing competency would be required.

We ask the Board to consider our concerns so that all pharmacies may continue to engage in nonsterile basic compounding. We fear that if the proposed rules were adopted as currently written, most pharmacies would choose not to engage in any compounding due to the unnecessarily burdensome nature of the rules as they relate to nonsterile basic compounded products. We understand the Board must consider all factors that might affect public health and safety; we urge the Board to consider the difficulty consumers would face in obtaining nonsterile, basic, compounded products as a factor in your deliberation.

Under proposed Section 1735.1(a), the Board would require a dispensing pharmacist to establish a professional relationship with both a prescriber and a patient prior to compounding a drug. We ask that the Board require the dispensing pharmacist to establish a professional relationship only with the prescriber prior to compounding the drug, and with the patient prior to dispensing the compounded drug.

Some prescribers frequently prescribe the same compounded drug or drugs over time. For these prescribers, it is helpful for the prescriber, pharmacist, and patients for the pharmacist to be able to compound such drugs ahead of time based upon the prescriber's

routine prescribing habits. This way compounded products can be readily available for patients.

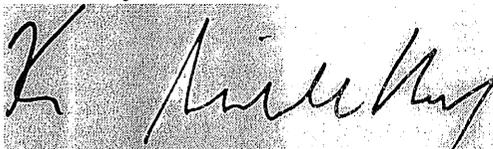
Compounding drugs can be a time-consuming process. Pharmacists may not have time to compound drugs during busy days, and may need to delay compounding a drug to another day, or perhaps over a weekend, when prescription volumes are lower. Allowing a pharmacist to compound ahead of time based on routine prescribing habits would allow pharmacists to plan ahead, rather than have to make patients wait hours or days for their compounded drugs. With demands on pharmacies ever increasing, pharmacies find it helpful to have available for patients compounded drugs that are commonly prescribed.

Under proposed rule 1735.2(b), we ask the Board to allow pharmacies to maintain in readily-retrievable centralized records information on the acquisition, storage, and proper destruction of chemicals, drugs, and components used in compounding. Many pharmacies presently maintain this information in this manner, and we ask the Board to clarify that pharmacies may continue to do so.

Finally, we ask the Board to clarify that adding a flavoring agent to a commercially-available product is not considered "compounding." Many patients prefer to have the flavor of an oral liquid medication changed to better suit their tastes; pharmacists oblige, recognizing that doing so will increase patient adherence to their medication therapy. Please clarify that merely changing the flavor of a medication is not considered "compounding," as doing so does not change the therapeutic effect of the medication and can positively affect patient adherence. Considering this service to be compounding would only act as a deterrent for pharmacists to provide this service, as having to comply with compounding requirements would be unnecessary burdens.

We thank the Board for considering our comments. Please do not hesitate to contact us if we can further assist you.

Sincerely,

A handwritten signature in black ink, appearing to read "Kevin Nicholson", is written over a grey rectangular background.

Kevin Nicholson, R.Ph., J.D.  
Vice President  
Pharmacy Regulatory Affairs



# californiapharmacistsassociation

## Comments on Proposed Compounding Regulations

Licensing Committee

May 30, 2007

Submitted by the California Pharmacists Association

### Comments with General Applicability:

1. Our prior comments regarding consistent use of "expiration date" have been incorporated. We think the approach used in §1735.2(f) is acceptable. Likewise, our comment regarding incorporation of "readily retrievable" for much of the required documentation has been incorporated into the language.
2. In the memo that accompanied the original language and this amended language, the Board makes note of its review of "the federal bill associated with Senator Kennedy" This bill has never been introduced and appears to have lost much of its support. Any language in this proposed text that has been influenced by the legislative draft circulated at the federal level should be reconsidered.
3. There are some errors in numbering in the draft document – we noticed that there are two sections numbered §1735.2, and within the first §1735.2 there are two subsection (d)'s.

### Specific sections:

#### 1735 Compounding in Licensed Pharmacies

The problem of defining "compounding" has been a problem for many years. Although the language here has been used for some time, CPhA believes the language has considerable flaws and needs to be considered more carefully before being finalized – for instance, "altering the dosage form or delivery system of a drug" or "altering the strength of a drug" could place tablet splitting within the definition of "compounding." In addition, the language in the definition that limits "compounding" to "activities occurring in a licensed pharmacy or under the supervision of a licensed pharmacist" would exclude similar activities either on a hospital floor or a physician's office. It seems impossible to meet the public safety goals this regulation intends to accomplish without including all sites where compounding activity occurs.

#### §1735.1. Compounding Definitions

Reflects our recommendation to shift certain provisions into separate sections. Along with the addition of the definition of "Potency" and the revised definition of "Quality," this is an improvement over the prior version.

#### §1735.2 Compounding Limitations and Requirements

In general, this section is much improved from the prior version, better reflects the Board's intent and generally provides a more cohesive approach to the issues.



# californiapharmacistsassociation

CPhA does have some comments with regard to Subsection (b):

- Overall, the language may be too restrictive (i.e. narrow) for practical purposes. The apparent requirement for a “documented history of prescriptions for [an identified population of patients]” which is used to establish “solely” the “quantity as is necessary” that may be compounded in advance sets an overly strict standard for estimating typical or historical usage. How could a pharmacy ever comply with this requirement? What sort of documentation would a pharmacy need to produce to support its advance compounding? What guidelines and flexibility will Board Inspectors have to gauge compliance with this section? Pharmacies should be allowed to justify advance compounding based on reasonable estimates of projected need.
- As it relates to defining a “quantity necessary to ensure continuity of care” the language used could be interpreted to establish a one day’s supply as the quantity of a product that can reasonably be compounded in advance of receipt of a prescription. If this is the intent of this language, CPhA feels it is inappropriate. If not, the language should be revised for clarity. Pharmacies should be allowed to compound in advance batch sizes that would be larger than the amount used in a single day.

Subsection (d)(4): we continue to believe the language should be changed to: “Quality reviews required at appropriate steps in the preparation of the compounded preparation.” Not all steps in the compounding process require quality review.

Subsection (f) We renew our prior comment: Eliminate the word “stability” before “studies” in the third line. The expense of a formal “stability study” is not an appropriate requirement; what is needed is some form of study that supports an extended beyond use date for a compounded drug product.

## **§1735.2 Records of Compounded Drug Products**

We renew our prior comments:

(a)(7) More detail is needed on what “equipment used” really should include.

(c) Change the last sentence to: “Certificates of purity or analysis are not required for *components used in compounding* that are approved by the Federal Food and Drug Administration.” An important consideration here is to either include or exempt foods, food colorings, flavorings or other components that are not subject to the drug approval process.

## **§1735.4 Compounding Policies and Procedures**

CPhA continues to think this section is drafted in a less than optimal way. We believe our previous suggestion continues to be clearer:



Change to:

Pharmacies must maintain a readily retrievable policy and procedure manual for compounding activities that includes at least:

- (a) Procurement procedures for components used in compounding;
- (b) Methods for the determining formulations and compounding processes for drug products;
- (c) Requirements for general cleaning and maintenance of facilities and equipment;
- (d) Standard operating procedures for the pharmacy;
- (e) Procedures for recalling dispensed compounded products;
- (f) Procedures for maintenance, storage, calibration, cleaning and disinfecting equipment used in compounding drug products;
- (g) Steps used to ensure that compounded drugs products have their labeled strength, consistent with standards for the profession;
- (h) Methods to notify the staff assigned to compounding duties of any changes in the policy and procedure manual.

The policy and procedure manual shall be reviewed annually by the pharmacist-in-charge.

#### **§1735.5 Compounding Facilities and Equipment**

Little has been done to address our previous concern. The use of the word "documentation" here is confusing. What needs to be documented or what sort of documentation is needed?

#### **§1735.6 Training of Compounding Staff**

We renew our previous comment that the section should add at the end of subsection (b): "The ongoing training and competency evaluation process shall include the procedures for maintenance, storage, calibration, cleaning and disinfecting of equipment used in compounding drug products." Although the Board may feel that its language adequately addresses this issue, we feel this language will improve the clarity of the section.

#### **§1735.7 Compounding Quality Assurance**

The new language incorporates our prior comment.

May 25, 2007

Virginia Herold  
Licensing Committee  
California State Board of Pharmacy  
1625 North Market Blvd., Suite N219  
Sacramento, CA 95834



Dear Ms. Herold,

We recommend changing section 1735.4 of the proposed regulation requirements for Pharmacies that Compound Medication that are scheduled to be presented at the Licensing Committee on May 30, 2007. That change is in section 1735.4. Recommended changes are in bold and underlined.

Section 1735.3 Labeling of Compounded Drug Products

(a) In addition to the labeling information required under Business and Professions Code Section 4076, the label of a compounded drug product shall contain the generic name(s) of the principal active ingredients(s).

(b) A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient.

(c) Drug products compounded into unit-dose containers shall be labeled with the name(s) of the active ingredients(s), concentration or strength, volume or weight, **lot or control number, name of pharmacy,** and expiration date. **If the unit-dose container is too small or is otherwise unable to accommodate a label with sufficient space to bear all of this information, the information shall appear on the outer container or the information shall appear on a leaflet within the package with the unit-doses.**

Very best wishes,

McGuff Compounding Pharmacy Services, Inc.

  
William J. Blair, Pharm. D., MBA  
Director of Pharmacy Services

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June 8, 2007

Virginia Herold  
Executive Officer, California Board of Pharmacy  
1625 N. Market Blvd N219  
Sacramento, California 95834

**Re: Proposed Regulations - Article 4.5 General Compounding**

Dear Executive Officer Herold:

The California Society of Health-System Pharmacists (CSHP) is in support of regulations on **non-sterile** compounding. We agree that this area of pharmacy practice needs specific regulation to protect the safety of our patients. Upon further review of these regulations, it has come to our attention that minor technical changes are needed.

We recommend that **sterile** and **non-sterile** compounding be maintained in separate regulations. Current California regulations, Article 7 Section 1751 (Sterile Injectable Compounding) and Business & Professions Code Section 4127 (Injectable Sterile Drug Products) cover the issues related to **sterile** compounding. These current regulations contain the required elements (e.g., facility and equipment standards, policies and procedures, labeling and recordkeeping requirements, training and quality assurance processes) for the safe practice of **sterile** compounding and requirement of additional licensure or accreditation to perform the functions of **sterile** compounding.

The requirements for the safe preparation of **sterile** and **non-sterile** compounds are distinctly different. The United States Pharmacopeia (USP) regulates these processes separately in 2 distinct chapters. USP 797 deals with Pharmaceutical Compounding -- Sterile Preparations and USP 795 deals with Pharmaceutical Compounding -- Nonsterile Preparations.

Therefore we recommend the following changes to the proposed regulation to assure there is no confusion and that the regulations are clear as to the intent and requirements of both **sterile** and **non-sterile** compounding:

- Section 1735 Add  
(d) This section does not apply to Sterile Injectable Compounding as defined and regulated under Article 7, Section 1751 and Business & Professions Code Section 4127.
- Since Section 1716 is proposed to be deleted, the following change is needed in Section 1751 to update references on anticipatory compounding and recordkeeping in **sterile** compounding.

**§1751.3. Recordkeeping Requirements.**

(a) Pharmacies compounding sterile injectable products for future use pursuant to section ~~1716.1~~1735.2 shall, in addition to those records required by section ~~1716.2~~



CALIFORNIA SOCIETY OF  
HEALTH-SYSTEM PHARMACISTS  
*Partners in Medication Management*

1735.2, have records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.

- To correct the numbering error in the regulations as proposed in Sections 1735.2-1735.7, where 2 sections have the same number.

Founded in 1962, CSHP represents nearly 4,000 pharmacists and associates who serve patients and the public through the promotion of wellness and rational drug therapy. CSHP members practice in a variety of organized healthcare settings, including, but not limited to, hospitals, integrated healthcare systems, clinics, home healthcare and ambulatory care settings.

If you have any questions, please do not hesitate to contact me at (916) 447-1033 or CSHP's Legislative Advocate, Bryce W.A. Docherty at (916) 446-4343.

Respectfully,

Dawn Benton  
Interim, Executive Vice President

cc. Bryce Docherty

# Attachment 2

## *Proposed State Protocols for Pharmacists to Administer Immunizations*

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

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

(2) Transmit a valid prescription to another pharmacist.

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

(4) Perform procedures or functions in a licensed health care facility as authorized by Section 4052.1.

(5) Perform procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, as authorized by Section 4052.2.

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

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

(8) Furnish emergency contraception drug therapy as authorized by Section 4052.3.

(9) Administer immunizations pursuant to a protocol with a prescriber or pursuant to the recommendations of the Advisory Committee on Immunization Practices (ACIP) of the federal Centers for Disease Control and Prevention.

(b) A pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy pursuant to this section shall personally register with the federal Drug Enforcement Administration.

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

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

## Pharmacy Immunization Protocol

### Pharmacy Name

#### Authorizing Prescriber Statement for Vaccination

<Pharmacist, RPh> of the <Pharmacy>, and other licensed pharmacists employed by the <Pharmacy>, pharmacy students of the <Pharmacy>, acting as delegates for <Physician>, M.D. according to and in compliance with Article 3 of the Business and Professional Code 4052.(a).(4).(C) and B&P code 4052.(a).(5).(A).(iii) of the California Pharmacy Scope of Practice section, will independently determine the need for and administer vaccinations and epinephrine, on the premises of the USC Campus Pharmacies, or a suitable alternate location as authorized under Appendix A, and for a fee.

#### Qualifications of Persons Administering Vaccine

1. CPR certified (BLS) – American Red Cross or American Heart Association or equivalent
2. Certificate of completion of an appropriate immunization program (see Appendix B)

#### Vaccine(s) to be administered (see Appendix C)

- Influenza (IM and Intranasal)
- Tetanus-diphtheria (Td)
- Tetanus-diphtheria-pertussis (Tdap)
- Pneumococcal (PPV23 adult)
- MMR (for adults)
- HPV
- Meningococcal (MCV4 and MPSV4)
- Varicella Zoster
- Herpes Zoster
- Hepatitis B

#### Policies

1. A standard form will be used to document immunizations and the pharmacy will maintain a patient record of administration, including, but not limited to, patient name, date, vaccine given (manufacturer, lot #, and expiration date), and signature of person administering vaccine (Appendix D)
2. The screening form contained in this protocol will be maintained as documentation (Appendix D)
3. The current Vaccine Information Statement for each vaccine will be discussed and given to each patient
4. Written informed consent will be obtained for each patient prior to vaccination (Appendix D)
5. The pharmacist will notify the patient's primary care provider of immunization when contact information is available (see Appendix E).
6. All supplies needed for vaccination and vaccine adverse event management as detailed in this protocol will be available and not expired.
7. Authorizing prescriber will be periodically notified of vaccinated patients

#### Emergencies

Authorize use of the Pharmacy Procedure and Standing Orders for Management of Allergic or Anaphylactic Reactions for emergencies (Appendix F)

#### Physician Authorization:

Physician Name: \_\_\_\_\_ *Physician, M.D.* \_\_\_\_\_ Affiliation (Clinic): \_\_\_\_\_

Phone: \_\_\_\_\_ Fax: \_\_\_\_\_ Pager/Mobile: \_\_\_\_\_

Physician CA license number: \_\_\_\_\_ Physician DEA number: \_\_\_\_\_

\_\_\_\_\_  
Date

\_\_\_\_\_  
<Physician>, MD

#### Principle Authorized Pharmacist

\_\_\_\_\_  
Date

\_\_\_\_\_  
<Pharmacist, RPh>

This authorization will be in effect for 2 years unless rescinded earlier in writing by either party. Any changes in the protocol must be agreed upon by both parties.

**Pharmacy Immunization Protocol**

**APPENDIX A.      Alternate Location Request for Vaccine Administration**

The pharmacists and intern pharmacists authorized under this protocol may provide vaccination services at the following location in California for the time period specified. All provisions under the policy, procedure and protocol shall remain in effect. Cold chain for storage and subsequent administration of vaccines shall be maintained.

**Location and/or Name of Event:** \_\_\_\_\_

**Address:** \_\_\_\_\_

**Date(s):** \_\_\_\_\_

**Signature:**

\_\_\_\_\_  
<Physician> , M.D.

**Date** \_\_\_\_\_

## APPENDIX B. Immunization Training

Certificate of completion of an appropriate immunization-training program that includes the *current guidelines and recommendations of the Advisory Committee on Immunization Practices* and uses the core curriculum of the CDC (Epidemiology and Prevention of Vaccine-Preventable Diseases). An appropriate training program shall include, at a minimum, instruction on how to:

- A. Identify persons eligible for vaccination based on current ACIP guidelines. (Factors taken into consideration will include age, vaccination status (e.g., persons previously unvaccinated or due for vaccination according to the recommended schedule), or the presence of a medical condition that puts them at high risk, etc.).
- B. Screen patients for contraindications and precautions to vaccination (e.g., severe illness, previous allergic reaction, egg allergy, etc.).
- C. Provide adequate information to patients or their guardians regarding the risks for and benefits of a vaccine and documenting the delivery of that information. (i.e. Distribution/discussion of Vaccination Information Statements as required by law).
- D. Administer vaccines.
- E. Monitor patients for adverse events.
- F. Manage anaphylactic reactions according to protocol
- G. Report adverse outcomes to the Vaccine Adverse Events Reporting System (VAERS).
- H. Record administration of a vaccine(s)
- I. Provide documentation of vaccine administration to patients and whenever possible, their primary-care providers.
- J. Follow Universal Precautions and Infection Control and pertinent OSHA regulations (i.e. for Blood Borne Pathogens).

**Appendix C.      Criteria for Patients to Receive Vaccine**

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## Standing Orders for Administering Hepatitis B Vaccine to Adults

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**Purpose:** To reduce morbidity and mortality from hepatitis B virus (HBV) infection by vaccinating all patients who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

**Policy:** Under these standing orders, eligible nurses may vaccinate patients who meet the criteria below.

**Procedure:**

1. Identify adults in need of hepatitis B vaccination based on the following criteria:
  - a. Persons less than 19 years of age who have not received the vaccine
  - b. Age 19 years or older meeting any of the following criteria:
    - having had more than one sex partner in the previous 6 months, a recently acquired sexually transmitted disease, or recent treatment for a sexually transmitted disease
    - male who has had sex with males
    - injection drug user
    - sex partner or household member of a person who is chronically infected with HBV (including an HBsAg-positive adopted child)
    - at occupational risk of infection through exposure to blood or blood-contaminated body fluid (e.g., health care worker, public safety worker, trainee in a health professional or allied health school)
    - client or staff of an institution for the developmentally disabled
    - hemodialysis patient or patient with early renal failure (who will become a dialysis patient)
    - receiving clotting-factor concentrate
    - planning to travel to or live in a high endemic area of the world for more than 6 months and will have close contact with the local population; also short-term travelers who are likely to have contact with blood (e.g., in a medical setting) or sexual contact with residents of areas with high or intermediate levels of endemic disease
    - housed in a long-term correctional facility
2. Screen all patients for contraindications and precautions to hepatitis B vaccine:
  - a. **Contraindications:** a history of a serious reaction (e.g., anaphylaxis) after a previous dose of hepatitis B vaccine or to a hepatitis B vaccine component. For a list of vaccine components, go to [www.cdc.gov/nip/publications/pink/appendices/a/excipient.pdf](http://www.cdc.gov/nip/publications/pink/appendices/a/excipient.pdf)
  - b. **Precautions:** a moderate or severe acute illness with or without fever
3. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Provide non-English speakers with the VIS in their native language if available; these can be found at [www.immunize.org/vis](http://www.immunize.org/vis)
4. For persons 20 years of age or older, administer 1.0 mL hepatitis B vaccine IM (22–25g, 1–1½" needle) in the deltoid muscle. For persons 19 years of age or younger, administer 0.5 mL hepatitis B vaccine IM (22–25g, 1–1½" needle) in the deltoid muscle.
5. Provide subsequent doses of hepatitis B vaccine to complete each patient's 3-dose schedule by observing a minimum interval of 4 weeks between the first and second doses, 8 weeks between the second and third doses, and at least 4 months between the first and third doses.
6. Document each patient's vaccine administration information and follow up in the following places:
  - a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
  - b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
7. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
8. Report all adverse reactions to hepatitis B vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at [www.vaers.org](http://www.vaers.org) or by calling (800) 822-7967. VAERS report forms are available at [www.vaers.org](http://www.vaers.org)

This policy and procedure shall remain in effect for all patients of the \_\_\_\_\_ until rescinded or until \_\_\_\_\_ (date). (name of practice or clinic)

Medical Director's signature: \_\_\_\_\_ Effective date: \_\_\_\_\_

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## Herpes Zoster (HZ Shingles) vaccine

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**Purpose:** To reduce morbidity and mortality from herpes zoster shingles infection by vaccinating all patients who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

**Procedure:**

1. Identify adults in need of herpes zoster shingle vaccination based on meeting the following criteria:  
Any adult 60 years of age or older who has had a case of chicken-pox or received the chicken-pox vaccine previously
2. Screen all patients for contraindications and precautions to shingles vaccine:
  - a. **Contraindications:**
    - Are < 60 years of age
    - Serious life-threatening allergic reaction to gelatin, the antibiotic neomycin, or any other component of the HZ shingles vaccine. For a list of vaccine components, go to [www.cdc.gov/nip/publications/pink/appendices/b/excipient-table-2.pdf](http://www.cdc.gov/nip/publications/pink/appendices/b/excipient-table-2.pdf)
    - Pregnant now, or may become pregnant within three months of receiving the shingles vaccine
    - History of primary or acquired immune deficiency including HIV/AIDS, leukemia, lymphomas of any type, and other malignant neoplasms affecting the bone marrow or lymphatic system
    - Are on immune suppressive therapy including high dose corticosteroids
    - Have active untreated tuberculosis
  - b. **Possible adverse reactions:** redness, pain, swelling, itching, warmth, bruising at the injection site, and headache.
3. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Provide on-English speakers with the VIS in their native language if available; these can be found at [www.immunize.org/vis](http://www.immunize.org/vis)
4. Administer 0.65mL of Zostavax given SC (23-25g, 5/8-3/4" needle) for 1 dose only.
5. Document each patient's vaccine administration information and follow up in the following places:
  - a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
  - b. **Personal Immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
6. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
7. Report all adverse reactions to shingles vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at [www.vaers.org](http://www.vaers.org) or by calling (800) 822-7967. VAERS report forms are available at [www.vaers.org](http://www.vaers.org)

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## Human Papillomavirus Virus (HPV) Vaccine

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**Purpose:** To reduce morbidity and mortality from human papillomavirus (HPV) infection by vaccinating all patients who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

**Procedure:**

1. Identify adolescents and adults in need of HPV vaccination based on meeting any of the following criteria:
  - a. females 11-12 years of age (females 9 years of age may also be considered for the vaccine)
  - b. females 13-26 years of age who have not been vaccinated previously or who have not completed the full vaccine series
2. Screen all patients for contraindications and precautions to HPV vaccine:
  - a. **Contraindications:**
    - Serious life-threatening allergic reaction to yeast, or after receiving a previous dose of HPV vaccine, or any other component of HPV vaccine. For a list of vaccine components, go to [www.cdc.gov/nip/publications/pink/appendices/b/excipient-table-2.pdf](http://www.cdc.gov/nip/publications/pink/appendices/b/excipient-table-2.pdf)
    - Avoid use in pregnancy
      - If a woman is found to be pregnant after the series is initiated, the remaining doses should be delayed until after completion of the pregnancy.
      - Merck maintains a Pregnancy Registry to monitor fetal outcomes of pregnant women exposed to Gardasil®. Patients and health care providers are encouraged to report any exposure to Gardasil® during pregnancy by calling 800-986-8999
    - Consider postponing vaccination in persons with moderate or severe illness, with or without fever, until recovery, to minimize potential adverse effects. Low-grade fever itself and mild upper respiratory infection are not generally contraindications to vaccination.
  - b. **Precautions:** moderate to severe fever and pain, redness, or tenderness at the injection site
3. Provide all patients with a copy of the most current federal Vaccine information Statement (VIS). You must document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Provide on-English speakers with the VIS in their native language if available; these can be found at [www.immunize.org/vis](http://www.immunize.org/vis)
4. For persons 9-26 years of age, administer 0.5mL per dose given IM (22-25g, 1-1 1/2" needle) in the deltoid region of the upper arm or higher anterolateral areas of the thigh.
5. Provide subsequent doses of HPV vaccine to complete each patient's 3 dose schedule by observing a minimum interval of 2 months for the second dose, and 6 months for the third dose.
6. Document each patient's vaccine administration information and follow up in the following places:
  - a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
  - b. **Personal Immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
7. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
8. Report all adverse reactions to HPV vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at [www.vaers.org](http://www.vaers.org) or by calling (800) 822-7967. VAERS report forms are available at [www.vaers.org](http://www.vaers.org)

Updated 11/19/2006

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## Influenza Vaccine

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**Purpose:** To reduce morbidity and mortality from influenza by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

**Procedure:**

1. Identify adults in need of influenza vaccination based on meeting any of the following criteria:
  - a. Age 50 years or older
  - b. Having any of the following conditions:
    - chronic disorder of the pulmonary or cardiovascular system, including asthma
    - chronic metabolic disease (e.g., diabetes), renal dysfunction, hemoglobinopathy, or immunosuppression (e.g., caused by medications, HIV) that has required regular medical follow-up or hospitalization during the preceding year
    - any condition that compromises respiratory function or the handling of respiratory secretions or that can increase the risk of aspiration (e.g., cognitive dysfunction, spinal cord injury, seizure disorder or other neuromuscular disorder)
    - will be pregnant during the influenza season
  - c. Residence in a nursing home or other chronic-care facility that houses persons of any age who have chronic medical conditions
  - d. In an occupation or living situation that puts one in proximity to persons at high risk, including
    - a healthcare worker, caregiver, or household member in contact with person(s) at high risk of developing complications from influenza
    - a household contact or out-of-home caretaker of a child age 0–59 months
  - e. Wish to reduce the likelihood of becoming ill with influenza
2. Screen all patients for contraindications and precautions to influenza vaccine:
  - a. **Contraindications:** serious reaction (e.g., anaphylaxis) after ingesting eggs or after receiving a previous dose of influenza vaccine or an influenza vaccine component. For a list of vaccine components, go to [www.cdc.gov/nip/publications/pink/appendices/b/excipient-table-2.pdf](http://www.cdc.gov/nip/publications/pink/appendices/b/excipient-table-2.pdf). Do not give live attenuated influenza vaccine (LAIV) to pregnant women, immunosuppressed persons, or persons who have a history of Guillain-Barré syndrome. Use of inactivated influenza vaccine is preferred over LAIV for close contacts of severely immunosuppressed persons during periods when the immunocompromised person requires a protective environment.
  - b. **Precautions:** moderate or severe acute illness with or without fever
3. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). You must document in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Provide non-English speaking patients with a copy of the VIS in their native language, if available; these can be found at [www.immunize.org/vis](http://www.immunize.org/vis).
4. Administer 0.5 mL of injectable trivalent inactivated influenza vaccine (TIV) IM (22–25g, 1–1½" needle) in the deltoid muscle. Alternatively, healthy persons ages 5–49 years without contraindications may be given 0.5 mL of intranasal LAIV; 0.25 mL is sprayed into each nostril while the patient is in an upright position.
5. Document each patient's vaccine administration information and follow up in the following places:
  - a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
  - b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
6. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
7. Report all adverse reactions to influenza vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at [www.vaers.hhs.gov](http://www.vaers.hhs.gov) or (800) 822-7967. VAERS report forms are available at [www.vaers.hhs.gov](http://www.vaers.hhs.gov).

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## Measles, Mumps, & Rubella Vaccine

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**Purpose:** To reduce morbidity and mortality from measles, mumps, and rubella by vaccinating all patients who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

### Procedure

1. Identify adults in need of initial vaccination against measles, mumps, or rubella who were born in 1957 or later with no history of receipt of live, measles-, mumps-, and/or rubella-containing vaccine given at 12 months of age or older or other acceptable evidence of immunity (e.g., laboratory evidence). Combination MMR vaccine is recommended if one or more component is indicated.
2. Identify adults born in 1957 or later in need of a second dose of measles, mumps, and rubella (MMR) vaccine who are either planning to travel internationally, a student in a college, university, technical or vocational school, or a health care worker.
3. Screen all patients for contraindications and precautions to measles, mumps, and rubella (MMR) vaccine:
  - a. **Contraindications:**
    - a history of a serious reaction (e.g., anaphylaxis) after a previous dose of MMR vaccine or to an MMR vaccine component. For a list of vaccine components, go to [www.cdc.gov/nip/publications/pink/appendices/a/excipient.pdf](http://www.cdc.gov/nip/publications/pink/appendices/a/excipient.pdf)
    - pregnant now or may become pregnant within 1 month
    - known severe immunodeficiency (e.g., hematologic and solid tumors; congenital immunodeficiency; long-term immunosuppressive therapy, or severely symptomatic HIV infection)
  - b. **Precautions:**
    - recent (<11 months) receipt of antibody-containing blood product (specific interval depends on product)
    - history of thrombocytopenia or thrombocytopenic purpura
    - moderate or severe acute illness with or without fever
4. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Provide non-English speaking patients with a copy of the VIS in their native language; these can be found at [www.immunize.org/vis](http://www.immunize.org/vis)
5. Administer 0.5 mL MMR vaccine SC (23–25g, 5/8–3/4" needle) in the posterolateral section of the upper arm.
6. For adults in need of second doses of MMR, observe a minimum interval of 4 weeks between the first and second doses.
7. Document each patient's vaccine administration information and follow up in the following places:
  - a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
  - b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
8. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
9. Report all adverse reactions to MMR vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at [www.vaers.org](http://www.vaers.org) or (800) 822-7967. VAERS report forms are available at [www.vaers.org](http://www.vaers.org)

This policy and procedure shall remain in effect for all patients of the \_\_\_\_\_ clinic until rescinded or until \_\_\_\_\_ (date).

Medical Director's signature: \_\_\_\_\_ Effective date: \_\_\_\_\_

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## Meningococcal Vaccine

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**Purpose:** To reduce morbidity and mortality from meningococcal disease by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

### Procedure

- Identify adults in need of vaccination against meningococcal disease based on any of the following criteria:
  - anticipated college enrollment, particularly anticipated residence in an on-campus dormitory
  - anticipated travel to a country in the "meningitis belt" of sub-Saharan Africa or other location of epidemic meningococcal disease, particularly if contact with the local population will be prolonged
  - anticipated travel to Mecca, Saudi Arabia, for the annual Hajj
  - diagnosis of a damaged spleen; splenectomy
  - diagnosis of terminal complement component deficiency (an immune system disorder)
  - employment as a microbiologist with routine exposure to isolates of *N. meningitidis*
  - military recruits
  - any other adult wishing to decrease their risk for meningococcal disease
  - age 55 years or younger with history of receiving **meningococcal polysaccharide vaccine (MPSV4)** at least 5 years earlier and with continued risk for infection (e.g., living in epidemic disease areas).
- Screen all patients for contraindications and precautions to meningococcal vaccine:
  - Contraindications:** a history of a serious reaction (e.g., anaphylaxis) after a previous dose of meningococcal vaccine or to a meningococcal vaccine component, including diphtheria toxoid for **meningococcal conjugate vaccine (MCV4)**. For a list of vaccine components, go to [www.cdc.gov/nip/publications/pink/appendices/b/excipient-table-2.pdf](http://www.cdc.gov/nip/publications/pink/appendices/b/excipient-table-2.pdf).
  - Precautions:** moderate or severe acute illness with or without fever
- Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). Although not required by federal law, it is prudent to document in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Provide non-English speaking patients with a copy of the VIS in their native language, if available; these can be found at [www.immunize.org/vis](http://www.immunize.org/vis).
- For adults ages 55 years and younger, administer 0.5 mL MCV4 via the intramuscular route (22–25g, 1–1½" needle) in the deltoid muscle. If MCV4 is unavailable, MPSV4 is an acceptable alternative, although it must be given subcutaneously. For adults older than age 55 years, administer 0.5 mL MPSV4 via the subcutaneous route (23–25g, 5/8" needle) in the posterolateral fat of the upper arm.
- Document each patient's vaccine administration information and follow up in the following places:
  - Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
  - Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
- Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
- Report all adverse reactions to meningococcal vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at [www.vaers.hhs.gov](http://www.vaers.hhs.gov) or (800) 822-7967. VAERS report forms are available at [www.vaers.hhs.gov](http://www.vaers.hhs.gov).

This policy and procedure shall remain in effect for all patients of the \_\_\_\_\_ until rescinded or until \_\_\_\_\_ (date).  
(name of practice or clinic)

Medical Director's signature: \_\_\_\_\_ Effective date: \_\_\_\_\_

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## Pneumococcal Vaccine - Adults

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**Purpose:** To reduce morbidity and mortality from pneumococcal disease by vaccinating all patients who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

### Procedure

1. Identify adults in need of vaccination with pneumococcal polysaccharide vaccine (PPV) based on the following criteria:
  - a. Age 65 years or older with no or unknown history of prior receipt of PPV
  - b. Age 18–64 years with no or unknown history of prior receipt of PPV and any of the following conditions:
    - i. chronic cardiovascular disease (e.g., congestive heart failure, cardiomyopathies)
    - ii. chronic pulmonary disease (e.g., emphysema or chronic obstructive pulmonary disease [not asthma])
    - iii. diabetes mellitus, alcoholism, chronic liver disease (cirrhosis), or cerebrospinal fluid leaks
    - iv. functional or anatomic asplenia (e.g., sickle cell disease, splenectomy)
    - v. immunosuppressive conditions (e.g., HIV infection, leukemia, congenital immunodeficiency, Hodgkin's disease, lymphoma, multiple myeloma, generalized malignancy)
    - vi. immunosuppressive chemotherapy (e.g., alkylating agents, antimetabolites, long-term systemic corticosteroids)
    - vii. organ or bone marrow transplantation
    - viii. chronic renal failure or nephrotic syndrome
    - ix. candidate for or recipient of cochlear implant
2. Identify adults in need of a second and final dose of PPV if five or more years have elapsed since the previous vaccination and the patient is:
  - a. Age 65 years or older and received prior PPV vaccination when less than age 65 years
  - b. At highest risk for serious pneumococcal infection and/or likely to have a rapid decline in pneumococcal antibody levels (i.e., categories iv.-viii. above)
3. Screen all patients for contraindications and precautions to PPV vaccine.
  - a. **Contraindications:** a history of a serious reaction (e.g., anaphylaxis) after a previous dose of PPV or to a vaccine component. For a list of vaccine components, go to [www.cdc.gov/nip/publications/pink/appendices/a/excipient.pdf](http://www.cdc.gov/nip/publications/pink/appendices/a/excipient.pdf)
  - b. **Precautions:** a moderate or severe acute illness with or without fever
4. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). Although not required by federal law, it is prudent to document in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Provide non-English speaking patients with a copy of the VIS in their native language, if available. These can be found at [www.immunize.org/vis](http://www.immunize.org/vis)
5. Administer 0.5 mL PPV vaccine either IM (22–25g, 1–2" needle) or SC (23–25g, 5/8–3/4" needle).
6. Document each patient's vaccine administration information and follow up in the following places:
  - a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
  - b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
7. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
8. Report all adverse reactions to PPV to the federal Vaccine Adverse Event Reporting System (VAERS) at [www.vaers.org](http://www.vaers.org) or by calling (800) 822-7967. VAERS report forms are available at [www.vaers.org](http://www.vaers.org)

This policy and procedure shall remain in effect for all patients of the \_\_\_\_\_ clinic until rescinded or until \_\_\_\_\_ (date).

Medical Director's signature: \_\_\_\_\_ Effective date: \_\_\_\_\_

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## Standing Orders for Administering Tetanus-Diphtheria Toxoids & Pertussis Vaccine (Td/Tdap) to Adults

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**Purpose:** To reduce morbidity and mortality from tetanus, diphtheria, and (where indicated) pertussis by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

**Policy:** Under these standing orders, eligible nurses may vaccinate adults who meet the criteria below.

### Procedure

- Identify adults in need of vaccination against tetanus, diphtheria, and (where indicated) pertussis based on the following criteria:
  - lack of documentation of at least 3 doses of tetanus- and diphtheria-containing toxoids
  - younger than age 65 years with no history of pertussis-containing vaccine given since age 10 years
  - completion of a 3-dose primary series of tetanus- and diphtheria-containing toxoids with receipt of the last dose being 10 years ago or longer
  - recent deep and dirty wound (e.g., contaminated with dirt, feces, saliva) and lack of evidence of having received tetanus toxoid-containing vaccine in the previous 5 years
- Screen all patients for contraindications and precautions to tetanus and diphtheria toxoids (Td) and, if applicable, pertussis vaccine (Tdap):
  - Contraindications:**
    - a history of a serious reaction (e.g., anaphylaxis) after a previous dose of Td or to a Td or Tdap component. For a list of vaccine components, go to [www.cdc.gov/nip/publications/pink/appendices/b/excipient-table-2.pdf](http://www.cdc.gov/nip/publications/pink/appendices/b/excipient-table-2.pdf).
    - for Tdap only, a history of encephalopathy within 7 days following DTP/DTaP given before age 7 years
  - Precautions:**
    - history of Guillain-Barré syndrome within 6 weeks of previous dose of tetanus toxoid-containing vaccine
    - an unstable neurologic condition
    - moderate or severe acute illness with or without fever

Note: Use of Td or Tdap is not contraindicated in pregnancy. At the provider's discretion, either vaccine may be administered during the 2nd or 3rd trimester.
- Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Provide non-English speaking patients with a copy of the VIS in their native language, if available; these can be found at [www.immunize.org/vis](http://www.immunize.org/vis).
- Administer 0.5 mL Td (or Tdap, if appropriate) vaccine intramuscularly (22–25g, 1–1½" needle) in the deltoid muscle.
- Provide subsequent doses of Td (a one-time dose of Tdap may be substituted for Td if younger than 65 years) to adults as follows:
  - to complete the primary 3-dose schedule: observe a minimum interval of 4 weeks between the first and second doses, and 6 months between the second and third doses.
  - to boost after primary schedule is complete: observe a 10-year interval since previous dose of Td/Tdap; if protection against pertussis is needed, an interval of 5 years is recommended and intervals as short as 2 years or less can be observed for parents and caregivers of infants younger than age 12 months, healthcare workers having direct patient contact, and adults in a pertussis outbreak setting.
  - In pregnancy, when indicated, give Td or Tdap in 2nd or 3rd trimester. If not administered during pregnancy, give Tdap in immediate postpartum period.
- Document each patient's vaccine administration information and follow up in the following places:
  - Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
  - Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
- Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
- Report all adverse reactions to Td and Tdap vaccines to the federal Vaccine Adverse Event Reporting System (VAERS) at [www.vaers.hhs.gov](http://www.vaers.hhs.gov) or (800) 822-7967. VAERS report forms are available at [www.vaers.hhs.gov](http://www.vaers.hhs.gov).

This policy and procedure shall remain in effect for all patients of the \_\_\_\_\_ until rescinded or until \_\_\_\_\_ (date). (name of practice or clinic)

Medical Director's signature: \_\_\_\_\_ Effective date: \_\_\_\_\_

[www.immunize.org/catg.d/p3078.pdf](http://www.immunize.org/catg.d/p3078.pdf) • Item #P3078 (9/06)

Pharmacy Name  
 Address 1  
 Address 2  
 Phone#

Patient Name: \_\_\_\_\_  
 DOB: \_\_\_\_\_  
 Today's Date: \_\_\_\_\_

**VACCINE ADMINISTRATION RECORD, SCREENING and PATIENT CONSENT**

- |  | YES   | NO    |
|--|-------|-------|
| 1. Have you ever had a severe reaction to any vaccine that required medical care?<br>If yes, describe: _____                                     | _____ | _____ |
| 2. Do you have any allergies to food, medications, or vaccines?  | _____ | _____ |
| 3. Are you sick today?   | _____ | _____ |
| 4. Have you had Guillain-Barre Syndrome, seizure, brain, or nerve problems?  | _____ | _____ |
| 5. Are you pregnant or planning to become pregnant in the next 3 months?   | _____ | _____ |
| 6. Are you or anyone in your household being treated with chemotherapy or radiation for cancer, have HIV/AIDS or any immune deficiency disorder? | _____ | _____ |
| 7. Do you or anyone in your household take oral prednisone (>20mg/day) or other oral steroids, or anticancer drugs?                              | _____ | _____ |
| 8. Do you have a bleeding disorder or take "blood thinners" like coumadin or heparin?  | _____ | _____ |

The following questions will help determine any other indications or contraindications

1. What adult vaccinations has this patient received (vaccine and date)?  
 \_\_\_\_\_  
 \_\_\_\_\_
2. List all Rx and OTC medications this patient is currently taking  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_
3. List all current medical conditions  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

**INFORMATION ABOUT PERSON TO RECEIVE VACCINE (please print)**

NAME last	first	middle initial	SOCIAL SECURITY NUMBER
ADDRESS	CITY	STATE/ZIP	PHONE#
BIRTHDATE	SEX	PHYSICIAN	PHYSICIAN PHONE OR FAX

Yes  No I request to have this information sent to the physician's office specified above

**~~DO NOT WRITE BELOW THIS LINE - For Pharmacy Use Only~~**

VACCINE	LOT #	EXP DATE	MANUFACTURER	DOSE (mL)	ADMINISTRATOR	VIS DATE

**Please read the following statements and sign below on the signature line.**

I have read or have had explained the information provided about the vaccine I am to receive. I have had a chance to ask questions that were answered to my satisfaction. I believe I understand the benefits and risks of vaccination and ask that the vaccine be given to me or to the person named above for whom I am authorized to make this request.

Medicare, I do hereby authorize the <Pharmacy> to release information and request payment. I certify that the information given by me in applying for payment under Medicare is correct. I authorize release of all records to act on this request. I request that payment of authorized benefits be made on my behalf.

X \_\_\_\_\_ DATE: \_\_\_\_\_  
 Signature of person to receive vaccine or person authorized to make the request (parent or guardian)

APPENDIX E

University of Southern California  
USC Medical Plaza Pharmacy  
1510 San Pablo Street, #144 Los Angeles, CA 90033  
(323) 442-8411

Facsimile Transmittal

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To:	Fax: ( ) -
From:	Date: / /
Re: Patient Name	Pt. DOB:

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CC:	Pages:
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This fax has been sent to you with the consent of your patient to notify you that the patient named above received the following vaccination(s) at our pharmacy on the date that is listed below. Please make a note of this in the patient's chart and feel free to call at the number above with any questions.

Administration Date	Product	Dose	Comments

**Confidentiality Notice:** This facsimile, including any attachments, is for the sole use of the intended recipient(s) and may contain confidential and privileged information. Any unauthorized review, use, disclosure or distribution is prohibited. If you are not the intended recipient, please contact the sender and destroy all copies of the original message.

## Medical Management of Vaccine Reactions in Adult Patients

All vaccines have the potential to cause an adverse reaction. In order to minimize adverse reactions, patients should be carefully screened for precautions and contraindications before vaccine is administered. Even with careful screening, reactions may occur. These reactions can vary from trivial and inconvenient (e.g., soreness, itching) to severe and life threatening (e.g., anaphylaxis). If reactions occur, staff should be prepared with procedures for their management. The table below describes procedures to follow if various reactions occur.

Reaction	Symptoms	Management
<b>Localized</b>	Soreness, redness, itching, or swelling at the injection site	Apply a cold compress to the injection site. Consider giving an analgesic (pain reliever) or antipruritic (anti-itch) medication.
	Slight bleeding	Apply an adhesive compress over the injection site.
	Continuous bleeding	Place thick layer of gauze pads over site and maintain direct and firm pressure; raise the bleeding injection site (e.g., arm) above the level of the patient's heart.
<b>Psychological fright and syncope (fainting)</b>	Fright before injection is given	Have patient sit or lie down for the vaccination.
	Extreme paleness, sweating, coldness of the hands and feet, nausea, light-headedness, dizziness, weakness, or visual disturbances	Have patient lie flat or sit with head between knees for several minutes. Loosen any tight clothing and maintain an open airway. Apply cool, damp cloths to patient's face and neck.
	Fall, without loss of consciousness	Examine the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated.
	Loss of consciousness	Check the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated. Call 911 if patient does not recover immediately.
<b>Anaphylaxis</b>	Sudden or gradual onset of generalized itching, erythema (redness), or urticaria (hives); angioedema (swelling of the lips, face, or throat); severe bronchospasm (wheezing); shortness of breath; shock; abdominal cramping; or cardiovascular collapse.	See "Emergency Medical Protocol for Management of Anaphylactic Reactions in Adults" on the next page for detailed steps to follow in treating anaphylaxis.

(continued on page 2)

## Emergency Medical Protocol for Management of Anaphylactic Reactions in Adults

### Supplies Needed

- |   |  |
|---|--|
| <input type="checkbox"/> Aqueous epinephrine 1:1000 (i.e., 1 mg/mL) dilution, in ampules, vials of solution, or prefilled syringes, including epinephrine autoinjectors (e.g., EpiPen). If EpiPens are stocked, at least three adult EpiPens (0.30 mg) should be available. | <input type="checkbox"/> Adult airways (small, medium, and large)                                  |
| <input type="checkbox"/> Diphenhydramine (Benadryl) injectable (50 mg/mL solution) and 25 mg or 50 mg capsules or tablets and syrup (12.5 mg/5 mL suspension)   | <input type="checkbox"/> Sphygmomanometer (adult and extra-large cuffs) and stethoscope            |
| <input type="checkbox"/> Syringes: 1–3 cc, 22–25g, 1", 1½", and 2" needles for epinephrine and diphenhydramine (Benadryl)   | <input type="checkbox"/> Adult size pocket mask with one-way valve                                 |
| <input type="checkbox"/> Wristwatch with second hand  | <input type="checkbox"/> Alcohol swabs   |
|   | <input type="checkbox"/> Tourniquet  |
|   | <input type="checkbox"/> Tongue depressors   |
|   | <input type="checkbox"/> Flashlight with extra batteries (for examination of the mouth and throat) |
|   | <input type="checkbox"/> Cell phone or access to an on-site phone                                  |

### Signs and Symptoms of Anaphylactic Reaction

Sudden or gradual onset of generalized itching, erythema (redness), or urticaria (hives); angioedema (swelling of the lips, face, or throat); bronchospasm (wheezing); shortness of breath; shock; abdominal cramping; or cardiovascular collapse.

### Treatment in Adults

- If itching and swelling are confined to the injection site where the vaccination was given, observe patient closely for the development of generalized symptoms.
- If symptoms are generalized, activate the emergency medical system (EMS; e.g., call 911) and notify the on-call physician. This should be done by a second person, while the primary nurse assesses the airway, breathing, circulation, and level of consciousness of the patient.
- Administer aqueous epinephrine 1:1000 dilution intramuscularly, 0.01 mL/kg/dose (adult dose ranges from 0.3 mL to 0.5 mL, with maximum single dose of 0.5 mL).
- In addition, for systemic anaphylaxis, administer diphenhydramine either orally or by intramuscular injection; the standard dose is 1–2 mg/kg, up to 100 mg maximum single dose.
- Monitor the patient closely until EMS arrives. Perform cardiopulmonary resuscitation (CPR), if necessary, and maintain airway. Keep patient in supine position (flat on back) unless he or she is having breathing difficulty. If breathing is difficult, patient's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. If blood pressure is low, elevate legs. Monitor blood pressure and pulse every 5 minutes.
- If EMS has not arrived and symptoms are still present, repeat dose of epinephrine every 10–20 minutes for up to 3 doses, depending on patient's response.
- Record all vital signs, medications administered to the patient, including the time, dosage, response, and the name of the medical personnel who administered the medication, and other relevant clinical information.
- Notify the patient's primary care physician.

- Sources: 1. American Academy of Pediatrics. Passive Immunization. In: Pickering LK, ed. *Red Book: 2006 Report of the Committee on Infectious Diseases*. 27th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2006:64–66.
2. American Pharmacists Association, Grabenstein, JD, *Pharmacy-Based Immunization Delivery*, 2002.
3. *Got Your Shots? A Providers Guide to Immunizations in Minnesota*, Second Edition, Minnesota Department of Health, 2001:80-82.

These standing orders for the medical management of vaccine reactions in adult patients shall remain in effect for patients of the \_\_\_\_\_ until rescinded or until \_\_\_\_\_.

*name of clinic*

*date*

\_\_\_\_\_  
Medical Director's signature

\_\_\_\_\_  
Effective date

# Attachment 3

*Proposed Competencies for  
Pharmacist Interns Competing their  
Basic Level of Experience in Schools  
of Pharmacy*

## Competencies for Introductory Pharmacy Practice Experiences (IPPEs)

Through Introductory Pharmacy Practice Experiences (IPPEs), pharmacy students are expected to master foundational competencies in three domains: Communication and Professional Behavior, The Practice of Pharmacy, and Public Health. These competencies address the basic skills that prepare the student for the Advanced Pharmacy Practice Experiences (APPEs) offered through the pharmacy curriculum. As such, they represent an intermediate point in the professional development of a pharmacist. They are applicable across a spectrum of practice and other experiential settings and are expected to build in complexity over time.

### The Purpose of the Introductory Pharmacy Practice Experiences (IPPEs) is to:

- Develop the basic knowledge, skills, and attitudes for pharmacy practice
- Instill professionalism
- Expose students to the roles of the pharmacist and pharmacy practice settings

<b>I. Communication and Professional Behavior</b>
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Upon completion of the IPPEs, the pharmacy intern should be able to:

#### A. Communicate effectively.

1. Communicate accurate and appropriate medical and drug information to a pharmacist, preceptor or other health care professional in a clear and concise manner.
2. Determine the appropriate means of communication for the situation.
3. Actively listen to patients, peers, and other health care professionals.
4. Use proper grammar, spelling, and pronunciation in communications.
5. Explain medication information to patients in understandable terms.
6. Adjust communication based on contextual or cultural factors, including health literacy, language barriers, and cognitive impairment.
7. Routinely verify patient or recipient understanding of communicated information.
8. Demonstrate effective public-speaking skills and the appropriate use of audio-visual media when communicating with groups of patients, peers, and other health care professionals.
9. Develop effective written materials for patients, peers, and other health care professionals.

#### B. Interact with patients & the health care team.

1. Articulate the pharmacist's role as a member of the health care team.
2. Establish professional rapport with patients and healthcare professionals.
3. Demonstrate sensitivity to and respect for each individual's needs, values, and beliefs, including cultural factors, religious beliefs, language barriers, and cognitive abilities.
4. Demonstrate empathy and caring in interactions with others.
5. Maintain patient confidentiality and respect patients' privacy.
6. Demonstrate ability to resolve conflict in the pharmacy practice setting.

**C. Behave in a professional and ethical manner.**

1. Dress professionally and appropriately for the practice setting.
2. Arrive punctually and remain until all responsibilities are completed.
3. Use time effectively and efficiently.
3. Distinguish professional interests from personal interests and respond appropriately.
4. Demonstrate awareness of personal competence and limitations and seek guidance or assistance from preceptors when appropriate.
5. Accept responsibility for one's actions.
6. Respond appropriately to feedback from preceptors, patients, peers, and other health care professionals.
7. Show initiative in interactions with patients, peers, and other health care professionals.
8. Demonstrate passion and enthusiasm for the profession.
9. Be aware of and work appropriately within the culture of the assigned practice setting.
10. Demonstrate awareness of site or institutional policies and procedures.
11. Prioritize workload appropriately.
12. Identify issues involving ethical dilemmas.
13. Weigh and balance different options for responding to ethical dilemmas.
14. Propose steps to resolve ethical dilemmas.
15. Adhere to all state and federal laws and regulations as a pharmacy intern in the practice setting.

<b>II. The Practice of Pharmacy</b>
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**Upon completion of the IPPEs, the pharmacy intern should be able to:**

**A. Organize and Evaluate Information.**

1. Assess prescription or medication orders for completeness, authenticity, and legality.
2. Verify that dose, frequency, formulation, and route of administration on prescription or medication orders are correct.
3. Obtain any pertinent information from the patient, medical record, or prescriber as needed for processing prescription or medication orders (e.g., allergies, adverse reactions, diagnosis or desired therapeutic outcome, medical history).
4. Review the patient profile or medical record for any allergies or sensitivities.
5. Determine the presence of any potential medication-related problems.
6. Determine if it is legal and appropriate to refill a prescription, contacting the prescriber for authorization if necessary.

**B. Prepare and dispense medications.**

1. Accurately enter patient information into the patient's pharmacy profile or medication record.
2. Select the correct drug product, manufacturer, dose, and dosage form and prepare it for dispensing.
3. Assure that the medication label is correct and conforms to all state and federal regulations.

4. Assure that the label conveys directions in a manner that is understandable to the patient and that appropriate auxiliary labels are attached.
5. Select an appropriate container for storage or use of medications with special requirements (e.g., child-resistant containers, compliance devices).
6. Accurately perform and document the necessary calculations to correctly prepare the medication.
7. Perform the required technical and basic compounding steps to produce a pharmaceutically elegant product.
8. Demonstrate aseptic technique during the preparation of parenteral medications.
9. Document the preparation of any medication that has been compounded, repackaged, or relabeled.
10. Adjudicate third-party insurance claims using established billing systems
11. Determine the appropriate storage of medications before and after dispensing.
12. Comply with all legal requirements and professional scope of practice.

**C. Provide patient counseling.**

1. Communicate pertinent information to the patient to encourage proper use and storage of medications.
2. Discuss any precautions or relevant warnings about medications or other therapeutic interventions.
3. Assure that the patient comprehends the information provided, including what to do in the event that a medication-related problem occurs.
4. Assess and reinforce the patient's adherence to the prescribed therapeutic regimen.

**D. Maintain accurate records.**

1. Document the preparation and dispensing of medications.
2. Maintain manual or computerized files for prescription records that conform to state and federal laws and regulations.
3. Adhere to state and federal laws and regulations related to inventory control (e.g., controlled substances, investigational drugs).

**E. Assist patients seeking self care.**

1. Assess a patient's self-identified problem (e.g., common cold, fever, pain, gastrointestinal problems) to determine if the problem is appropriate for self care or requires referral.
2. Discuss options for treatment and recommend appropriate non-prescription product(s) if indicated.
3. Counsel the patient about the proper use of self care products
4. Instruct a patient about the proper use of a diagnostic agent or device, including directions for obtaining accurate results and how to interpret the results.
5. Teach a patient the proper and safe use of commonly used health products (e.g., condoms, thermometers, blood pressure monitoring devices, blood glucose meters, metered-dose devices, ear syringes, adherence devices).

**F. Contribute to the optimal use of medications**

1. Articulate the pharmacist's role in medication use oversight (e.g., formulary management, practice guidelines).
2. Participate in established medication safety and quality improvement activities (e.g., adverse drug reaction reporting, medication reconciliation).

3. Access, select, utilize, and cite appropriate references for health information and patient education materials.
4. Demonstrate basic proficiency with the technology used at assigned IPPE sites.

### III. Public Health

Upon completion of the IPPEs, the pharmacy intern should be able to:

**A. Participate in health education programs and community-based health interventions.**

1. Raise public awareness about the role of a pharmacist as a public health educator.
2. Participate in activities that promote health and wellness and the use of preventive care measures.
3. Articulate the concept of advocacy - what it means both professionally and personally.

**B. Demonstrate public health-related practice skills.**

1. Administer subcutaneous, intramuscular or intradermal injections, including immunizations.
2. Screen for common medical conditions and make appropriate referrals.
3. Conduct smoking-cessation interventions when appropriate.

*Developed by the California Pharmacy IPPE-OSCE Initiative work group representing California's seven schools and colleges of pharmacy, the California State Board of Pharmacy, and the practice sector.*

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