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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 September 5, 2007

Members:

Ruth Conroy, PharmD, Chairperson, Board Vice President
Robert Gaul, RPh,
Clarence Hiura, PharmD
Hank Hough, Public Member
Susan Ravnar, PharmD

Minutes of the Licensing Committee Meeting of September 5, 2007 are provided in **Attachment 10**.

ITEM 1: Approve Proposed New Amendments to 16 CCR Sections 1716.1, 1716.2, 1751-1751.8 and Adoption of Section 1735 - 1735.8 (including the Self Assessment Form) and Initiate Formal Rulemaking Process

FOR ACTION:

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, May and September 2007 Licensing Committee Meetings.

At the September Licensing Committee Meeting, the committee saw a new iteration of the regulation. The regulation now establishes requirements for all pharmacies that compound medication in Article 4.5 and then for those pharmacies that perform sterile injectable compounding, they must also comply with provisions Article 7. This structure seems a better format for compounding pharmacies.

At the September Meeting, Deputy Attorney General Joshua Room, walked committee members through the revisions made since the July 2007 Board Meeting. This also included removing redundancies between the regulations for compounding and sterile injectable compounding. In addition, the committee reviewed and provided amendments on the compounding self-assessment form required as part of the regulation proposal. The new version of the regulations is provided in **Attachment 1** consideration as a final draft.

In October 2007 the board received a letter from McGuff Compounding Pharmacy Services (also included in **Attachment 1**.)

Phillip Swanger, Director of Governmental Affairs for the California Society of Health-System Pharmacists (CSHP) stated that the proposed revisions discussed resolve concerns previously expressed by CSHP.

The committee believes that 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. The regulations distinguish between these two levels.

ITEM 2: Approve a legislative proposal for immunizations by pharmacists pursuant to published recommendations of the Advisory Committee on Immunization Practices (ACIP) of the Federal Centers for Disease Control and Prevention by pursuing an amendment to Business and Professions Code section 4052(a)(9) to adding section 4052.8.

FOR ACTION:

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 recommendations of the Advisory Committee on Immunization Practices (ACIP) of the federal Centers for Disease Control. The statutory language developed by staff is inserted into the text of section 4052 and via new section 4052.8 (**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 September Board Meeting, staff has further revised the proposal, based on comments received during the committee meeting as well as additional discussions with Dr. Jeff Goad of USC's School of Pharmacy, who has considerable expertise in this area.

Dr. Goad will attend the October Board Meeting and will be available to respond to questions.

The board previously agreed to sponsor statutory provisions to provide this authority. A coalition of pharmacy groups, patient advocates and others need to join the board is moving forward with this proposal.

ITEM 3: Approve a legislative proposal to authorize the licensing of mobile locations by the Board of Pharmacy for Emergencies by amending Business and Professions Code section 4062 and Business and Professions Code section 4110.

FOR ACTION:

The board received a request for guidance from Ralphs Grocery Co. about the appropriate use of mobile pharmacy trailers. Ralphs would like to use these trailers under emergency conditions or in the event an existing pharmacy is damaged or closed.

Ralphs requested guidance on two different situations - - damage to a pharmacy where a mobile trailer in the parking lot could allow for the continued service to customers or use of a trailer in the event of a declared disaster.

The use of mobile trainers is consistent with the NABP recommendation that pharmacies have mobile units available in the event of a declared disaster.

Department Counsel Spencer Walker advised the committee and board staff that current pharmacy law does not allow for the use of mobile trailers in either scenario and that statutory changes would be necessary.

The committee agreed that the use of mobile trailers in the event of an emergency is critical and that the board wants to be better prepared to perform its role during an emergency.

Attachment 3 contains draft statutory language developed after the Licensing Committee Meeting as well as the original request from Ralphs. This proposal will require refinement by the board with the hope that these statutory provisions will be introduced as proposed legislation next year.

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

ITEM 4: Update on Emergency Preparedness for California Pharmacy

FOR INFORMATION:

Disaster or emergency preparedness continues to be an important initiative of the Schwarzenegger Administration. The committee reviewed the following items at its September 5, 2007 meeting.

1. Rough and Ready 2007

Chairperson Conroy provided comments regarding her participation as an observer in a disaster response drill in Orange County in August. A major component of this drill was the demonstration of the state's three mobile hospitals (200 beds each).

At the next Licensing Committee meeting, the board will continue its discussions on disaster preparedness.

2. California Medical Volunteers

Board staff recently participated in the evaluation of the contract proposal for the implementation and operation of California's Emergency System for the Advanced Registration of Volunteer Health Professionals. This system, known as the California Medical Volunteers, will play an instrumental role in the deployment of registered health care professionals in response to disasters and terrorist events.

The board will continue to stress the need for pharmacists to become trained as emergency responders to provide for the public health.

3. Recent Articles

Several articles on emergency response were shared with the committee. These articles are provided in **Attachment 4**.

ITEM 5: California Schools of Pharmacy Proposal to Identify the Professional Competencies that Should Be Achieved by the End of Basic Intern Experience

FOR INFORMATION:

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.

The next phase of the project began in June 2007 and involved the schools developing an exam to assess student achievement of the basic competencies. The workgroup

hopes to complete the process in time for incorporation during the 2007-08 academic year.

In **Attachment 5** is the copy of the proposed competencies developed by the workgroup as well as a letter from Mary Anne Koda-Kimble of UCSF's School of Pharmacy. Dr. Koda-Kimble has requested that the board affirm its agreement with this document.

Discussion at the September 5, 2007 committee meeting included concern about the board's role in affirming agreement with this document, as the board does not normally become involved in curriculum development. The recommendation from the committee was that Dr. Koda-Kimble's letter be returned to the board in October for discussion.

ITEM 6: Request to Add the Exam for the Certification of Pharmacy of Pharmacy Technicians

FOR INFORMATION:

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.

The board had hoped 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.

The committee tabled this matter pending the recommendations for changes in pharmacy technician currently underway.

ITEM 7: Competency Committee Report

1. Examination Statistics:

FOR INFORMATION:

In **Attachment 6** are the biannual examination statistics for the CPJE and for those qualified in California who have taken the NAPLEX. The period of this report runs from April 1 through August 31, 2007.

Currently underway is a quality assurance review of the examination that was initiated on September 1. The required review is nearly completed and the board hopes to be able to release results in early November.

2. NAPLEX Compromised, Suspended and Reactivated

FOR INFORMATION:

In August, the National Association of Boards of Pharmacy learned that the NAPLEX had been compromised, and ceased administration of this examination nationally on August 25.

The compromise occurred in Georgia, and also resulted in the suspension of the administration of the Georgia MPJE.

On October 5, national administration of the NAPLEX resumed about one month earlier than projected.

Material on the compromise is provided in **Attachment 7**.

3. Proposed Amendment to 16 CCR Sections 1721 and 1723.1 Regarding Dishonest Conduct On a Pharmacist Licensure Examination

FOR ACTION:

The committee considered proposed amendments to 16 CCR 1721 and 1723.1 that would strengthen the penalty an applicant would incur for dishonest conduct during an examination as well as further clarify the penalty an applicant would incur for conveying or exposing any part of the licensing examination.

This recommendation was generated from the board's competency committee, which is responsible for the development of the CPJE examination. According to the board's current exam psychometrician, the cost to generate a new test item is \$2000/item. Compromised test items pose not only a financial loss to the board, but also inhibit the board's ability to test for minimum competency and if an otherwise incompetent applicant passes the exam because the exam has been compromised; such a breach is a public safety issue.

As recent as September 2005, the board disciplined two licensees for compromising the board examination and is currently working the NABP to address allegations of a recent candidate who allegedly cheated on the NAPLEX while attempting to qualify for a pharmacist license in California.

The committee recommends that the board approve the proposed language to strengthen the penalty of dishonest conduct by applicants by amending 16 CCR Sections 1721 and 1723.1. The proposed language is included in **Attachment 8**.

ITEM 8: CREIGHTON UNIVERSITY'S WEB-BASED PHARM D PROGRAM

FOR INFORMATION:

Board staff learned that the ACPE has approved its first online PharmD program. This program is being offered by Creighton University, which also offers a traditional PharmD program.

According to the ACPE, this online program began in 2000. ACPE determined this education pathway follows the same standards as the traditional PharmD program and as such obtained the same approval and accreditation as the traditional program.

Attachment 9 contains some information provided on Creighton University's Web site. The committee reviewed these materials without comment.

ITEM 9: MEETING SUMMARY OF THE SEPTEMBER 5, 2007 MEETING

FOR INFORMATION:

Minutes of the Licensing Committee Meeting held September 5, 2007, appear as **Attachment 10**.

ITEM 10: LICENSING STATISTICS

FOR INFORMATION:

Attachment 11 contains licensing statistics describing the Licensing Unit's processing activities for the first quarter of the fiscal year.

ITEM 3: FIRST QUARTERLY REPORT ON COMMITTEE GOALS FOR 2007/08

FOR INFORMATION

Attachment 12 contains the first quarterly report on the committee's strategic goals for 2007/08.

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 tablet splitting or 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.
- (d) The parameters and requirements stated by this Article 4.5 (Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile injectable compounding are stated by Article 7 (Section 1751 et seq.).

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, and 4052, and 4127, 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, including 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: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, and 4052, and 4127, 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; and
 - (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.¹

- (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:
- (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 17m-39 rev. 8/09). 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: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, ~~and~~ 4052, and 4127, Business and Professions Code.

¹ Moved from 1716.1

§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 or supplier 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.²
- (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: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, and 4052, and 4127, 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: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, and 4052, 4076 and 4127, 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.

² Imported in modified form from 1716.2

- (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 the following
 - (1) Procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedure manual.
 - (2) 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.
 - (3) 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.
 - (4) Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.
 - (5) Documentation of the methodology used to determine appropriate expiration dates for compounded drug products.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, and 4052, and 4127, 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: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, and 4052, and 4127, 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: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, and 4052, and 4127, 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: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, ~~and~~ 4052, and 4127, Business and Professions Code.

Article 7 Sterile Injectable Compounding

§1751. Sterile Injectable Compounding; Compounding Area.

- (a) Any pharmacy engaged in compounding sterile injectable drug products shall conform to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile injectable compounding.
- (b) The Any pharmacy doing sterile injectable compounding shall have a designated area for the preparation of sterile injectable products which shall meet the following standards:
- (1) Clean Room and Work Station Requirements, shall be in accordance with Section 490A.3.1 of Title 24, Part 2, Chapter 4A of the California Code of Regulations.
 - (2) Walls, ceilings and floors shall be constructed in accordance with Section 490A.3 of Title 24, Part 2, Chapter 4A of the California Code of Regulations.
 - (3) Be ventilated in a manner in accordance with Section 505.12 of Title 24, Part 4, Chapter 5 of the California Code of Regulations.
 - (4) Be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with standards adopted by the United States General Services Administration. Certification records must be retained for at least 3 years.
 - (5) The pharmacy shall be arranged in accordance with Section 490A.3 of Title 24, Part 2, Chapter 4A of the California Code of Regulations. Items related to the compounding of sterile injectable products within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.
 - (6) A sink shall be included in accordance in Section 490A.3.4 of Title 24, Part 2, Chapter 4A of the California Code of Regulations.
 - (7) There shall be a refrigerator and/or freezer of sufficient capacity to meet the storage requirements for all material requiring refrigeration.
- (c) Any pharmacy compounding a sterile injectable product from one or more non-sterile ingredients shall comply with Business and Professions Code section 4127.7.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4127 and 4127.7, Business and Professions Code; and Section 18944(a), Health and Safety Code.

§1751.3. 1751.1. Sterile Injectable Recordkeeping Requirements.³

- (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 make and keep 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 section 1735.3 and subdivisions (a), for sterile products compounded from one or more non-sterile ingredients, the following records must be ~~maintained for at least three years~~ made and kept by the pharmacy:
- (1) The training and competency evaluation of employees in sterile product procedures.
 - (2) Refrigerator and freezer temperatures.
 - (3) Certification of the sterile compounding environment.

³ Relocated from 1751.3 to 1751.1 to conform to sequence of Article 4.5.

- (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~~ 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: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

§1751.2. Sterile Injectable Labeling Requirements.⁴

In addition to ~~existing labeling requirements~~ to the labeling information required under Business and Professions Code section 4076 and section 1735.4, a pharmacy which compounds sterile injectable products shall include the following information on the labels for those products:

- (a) Telephone number of the pharmacy, except for sterile injectable products dispensed for inpatients of a hospital pharmacy.
- (b) Name and concentrations of ingredients contained in the sterile injectable product.
- (c) Instructions for storage and handling.
- (d) All cytotoxic agents shall bear a special label which states "Chemotherapy -Dispose of Properly."

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.

§1751.02. 1751.3. Sterile Injectable Policies and Procedures.⁵

- (a) ~~Written policies and procedures associated with the pharmacy's preparation and dispensing of sterile injectable products shall include, but not be limited to~~ Any pharmacy engaged in compounding sterile injectable drug products shall maintain a written policy and procedure manual for compounding that includes, in addition to the elements required by section 1735.5, written policies and procedures regarding the following:
- (1) Compounding, filling, and labeling of sterile injectable compounds.
 - (2) Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration.
 - (3) Equipment and supplies.
 - (4) Training of staff in the preparation of sterile injectable products.
 - (5) Procedures for handling cytotoxic agents.
 - (6) Quality assurance program.
 - (7) Record keeping requirements.

⁴ The order of the sections has been changed, but this section retains its original section number.

⁵ These sections have been consolidated and renumbered to reduce confusion; they have also been reordered to conform to the sequence of these subject areas in Article 4.5.

- (b) The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist.
- (c) Pharmacies compounding sterile injectable products shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic residues. The procedures shall include cleanup of spills and shall be in conformance with local health jurisdiction.⁶
- (d) Pharmacies compounding sterile injectable products from one or more non-sterile ingredients must have written policies and procedures that comply with the following:
 - (1) All written policies and procedures shall be immediately available to all personnel involved in these activities and board inspectors.
 - (2) All personnel involved must read the policies and procedures before compounding sterile injectable products, and any additions, revisions, and deletions to the written policies and procedures must be communicated to all personnel involved in sterile compounding.
 - (3) Policies and procedures must address at least the following:
 - (A) Competency evaluation.
 - (B) Storage and handling of products and supplies.
 - (C) Storage and delivery of final products.
 - (D) Process validation.
 - (E) Personnel access and movement of materials into and near the controlled area.
 - (F) Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (e.g., laminar-airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations).
 - (G) Regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules and the alternation of disinfectants in lieu of complying with this subdivision.
 - (H) Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area.
 - (I) For sterile batch compounding, written policies and procedures must be established for the use of master formulas and work sheets and for appropriate documentation.
 - (J) Sterilization.
 - (K) End-product evaluation and testing.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

§1751.01. 1751.4. Facility and Equipment Standards for Sterile Injectable Compounding⁵ from Non-Sterile Ingredients.

- (a) No sterile injectable product shall be ~~prepared~~-compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile injectable drug products.

⁶ This subdivision was moved and slightly modified from former section 1751.6, to consolidate similar provisions.

- (b) During the preparation of sterile injectable products, access to the designated area or cleanroom must be limited to those individuals who are properly attired.
- (c) All equipment used in the designated area or cleanroom must be made of a material that can be easily cleaned and disinfected.
- (d) Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination.
- (e) Pharmacies preparing parenteral cytotoxic agents shall do so in accordance with Section 4-1106(b) of Title 24 of the California Administrative Code, requiring a laminar air flow hood. The hood must be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised May, 1983 (available from the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769-8010) or manufacturer's specifications. Certification records must be retained for at least 3 years.⁷

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code; and Section 18944(a), Health and Safety Code.

§1751.02. Policies and Procedures.

- (e) ~~Written policies and procedures associated with the pharmacy's preparation and dispensing of sterile injectable products shall include, but not be limited to:~~
 - (8) ~~Compounding, filling, and labeling of sterile injectable compounds.~~
 - (9) ~~Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration.~~
 - (10) ~~Equipment and supplies.~~
 - (11) ~~Training of staff in the preparation of sterile injectable products.~~
 - (12) ~~Procedures for handling cytotoxic agents.~~
 - (13) ~~Quality assurance program.~~
 - (14) ~~Record keeping requirements.~~
- (f) ~~The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist.~~
- (g) ~~Pharmacies compounding sterile injectable products from one or more non-sterile ingredients must have written policies and procedures that comply with the following:~~
 - (4) ~~All written policies and procedures shall be immediately available to all personnel involved in these activities and board inspectors.~~
 - (5) ~~All personnel involved must read the policies and procedures before compounding sterile injectable products, and any additions, revisions, and deletions to the written policies and procedures must be communicated to all personnel involved in sterile compounding.~~
 - (6) ~~Policies and procedures must address at least the following:~~
 - (A) ~~Competency evaluation.~~
 - (B) ~~Storage and handling of products and supplies.~~
 - (C) ~~Storage and delivery of final products.~~

⁷ This subdivision was moved and slightly modified from former section 1751.1, to consolidate similar provisions.

- ~~(D) Process validation.~~
- ~~(E) Personnel access and movement of materials into and near the controlled area.~~
- ~~(F) Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (e.g., laminar airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations).~~
- ~~(G) Regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules and the alternation of disinfectants in lieu of complying with this subdivision.~~
- ~~(H) Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area.~~
- ~~(I) For sterile batch compounding, written policies and procedures must be established for the use of master formulas and work sheets and for appropriate documentation.~~
- ~~(J) Sterilization.~~
- ~~(K) End product evaluation and testing.~~

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

§1751.1. Laminar Flow Biological Safety Cabinet.

Pharmacies preparing parenteral cytotoxic agents shall be in accordance with Section 4-1106(b) of Title 24 of the California Administrative Code. The hood must be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised May, 1983 (available from the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769-8010) or manufacturer's specifications. Certification records must be retained for at least 3 years.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code; and Section 18944(a), Health and Safety Code.

§1751.2. Labeling Requirements.

In addition to existing labeling requirements, a pharmacy which compounds sterile injectable products shall include the following information on the labels for those products:

- ~~(e) Telephone number of the pharmacy, except for sterile injectable products dispensed for inpatients of a hospital pharmacy.~~
- ~~(f) Name and concentrations of ingredients contained in the sterile injectable product.~~
- ~~(g) Instructions for storage and handling.~~
- ~~(h) All cytotoxic agents shall bear a special label which states "Chemotherapy—Dispose of Properly."~~

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

§1751.3. Recordkeeping Requirements.

- (d) ~~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.~~
- (e) ~~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:~~
 - (7) ~~The training and competency evaluation of employees in sterile product procedures.~~
 - (8) ~~Refrigerator and freezer temperatures.~~
 - (9) ~~Certification of the sterile compounding environment.~~
 - (10) ~~Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).~~
 - (11) ~~Inspection for expired or recalled pharmaceutical products or raw ingredients.~~
 - (12) ~~Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.~~
- (f) ~~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

§1751.4. 1751.5. Sterile Injectable Compounding Attire.

- (a) When preparing cytotoxic agents, gowns and gloves shall be worn.
- (b) When compounding sterile products from one or more non-sterile ingredients the following standards must be met:
 - (1) Cleanroom garb consisting of a low-shedding coverall, head cover, face mask, and shoe covers must be worn inside the designated area at all times.
 - (2) Cleanroom garb must be donned and removed outside the designated area.
 - (3) Hand, finger, and wrist jewelry must be eliminated. If jewelry cannot be removed then it must be thoroughly cleaned and covered with a sterile glove.
 - (4) Head and facial hair must be kept out of the critical area or be covered.
 - (5) Gloves made of low-shedding materials are required.
- (c) The requirements of this subdivision (b) do not apply if a barrier isolator is used to compound sterile injectable products from one or more non-sterile ingredients.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

§1751.5. 1751.6. Training of Sterile Injectable Compounding Staff, Patient, and Caregiver.

- (a) Consultation shall be available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy.
- (b) The pharmacist-in-charge shall be responsible to ensure all pharmacy personnel engaging in compounding sterile injectable drug products shall have training and demonstrated competence in the safe handling and compounding of sterile injectable products, including cytotoxic agents if the pharmacy compounds products with cytotoxic agents.
- (c) Records of training and demonstrated competence shall be available for each individual and shall be retained for three years beyond the period of employment.
- (d) The pharmacist-in-charge shall be responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile injectable products.
- (e) Pharmacies that compound sterile products from one or more non-sterile ingredients must comply with the following training requirements:
 - (1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:
 - (A) Aseptic technique.
 - (B) Pharmaceutical calculations and terminology.
 - (C) Sterile product compounding documentation.
 - (D) Quality assurance procedures.
 - (E) Aseptic preparation procedures.
 - (F) Proper gowning and gloving technique.
 - (G) General conduct in the controlled area.
 - (H) Cleaning, sanitizing, and maintaining equipment used in the controlled area.
 - (I) Sterilization techniques.
 - (J) Container, equipment, and closure system selection.
 - (2) Each person assigned to the controlled area must successfully complete practical skills training in aseptic technique and aseptic area practices. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. Each person's proficiency and continuing training needs must be reassessed every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

§1751.6. Disposal of Waste Material.

~~Pharmacies compounding sterile injectable products shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic residues. The procedures shall include cleanup of spills and shall be in conformance with local health jurisdiction.~~

§1751.7. Sterile Injectable Compounding Quality Assurance and Process Validation.

- (a) Any pharmacy engaged in compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, There shall be a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist in charge to assure that it meets required specifications. The Quality Assurance Program shall include at least the following:
- (1) Cleaning and sanitization of the parenteral medication preparation area.
 - (2) The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature.
 - (3) Actions to be taken in the event of a drug recall.
 - (4) Written justification of the chosen expiration dates for compounded sterile injectable products.
 - (5) End-product testing and process validation procedures.
- (b) Each individual involved in the preparation of sterile injectable products must first successfully complete a validation process on technique before being allowed to prepare sterile injectable products. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. The same personnel, procedures, equipment, and materials are must be involved. Completed medium samples must be incubated. If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken, and the validation process repeated. Personnel competency must be revalidated at least every twelve months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed. Revalidation must be documented.
- (c) Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.
- (d) Batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist-in-charge and described in the written policies and procedures.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

§1751.9. 1751.8. Sterile Injectable Compounding Reference Materials.

In any pharmacy engaged in compounding sterile injectable drug products, There shall be current and appropriate reference materials regarding the compounding of sterile injectable products located in or immediately available to the pharmacy.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.



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STATE AND CONSUMER SERVICES AGENCY
 DEPARTMENT OF CONSUMER AFFAIRS
 ARNOLD SCHWARZENEGGER, GOVERNOR

COMMUNITY PHARMACY & HOSPITAL OUTPATIENT PHARMACY COMPOUNDING SELF-ASSESSMENT

The California Code of Regulations section 1735.2 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code that compounds drug product to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. **The assessment shall be performed before July 1 of every odd-numbered year. The pharmacist-in-charge must also complete a self-assessment within 30 days whenever; (1) a new pharmacy permit has been issued, or (2) there is a change in the pharmacist-in-charge. The primary purpose of the self-assessment is to promote compliance through self-examination and education.**

The self-assessment must be completed in entirety and may be completed online, printed and retained in the pharmacy. Do not copy a previous assessment.

Note: If a hospital pharmacy dispenses prescriptions for outpatient use, a Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment must be completed in addition to the Hospital Pharmacy Self-Assessment.

Each self-assessment must be kept on file in the pharmacy for three years after it is performed.

Pharmacy Name: _____

Address: _____ Phone: _____

Ownership: Sole Owner Partnership Corporation LLC
 Non-Licensed Owner Other (please specify) _____

Permit #: _____ Exp. Date: _____ Other Permit #: _____ Exp. Date: _____

Licensed Sterile Compounding Permit # _____ or Accredited by: _____

DEA Registration #: _____ Exp. Date: _____ Date of DEA Inventory: _____

Hours: Daily _____ Sat _____ Sun. _____ 24 Hours _____

PIC: _____ RPH # _____ Exp. Date: _____

Pharmacy Staff (pharmacists, intern pharmacists, pharmacy technicians assigned to compounding duties):
(Please use an additional sheet if necessary)

2.	_____	RPH # _____	Exp. Date: _____
3.	_____	RPH # _____	Exp. Date: _____
4.	_____	RPH # _____	Exp. Date: _____
5.	_____	RPH # _____	Exp. Date: _____
6.	_____	RPH # _____	Exp. Date: _____
7.	_____	INT # _____	Exp. Date: _____
8.	_____	INT # _____	Exp. Date: _____
9.	_____	INT # _____	Exp. Date: _____
10.	_____	TCH # _____	Exp. Date: _____
11.	_____	TCH # _____	Exp. Date: _____
12.	_____	TCH # _____	Exp. Date: _____
13.	_____	TCH # _____	Exp. Date: _____
14.	_____	TCH # _____	Exp. Date: _____
15.	_____	TCH # _____	Exp. Date: _____
16.	_____	TCH # _____	Exp. Date: _____

COMMUNITY PHARMACY & HOSPITAL OUTPATIENT PHARMACY COMPOUNDING SELF-ASSESSMENT

All references to the California Code of Regulations (CCR) are to Title 16 unless otherwise noted.

Please mark the appropriate box for each question. If "NO", enter an explanation on "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, you may add additional sheets.

COMPOUNDING

1. Definitions (CCR 1735 and 1735.1)

Yes No N/A

The pharmacy compounds prescriptions as defined in CCR 1735.

The compounding pharmacist understands the definitions of integrity, potency, quality and strength as defined in CCR 1735.1.

2. Compounded Limitations and Requirements (CCR 1735.2)

The pharmacy does not compound drug product prior to receipt of a valid prescription unless under the following conditions. (CCR 1735.2[a])

Yes No N/A

The pharmacy prepares and stores a limited quantity of a compounded drug product in advance of receipt of a patient specific prescription solely in such quantity as is necessary to ensure continuity of care of an identified patient population as defined. (CCR 1735.2[b])

The pharmacy compounds a reasonable quantity of drug product that is furnished to a prescriber for office use upon prescriber order as allowed in CCR 1735.2 (c) that:

Is sufficient for administration or application to patients in the prescriber's office or for distribution of not more than a 72-hour supply, (CCR 1735.2[c][1])

Is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice, (CCR 1735.2[c][2]) AND

Is an amount, which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength for any individual prescriber or for all prescribers taken as a whole. (CCR 1735.2[c][3])

The pharmacy does not compound medication until it has prepared a written master formula that includes the following elements (CCR 1735.2[d][1-6]):

Active ingredients used.

Inactive ingredients used.

Process and/or procedure used to prepare the drug.

Quality reviews required at each step in the preparation of the drug.

Post-compounding process or procedures if required.

Expiration dating requirements.

The master formula for a drug product that is not routinely compounded by the pharmacy is recorded on the prescription document itself. (CCR 1735.2 [e])

All chemicals, bulk drug substances, drug products and other components for compounding are stored and used according to compendial and other applicable requirements to maintain their integrity, potency, quality and labeled strength. (CCR 1735.2 [g])

Compounded drug products are given an expiration date representing the date beyond which, in the professional judgment of the pharmacist, it should not be used as defined in CCR 1735.2 (h) and does not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product. (CCR 1735.2[h])

CORRECTIVE ACTION OR ACTION PLAN: _____

3. Records of Compounded Drug Products (CCR 1735.3)

Yes No N/A

A record for each compounded drug product includes the following (CCR 1735.3[a][1-10]):

The master formula record.

The date the drug product was compounded.

The identity of the pharmacy personnel who compounded the drug product.

The identity of the pharmacist reviewing the final drug product.

The quantity of each component used in compounding the drug product.

The manufacturer or supplier and lot number of each component.

The equipment used in compounding the drug product.

The pharmacy assigned reference or lot number for the compounded drug product.

The expiration date of the final compounded drug product.

The quantity or amount of drug product compounded.

The pharmacy maintains records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products and components used in compounding. (CCR 1735.3 [b])

- Chemicals, bulk drug substances, drug products, and components used to compound drug products are obtained from reliable suppliers. (CCR 1735.3 [c])
- The pharmacy acquires and retains any available certificates of purity or analysis for chemicals, bulk drug substances, drug products and components used in compounding. (This is not a requirement for drug products approved by the FDA.) (CCR 1735.3 [c])
- The pharmacy maintains and retains all records required in the pharmacy in a readily retrievable form for at least three years (CCR 1735.3 [d]).

4. Labeling of Compounded Drug Products (CCR 1735.4)

Yes No N/A

- The label of the compounded drug product contains the generic name(s) of the principle active ingredient(s). (CCR 1735.4[a])
- The prescription label contains all the information required in B&PC 4076. (CCR 1735.4[a])
- The container or receipt contains a statement that the drug has been compounded by the pharmacy. (CCR 1735.4[b])
- Drug products compounded into unit-dose containers that are too small or otherwise impractical for full compliance are labeled with the name(s) of the active ingredient(s), concentration of strength, volume or weight, and expiration date. (CCR 1735.4[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

5. Compounding Policies and Procedures (CCR 1735.5)

Yes No N/A

- The pharmacy maintains a written policy and procedure manual for compounding that establishes the following (CCR 1735.5 [a]):
 - Procurement procedures.
 - Methodologies for the formulation and compounding of drugs.
 - Facilities and equipment cleaning, maintenance and operations.
 - Other standard operating procedures related to compounding.
- The policy and procedure manual is reviewed on an annual basis by the pharmacist-in-charge and is updated whenever changes in process are implemented. (CCR 1735.5 [b])
- The policy and procedure manual includes procedures for notifying staff assigned to compounding duties of any changes in process or to the policy and procedure manual. (CCR 1735.5[c])

- The manual includes 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. (CCR 1735.5[d])
- The manual includes procedures for maintaining, storing, calibrating, cleaning and disinfecting equipment used in compounding and for training on these procedures. (CCR 1735.5[e])
- The manual includes documentation on the methodology used to test integrity, potency, quality and labeled strength of compounded drug products. (CCR 1735.5[f])
- The manual includes documentation of the methodology used to determine appropriate expiration dates for compounded drug products. (CCR 1735.5[g])

CORRECTIVE ACTION OR ACTION PLAN: _____

6. Compounding Facilities and Equipment (CCR 1735.6)

Yes No N/A

- The pharmacy maintains written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug products to include records of certification of facilities or equipment, if applicable. (CCR 1735.6[a])
- All equipment used to compound drug products is stored, used and maintained in accordance with manufacturers' specifications. (CCR 1735.6[b])
- All equipment used to compound drug products is calibrated prior to used to ensure accuracy. (CCR 1735.6[c])
- Documentation of each calibration is recorded in writing and maintained and retained in the pharmacy. (CCR 1735.6[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

7. Training of Compounding Staff (CCR 1735.7)

Yes No N/A

- The pharmacy maintains written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform assigned responsibilities relating to compounding. (CCR 1735.7[a])
- The pharmacy develops and maintains an on-going competency evaluation process for pharmacy personnel involved in compounding. (CCR 1735.7[b])

Documentation on any and all such training for pharmacy personnel is maintained. (CCR 1735.7[b])

Pharmacy personnel assigned to compounding duties demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug product. (CCR 1735.7[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

8. Compounding Quality Assurance (CCR 1735.8)

Yes No N/A

The pharmacy maintains as part of its written policies and procedures, a written quality assurance plan to monitor and ensure the integrity, potency, quality and labeled strength of compounded drug products. (CCR 1735.8[a])

The pharmacy's quality assurance plan includes the written procedures and standards for the following:

Verification, monitoring and review of the adequacy of the compounding processes as well as documentation of review of those processes by qualified pharmacy personnel. (CCR 1735.8[b])

Qualitative and quantitative integrity, potency, quality and labeled strength analysis of compounded drug products. (CCR 175.8[c])

Such reports are retained by the pharmacy and collated with the compounding record and master formula. (CCR 1735.8[c])

Scheduled action in the event any compounded drug product is ever discovered to be below minimum standards for integrity, potency, quality or labeled strength. (CCR 1735.8[d])

COMPOUNDING STERILE INJECTABLE DRUGS

FOR PHARMACIES THAT COMPOUND STERILE INJECTABLE DRUGS

Yes No N/A

Pharmacy has a board issued Licensed Sterile Compounding permit or has current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other board approved accreditation agency. (B&PC 4127.1[a] and 4127.1[d])

LSC # _____ OR

Name of accreditation agency _____

9. Compounding Drug for Other Pharmacy for Parenteral Therapy (B&PC 4123)

Yes No N/A

The pharmacy contracts to compound a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy.

The contractual arrangement is reported to the board within 30 days of commencing that compounding.

10. Sterile Injectable Compounding; Compounding Area (CCR 1751)

Yes No N/A

If the pharmacy compounds sterile injectable drugs from a nonsterile source, the pharmacy has a designated area or cleanroom for the preparation of sterile products that has one the following:

An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom. A positive air pressure differential in the cleanroom that is relative to adjacent areas; (B&PC 4127.7[a])

An ISO class 5 cleanroom (B&PC 4127.7[b])

A barrier isolator that provides an ISO class 5 environment for compounding. (B&PC 4127.7[c])

The cleanroom walls, ceiling and floors are made of non-porous, cleanable surfaces and the room is well ventilated (CCR 1751)

The laminar airflow hoods and clean room are certified annually; (CCR 1751)

Supplies are stored in a manner, which maintains integrity of an aseptic environment; (CCR 1751)

A sink with hot and cold running water; (CCR 1751)

A refrigerator of sufficient capacity to meet the storage requirements for all material requiring refrigeration. (CCR 1751)

CORRECTIVE ACTION OR ACTION PLAN: _____

11. Sterile Injectable Recordkeeping Requirements. (CCR 1751.1)

Yes No N/A

Pharmacy records are made and kept for sterile injectable products produced for future use (pursuant to section 1735.2), in addition to record requirements of section 1735.3, contain the name, lot number, amount, and date on which the products were provided to a prescriber. (CCR 1751.1[a])

Records for sterile products compounded from one or more non-sterile ingredients are made and kept and contain the following: (CCR 1751.1[b][1-6])

The training and competency evaluation of employees in sterile product procedures;

Refrigerator and freezer temperatures;

Certification of the sterile compounding environment;

Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment);

Inspection for expired or recalled pharmaceutical products or raw ingredients; and

Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.

The pharmacy maintains and retains all records required in the pharmacy in a readily retrievable form for at least three years from the date the record was created. (CCR 1751.1[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

12. Sterile Injectable Labeling Requirements (CCR 1751.2)

Yes No N/A

The pharmacy's compounded sterile injectable product labels contain: (CCR 1751.2[a-d])

Telephone number of the pharmacy, unless dispensed for a hospital in-patient;

Name and concentrations of ingredients contained in the product;

Instructions for storage and handling; and

A special label that states "Chemotherapy—Dispose of Properly" for all cytotoxic agents.

CORRECTIVE ACTION OR ACTION PLAN: _____

13. Sterile Injectable Policies and Procedures (CCR 1751.3)

Yes No N/A

The pharmacy has a written manual documenting the policies and procedures associated with the preparation and dispensing of sterile injectable products and includes: (CCR 1751.2[a][1-7])

Compounding, filling, and labeling of sterile injectable compounds;

Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration;

Equipment and supplies;

Training of staff in preparation of sterile injectable products;

Training of patient and/or caregiver in the administration of compounded sterile injectable products;

Procedures for the handling and disposal of cytotoxic agents;

Quality assurance program; and

Record keeping requirements.



Ingredients and compounding process for each preparation is determined in writing and reviewed by a pharmacist before compounding begins. (CCR 1751.3[b])



Policies and procedures address the disposal of infectious materials and/or materials containing cytotoxic residues and include cleanup of spills in conformance with local health jurisdictions. (CCR 1751.3 [c])



If compounding sterile injectable products from one or more non-sterile ingredients, the pharmacy has written policies and procedures that comply with the following: (CCR 1751.3[d][1-3])

Policies and procedures are immediately available to all compounding personnel and board inspectors (CCR 1751.3[d][1]); and

All compounding personnel have read the policies and procedures, any additions, revisions, and deletions before compounding. (CCR 1751.3 [d][2])



Policies and procedures address the following: (CCR 1751.3 [d][3] [A-K])

Competency evaluation;

Storage and handling of products and supplies;

Storage and delivery of final products;

Process validation;

Personnel access and movement of materials into and near the controlled area;

Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (e.g., laminar-airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations);

A regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules;

Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area;

For sterile batch compounding, written policies and procedures for the use of master formulas and work sheets and for appropriate documentation;

Sterilization; and

End-product evaluation and testing.

CORRECTIVE ACTION OR ACTION PLAN: _____

14. Facility & Equipment Standards for Sterile Injectable Compounding (CCR 1751.4)

Yes No N/A

The compounding environment meets criteria specified in the pharmacy's written policies and procedures for safe compounding of sterile injectable drugs. (CCR 1751.4[a])

Only those who are properly attired pursuant to (CCR 1751.5) are allowed in the cleanroom during the preparation of sterile injectable products. (CCR 1751.4[b])

All equipment used in the designated area or cleanroom is made of easily cleaned and disinfected material. (CCR 1751.4[c])

Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools are disinfected weekly and after any unanticipated event that could increase risk of contamination (CCR 1751.4[d])

The preparation of parenteral cytotoxic agents is done in accordance with Section 4-1006(b) of Title 24 of the California Administrative Code and includes: (CCR 1751.4[e])

A laminar airflow hood, which is certified annually.

Certification records are maintained for at least three years.

CORRECTIVE ACTION OR ACTION PLAN: _____

15. Sterile Injectable Compounding Attire (CCR 1751.5)

Yes No N/A

When preparing cytotoxic agents, gowns and gloves are worn.(CCR 1751.5[a])

When compounding sterile products from one or more non-sterile ingredients and a barrier isolator is not used: (CCR 1751.5[b][1-5])

Cleanroom garb is donned and removed outside the designated area; (CCR 1751.5[b][2])

Individuals in the cleanroom wear a low-shedding coverall, head cover, face mask, and shoe covers; (CCR 1751.5[b][1])

No hand, finger, or wrist jewelry is worn or if the jewelry cannot be removed, it is cleaned and covered with a sterile glove; (CCR 1751.5[b][3])

Head and facial hair is kept out of critical area or covered (CCR 1751.5[b][4]); and

Gloves of low-shedding material are worn. (CCR 1751.5[b][5])

CORRECTIVE ACTION OR ACTION PLAN: _____

16. Training of Sterile Injectable Compounding Staff, Patient, and Caregiver (CCR 1751.6)

Yes No N/A

Consultation is available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy. (CCR 1751.6[a])

The pharmacist-in-charge ensures that all pharmacy personnel engaging in compounding sterile injectable drug products has training and demonstrated competence in the safe handling of those products, including cytotoxic agents if the pharmacy compounds such agents. (CCR 1751.6[b])

Records of training and demonstrated competence are available for each individual and are retained for three years beyond the employment period. (CCR 1751.6[c])

The pharmacist-in-charge ensures the continuing competence of pharmacy personnel engaged in compounding sterile injectable products. (CCR 1751.6[d])

When compounding sterile products from one or more non-sterile ingredients, the pharmacy complies with the following training requirements: (CCR 1751.6[e])

The pharmacy follows a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation addresses the following: (CCR 1751.6[e][1][A-J])

Aseptic technique;

Pharmaceutical calculations and terminology;

Sterile product compounding documentation;

Quality assurance procedures;

Proper gowning and gloving technique;

General conduct in the controlled area;

Cleaning, sanitizing, and maintaining equipment used in the controlled area;

Sterilization techniques; and

Container, equipment, and closure system selection.

Each person assigned to the controlled area successfully completes practical skills training in aseptic technique and aseptic area practices. (CCR 1751.6[e][2])

Evaluation includes written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. (CCR 1751.6[e][2])

Each person's proficiency and continuing training is reassessed every 12 months. (CCR 1751.6[e][2])

Results of these assessments are documented and retained in the pharmacy for three years. (CCR 1751.6[e][2])

CORRECTIVE ACTION OR ACTION PLAN: _____

17. Sterile Injectable Compounding Quality Assurance and Process Validation (CCR 1751.7)

Yes No N/A

There is a written, documented, ongoing quality assurance program maintained by the pharmacy that monitors personnel performance, equipment, and facilities, and the pharmacist-in-charge assures that the end-product meets the required specifications by periodic sampling. (CCR 1751.7[a])

The Quality Assurance Program contains at least the following: (CCR 1751.7[a][1-4])

Cleaning and sanitization of the parenteral medication preparation area;

The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature;

Actions to be taken in the event of a drug recall; and

Written justification of the chosen expiration dates for compounded sterile injectable products in accordance with CCR 1735.2[h]).

Each individual involved in the preparation of sterile injectable products successfully completes a validation process on technique before being allowed to prepare sterile injectable products. (CCR 1751.7[b])

The validation process is carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. (CCR 1751.7[b])

The validation process is representative of all types of manipulations, products and batch sizes the individual is expected to prepare. (CCR 1751.7[b])

The same personnel, procedures, equipment, and materials are involved. (CCR 1751.7[b])

Completed medium samples are incubated. (CCR 1751.7[b])

If microbial growth is detected, the sterile preparation process is evaluated, corrective action taken, and the validation process is repeated. (CCR 1751.7[b])

Personnel competency is revalidated and documented at least every 12 months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever aseptic techniques are observed. (CCR 1751.7[b])

Batch produced sterile injectable drug products compounded from one or more non-sterile ingredients are subject to documented end product testing for sterility and pyrogens and are quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. (CCR 1751.7[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

18. Sterile Injectable Compounding Reference Materials (CCR 1751.8)

Yes No N/A

Current and appropriate reference materials regarding the compounding of sterile injectable products are maintained or immediately available to the pharmacy. (CCR 1751.8)

CORRECTIVE ACTION OR ACTION PLAN: _____

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (Please print) _____, RPH # _____ hereby certify that I have completed the self-assessment of this pharmacy of which I am the pharmacist-in-charge. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury that the information contained in this self-assessment form is true and correct.

Signature _____
(Pharmacist-in-Charge)

Date _____

RECEIVED BY CALIF.
BOARD OF PHARMACY

2007 OCT 10 PM 3:58

October 4, 2007

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



Dear Ms. Herold,

I request an additional revision to the proposed compounding regulations. The California Sterile Compounding Regulations should contain a provision where the pharmacist-in-charge of sterile compounding is required to be licensed in the State of California.

The purpose of having the pharmacist-in-charge of sterile compounding be licensed in California is to add an additional level of protection for California residents.

By having the pharmacist-in-charge of sterile compounding be licensed in the State of California this will insure that the responsible pharmacist is thoroughly knowledgeable with the rules and regulations of California.

Several other states have similar requirements. I know of at least Mississippi, New Mexico, Oklahoma, Washington, and Wyoming that require the pharmacist-in-charge to be licensed in their state.

Please contact me if you need any additional information.

Very best wishes,

McGuff Compounding Pharmacy Services, Inc.

A handwritten signature in black ink that reads 'William J. Blair'.

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

McGUFF
COMPOUNDING
PHARMACY
SERVICES

2921 W. MacArthur Blvd.
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Santa Ana, CA 92704-6929

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877.444.1155

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EMAIL: answers@mcguff.com

Attachment 2

*Proposed Legislation 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) ~~Initiate and administer immunizations pursuant to a protocol with a prescriber~~ as authorized by Section 4052.8.
- (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.

4052.8 (a) A pharmacist may initiate and administer immunizations pursuant to a protocol with a prescriber or pursuant to the current Recommended Adult (19+) and Adolescent (7-18) Immunization Schedules, provided by the Centers for Disease Control and Prevention (CDC) pursuant to published recommendations of the CDC Advisory Committee on Immunization Practices.

(b) Prior to administering an immunization pursuant to this section, a pharmacist shall have completed the American Pharmacists Association pharmacy-based immunization certificate program or another pharmacy-based immunization training program endorsed by the Centers for Disease Control and Prevention.

(c) A pharmacist administering any immunization pursuant to this section shall also complete 3 hours of immunization-related continuing education coursework annually. Failure at any time to meet this requirement shall, in addition to any other sanctions, require the pharmacist to re-take the training identified in subdivision (b) prior to administration of any further immunization(s).

(d) A pharmacist shall at all times maintain a current Basic Life Support certification.

(e) At the time of administration of an immunization, the pharmacist shall:

(1) Provide the patient or patient's agent with the appropriate Vaccine Information Statement for each immunization administered; and

(2) Provide documentation of administration of the immunization to the patient's physician or primary care provider, if one can be identified.

(f) Any pharmacist administering vaccines pursuant to this section may initiate and administer epinephrine by injection for severe allergic reactions.

(g) Any adverse event shall be reported to the Vaccine Adverse Event Reporting System within the U.S. Department of Health and Human Services.

(h) The pharmacist shall maintain an immunization administration record for each immunization, which includes the name of vaccine, expiration date, date of administration, manufacturer and lot number, administration site and route, Vaccine Information Statement date, and the name and title of the person administering, for the longer of the following periods:

(1) Ten years from the date of administration; or

(2) Three years beyond the patient's eighteenth birthday.

Vaccines & Immunizations

Publications:

ACIP Recommendations

On This Page:

- | [Comprehensive](#) (Recommendations applying to multiple or all vaccines)
- | [Vaccine-specific](#) (Recommendations applying to a single vaccine or disease)

Recently updated or added to this page:

- | [Varicella Recommendations](#) Updated (June 22, 2007)
- | [Influenza Recommendations](#) Updated (July 13, 2007)
- | [Meningococcal Supplement](#) (August 10, 2007)



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Comprehensive Recommendations

- [General Recommendations on Immunization \(12/1/06\)](#)
"General Recommendations on Immunization"
[.pdf version](#)
- [Adult \(11/15/91\)](#)
"Update on Adult Immunization"
[.pdf \(not available\)](#)
See also: [More MMWR publications](#)
- [Adolescent \(11/22/96\)](#)
"Immunization of Adolescents "
[.pdf version](#)
- [Combination Vaccines](#)
"Combination Vaccines for Childhood Immunization" (5/14/99)
[.pdf version](#)
See also: [FDA approval for combined Hep A and B vaccines](#)
- [Health-Care Workers](#)
"Immunization of Healthcare Workers" (12/26/97)
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See also: [Influenza Vaccination of Health-Care Personnel](#)
- [Immunocompromised Persons \(4/9/93\)](#)
"Use of Vaccines and Immune Globulins in Persons with Altered Immunocompetence "
[.pdf version](#)
- [Side Effects, Contraindications, etc. \(9/6/96\)](#)
"Update: Vaccine Side Effects, Adverse Reactions, Contraindications, and Precautions"
[.pdf version](#)
- [Assessment & Feedback \(3/15/96\)](#)
"Programmatic Strategies to Increase Vaccination Rates - Assessment and Feedback of Provider-Based Vaccination Coverage Information"
[.pdf version](#) (go to page 15)
- [Vaccination and WIC \(3/15/96\)](#)
"Programmatic Strategies to Increase Vaccination Coverage by Age 2 Years - Linkage of Vaccination and WIC Services"
[.pdf version](#) (go to page 13)

TOP

Recommended Adult Immunization Schedule, by Vaccine and Age Group UNITED STATES • OCTOBER 2006–SEPTEMBER 2007

Vaccine ▼	Age group ►	19–49 years	50–64 years	≥65 years
Tetanus, diphtheria, pertussis (Td/Tdap) ^{1,*}		1-dose Td booster every 10 yrs		
		Substitute 1 dose of Tdap for Td		
Human papillomavirus (HPV) ²		3 doses (females)		
Measles, mumps, rubella (MMR) ^{3,*}		1 or 2 doses	1 dose	
Varicella ^{4,*}		2 doses (0, 4–8 wks)	2 doses (0, 4–8 wks)	
Influenza ^{5,*}		1 dose annually	1 dose annually	
Pneumococcal (polysaccharide) ^{6,7}		1–2 doses		1 dose
Hepatitis A ^{8,*}		2 doses (0, 6–12 mos, or 0, 6–18 mos)		
Hepatitis B ^{9,*}		3 doses (0, 1–2, 4–6 mos)		
Meningococcal ¹⁰		1 or more doses		

*Covered by the Vaccine Injury Compensation Program. NOTE: These recommendations must be read with the footnotes (see reverse).

 For all persons in this category who meet the age requirements and who lack evidence of immunity (e.g., lack documentation of vaccination or have no evidence of prior infection)

 Recommended if some other risk factor is present (e.g., on the basis of medical, occupational, lifestyle, or other indications)

 Contraindicated

This schedule indicates the recommended age groups and medical indications for routine administration of currently licensed vaccines for persons aged ≥19 years, as of October 1, 2006. Licensed combination vaccines may be used whenever any components of the combination are indicated and when the vaccine's other components are not contraindicated. For detailed recommendations on all vaccines, including those used primarily for travelers or that are issued during the year, consult the manufacturers' package inserts and the complete statements from the Advisory Committee on Immunization Practices (www.cdc.gov/nip/publications/acip-list.htm).

Report all clinically significant postvaccination reactions to the Vaccine Adverse Event Reporting System (VAERS). Reporting forms and instructions on filing a VAERS report are available at www.vaers.hhs.gov or by telephone, 800-822-7967.

Information on how to file a Vaccine Injury Compensation Program claim is available at www.hrsa.gov/vaccinecompensation or by telephone, 800-338-2382. To file a claim for vaccine injury, contact the U.S. Court of Federal Claims, 717 Madison Place, N.W., Washington, D.C. 20005; telephone, 202-357-6400.

Additional information about the vaccines in this schedule and contraindications for vaccination is also available at www.cdc.gov/nip or from the CDC-INFO Contact Center at 800-CDC-INFO (800-232-4636) in English and Spanish, 24 hours a day, 7 days a week.

Recommended Adult Immunization Schedule, by Vaccine and Medical and Other Indications UNITED STATES • OCTOBER 2006–SEPTEMBER 2007

Vaccine ▼	Indication ►	Medical and Other Indications							
		Pregnancy	Congenital immunodeficiency, leukemia, ¹¹ lymphoma, generalized malignancy, cerebrospinal fluid leaks; therapy with alkylating agents, antimetabolites, radiation, or high-dose, long-term corticosteroids	Diabetes, heart disease, chronic pulmonary disease, chronic alcoholism	Asplenia ¹¹ (including elective splenectomy and terminal complement component deficiencies)	Chronic liver disease, recipients of clotting factor concentrates	Kidney failure, end-stage renal disease, recipients of hemodialysis	Human immunodeficiency virus (HIV) infection ^{12,13}	Healthcare workers
Tetanus, diphtheria, pertussis (Td/Tdap) ^{1,*}		1-dose Td booster every 10 yrs							
		Substitute 1 dose of Tdap for Td							
Human papillomavirus (HPV) ²		3 doses for females through age 26 yrs (0, 2, 6 mos)							
Measles, mumps, rubella (MMR) ^{3,*}									1 or 2 doses
Varicella ^{4,*}									2 doses
Influenza ^{5,*}		1 dose annually			1 dose annually				1 dose annually
Pneumococcal (polysaccharide) ^{6,7}		1–2 doses			1–2 doses				1–2 doses
Hepatitis A ^{8,*}		2 doses (0, 6–12 mos, or 0, 6–18 mos)			2 doses	2 doses (0, 6–12 mos, or 0, 6–18 mos)			
Hepatitis B ^{9,*}		3 doses (0, 1–2, 4–6 mos)				3 doses (0, 1–2, 4–6 mos)			
Meningococcal ¹⁰		1 dose			1 dose				1 dose

*Covered by the Vaccine Injury Compensation Program. NOTE: These recommendations must be read with the footnotes (see reverse).

 For all persons in this category who must the age requirements and who lack evidence of immunity (e.g., lack documentation of vaccination or have no evidence of prior infection)

 Recommended if some other risk factor is present (e.g., on the basis of medical, occupational, lifestyle, or other indications)

 Contraindicated

Approved by
the Advisory Committee on Immunization Practices,
the American College of Obstetricians and Gynecologists,
the American Academy of Family Physicians,
and the American College of Physicians



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION



Footnotes

Recommended Adult Immunization Schedule • UNITED STATES, OCTOBER 2006–SEPTEMBER 2007

1. **Tetanus, diphtheria, and acellular pertussis (Td/Tdap) vaccination.** Adults with uncertain histories of a complete primary vaccination series with diphtheria and tetanus toxoid-containing vaccines should begin or complete a primary vaccination series. A primary series for adults is 3 doses; administer the first 2 doses at least 4 weeks apart and the third dose 6–12 months after the second. Administer a booster dose to adults who have completed a primary series and if the last vaccination was received ≥ 10 years previously. Tdap or tetanus and diphtheria (Td) vaccine may be used; Tdap should replace a single dose of Td for adults aged < 65 years who have not previously received a dose of Tdap (either in the primary series, as a booster, or for wound management). Only one of two Tdap products (Adacel[®] [sanofi pasteur]) is licensed for use in adults. If the person is pregnant and received the last Td vaccination ≥ 10 years previously, administer Td during the second or third trimester; if the person received the last Td vaccination in < 10 years, administer Tdap during the immediate postpartum period. A one-time administration of 1 dose of Tdap with an interval as short as 2 years from a previous Td vaccination is recommended for postpartum women, close contacts of infants aged < 12 months, and all healthcare workers with direct patient contact. In certain situations, Td can be deferred during pregnancy and Tdap substituted in the immediate postpartum period, or Tdap can be given instead of Td to a pregnant woman after an informed discussion with the woman (see www.cdc.gov/nip/publications/acip-list.htm). Consult the ACIP statement for recommendations for administering Td as prophylaxis in wound management (www.cdc.gov/mmwr/preview/mmwrhtml/00041645.htm).

2. **Human papillomavirus (HPV) vaccination.** HPV vaccination is recommended for all women aged ≤ 26 years who have not completed the vaccine series. Ideally, vaccine should be administered before potential exposure to HPV through sexual activity; however, women who are sexually active should still be vaccinated. Sexually active women who have not been infected with any of the HPV vaccine types receive the full benefit of the vaccination. Vaccination is less beneficial for women who have already been infected with one or more of the four HPV vaccine types. A complete series consists of 3 doses. The second dose should be administered 2 months after the first dose; the third dose should be administered 6 months after the first dose. Vaccination is not recommended during pregnancy. If a woman is found to be pregnant after initiating the vaccination series, the remainder of the 3-dose regimen should be delayed until after completion of the pregnancy.

3. **Measles, mumps, rubella (MMR) vaccination.** *Measles component:* adults born before 1957 can be considered immune to measles. Adults born during or after 1957 should receive ≥ 1 dose of MMR unless they have a medical contraindication, documentation of ≥ 1 dose, history of measles based on healthcare provider diagnosis, or laboratory evidence of immunity. A second dose of MMR is recommended for adults who 1) have been recently exposed to measles or in an outbreak setting; 2) have been previously vaccinated with killed measles vaccine; 3) have been vaccinated with an unknown type of measles vaccine during 1963–1967; 4) are students in postsecondary educational institutions; 5) work in a healthcare facility; or 6) plan to travel internationally. Withhold MMR or other measles-containing vaccines from HIV-infected persons with severe immunosuppression.

Mumps component: adults born before 1957 can generally be considered immune to mumps. Adults born during or after 1957 should receive 1 dose of MMR unless they have a medical contraindication, history of mumps based on healthcare provider diagnosis, or laboratory evidence of immunity. A second dose of MMR is recommended for adults who 1) are in an age group that is affected during a mumps outbreak; 2) are students in postsecondary educational institutions; 3) work in a healthcare facility; or 4) plan to travel internationally. For unvaccinated healthcare workers born before 1957 who do not have other evidence of mumps immunity, consider giving 1 dose on a routine basis and strongly consider giving a second dose during an outbreak. *Rubella component:* administer 1 dose of MMR vaccine to women whose rubella vaccination history is unreliable or who lack laboratory evidence of immunity. For women of childbearing age, regardless of birth year, routinely determine rubella immunity and counsel women regarding congenital rubella syndrome. Do not vaccinate women who are pregnant or who might become pregnant within 4 weeks of receiving vaccine. Women who do not have evidence of immunity should receive MMR vaccine upon completion or termination of pregnancy and before discharge from the healthcare facility.

4. **Varicella vaccination.** All adults without evidence of immunity to varicella should receive 2 doses of varicella vaccine. Special consideration should be given to those who 1) have close contact with persons at high risk for severe disease (e.g., healthcare workers and family contacts of immunocompromised persons) or 2) are at high risk for exposure or transmission (e.g., teachers of young children; child care employees; residents and staff members of institutional settings, including correctional institutions; college students; military personnel; adolescents and adults living in households with children; nonpregnant women of childbearing age; and international travelers). Evidence of immunity to varicella in adults includes any of the following: 1) documentation of 2 doses of varicella vaccine at least 4 weeks apart; 2) U.S.-born before 1980 (although for healthcare workers and pregnant women, birth before 1980 should not be considered evidence of immunity); 3) history of varicella based on diagnosis or verification of varicella by a healthcare provider (for a patient reporting a history of or presenting with an atypical case, a mild case, or both, healthcare providers should seek either an epidemiologic link with a typical varicella case or evidence of laboratory confirmation, if it was performed at the time of acute disease); 4) history of herpes zoster based on healthcare provider diagnosis; or 5) laboratory evidence of immunity or laboratory confirmation of disease. Do not vaccinate women who are pregnant or might become pregnant within 4 weeks of receiving the vaccine. Assess pregnant women for evidence of varicella immunity. Women who do not have evidence of immunity should receive dose 1 of varicella vaccine upon completion or termination of pregnancy and before discharge from the healthcare facility. Dose 2 should be administered 4–8 weeks after dose 1.

5. **Influenza vaccination.** *Medical indications:* chronic disorders of the cardiovascular or pulmonary systems, including asthma; chronic metabolic diseases, including diabetes mellitus, renal dysfunction, hemoglobinopathies, or immunosuppression (including immunosuppression caused by medications or HIV); 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, or seizure disorder or other neuromuscular disorder); and pregnancy during the influenza season. No data exist on the risk for severe or complicated influenza disease among persons with asplenia; however, influenza is a risk factor for secondary bacterial infections that can cause severe disease among persons with asplenia. *Occupational indications:* healthcare workers and employees of long-term-care and assisted living facilities. *Other indications:* residents of nursing homes and other long-term-care and assisted living facilities; persons likely to transmit influenza to persons at high risk (e.g., in-home household contacts and caregivers of children aged 0–59 months, or persons of all ages with high-risk conditions); and anyone who would like to be vaccinated. Healthy, nonpregnant persons aged 5–49 years without high-risk medical conditions who are not contacts of severely immunocompromised persons in special care units can receive either intranasally administered influenza vaccine (FluMist[®]) or inactivated vaccine. Other persons should receive the inactivated vaccine.

6. **Pneumococcal polysaccharide vaccination.** *Medical indications:* chronic disorders of the pulmonary system (excluding asthma); cardiovascular diseases; diabetes mellitus; chronic liver diseases, including liver disease as a result of alcohol abuse (e.g., cirrhosis); chronic renal failure or nephrotic syndrome; functional or anatomic asplenia (e.g., sickle cell disease or splenectomy [if elective splenectomy is planned, vaccinate at least 2 weeks before surgery]); immunosuppressive conditions (e.g., congenital immunodeficiency, HIV infection [vaccinate as close to diagnosis as possible when CD4 cell counts are highest], leukemia, lymphoma, multiple myeloma, Hodgkin disease, generalized malignancy, or organ or bone marrow transplantation); chemotherapy with alkylating agents, antimetabolites, or high-dose, long-term corticosteroids; and cochlear implants. *Other indications:* Alaska Natives and certain American Indian populations and residents of nursing homes or other long-term-care facilities.

7. **Revaccination with pneumococcal polysaccharide vaccine.** One-time revaccination after 5 years for persons with chronic renal failure or nephrotic syndrome; functional or anatomic asplenia (e.g., sickle cell disease or splenectomy); immunosuppressive conditions (e.g., congenital immunodeficiency, HIV infection, leukemia, lymphoma, multiple myeloma, Hodgkin disease, generalized malignancy, or organ or bone marrow transplantation); or chemotherapy with alkylating agents, antimetabolites, or high-dose, long-term corticosteroids. For persons aged ≥ 65 years, one-time revaccination if they were vaccinated ≥ 5 years previously and were aged < 65 years at the time of primary vaccination.

8. **Hepatitis A vaccination.** *Medical indications:* persons with chronic liver disease and persons who receive clotting factor concentrates. *Behavioral indications:* men who have sex with men and persons who use illegal drugs. *Occupational indications:* persons working with hepatitis A virus (HAV)-infected primates or with HAV in a research laboratory setting. *Other indications:* persons traveling to or working in countries that have high or intermediate endemicity of hepatitis A (a list of countries is available at www.cdc.gov/travel/diseases.htm) and any person who would like to obtain immunity. Current vaccines should be administered

in a 2-dose schedule at either 0 and 6–12 months, or 0 and 6–18 months. If the combined hepatitis A and hepatitis B vaccine is used, administer 3 doses at 0, 1, and 6 months.

9. **Hepatitis B vaccination.** *Medical indications:* persons with end-stage renal disease, including patients receiving hemodialysis; persons seeking evaluation or treatment for a sexually transmitted disease (STD); persons with HIV infection; persons with chronic liver disease; and persons who receive clotting factor concentrates. *Occupational indications:* healthcare workers and public-safety workers who are exposed to blood or other potentially infectious body fluids. *Behavioral indications:* sexually active persons who are not in a long-term, mutually monogamous relationship (i.e., persons with > 1 sex partner during the previous 6 months); current or recent injection-drug users; and men who have sex with men. *Other indications:* household contacts and sex partners of persons with chronic hepatitis B virus (HBV) infection; clients and staff members of institutions for persons with developmental disabilities; all clients of STD clinics; international travelers to countries with high or intermediate prevalence of chronic HBV infection (a list of countries is available at www.cdc.gov/travel/diseases.htm); and any adult seeking protection from HBV infection. Settings where hepatitis B vaccination is recommended for all adults: STD treatment facilities; HIV testing and treatment facilities; facilities providing drug-abuse treatment and prevention services; healthcare settings providing services for injection-drug users or men who have sex with men; correctional facilities; end-stage renal disease programs and facilities for chronic hemodialysis patients; and institutions and nonresidential daycare facilities for persons with developmental disabilities. *Special formulation indications:* for adult patients receiving hemodialysis and other immunocompromised adults, 1 dose of 40 $\mu\text{g}/\text{mL}$ (Recombivax HB[®]) or 2 doses of 20 $\mu\text{g}/\text{mL}$ (Engerix-B[®]).

10. **Meningococcal vaccination.** *Medical indications:* adults with anatomic or functional asplenia, or terminal complement component deficiencies. *Other indications:* first-year college students living in dormitories; microbiologists who are routinely exposed to isolates of *Neisseria meningitidis*; military recruits; and persons who travel to or live in countries in which meningococcal disease is hyperendemic or epidemic (e.g., the “meningitis belt” of sub-Saharan Africa during the dry season [December–June]), particularly if their contact with local populations will be prolonged. Vaccination is required by the government of Saudi Arabia for all travelers to Mecca during the annual Hajj. Meningococcal conjugate vaccine is preferred for adults with any of the preceding indications who are aged ≤ 55 years, although meningococcal polysaccharide vaccine (MPSV4) is an acceptable alternative. Revaccination after 5 years might be indicated for adults previously vaccinated with MPSV4 who remain at high risk for infection (e.g., persons residing in areas in which disease is epidemic).

11. **Selected conditions for which *Haemophilus influenzae* type b (Hib) vaccine may be used.** Hib conjugate vaccines are licensed for children aged 6 weeks–71 months. No efficacy data are available on which to base a recommendation concerning use of Hib vaccine for older children and adults with the chronic conditions associated with an increased risk for Hib disease. However, studies suggest good immunogenicity in patients who have sickle cell disease, leukemia, or HIV infection or who have had splenectomies; administering vaccine to these patients is not contraindicated.

Summary of Recommendations for Adult Immunization

Vaccine name and route	For whom vaccination is recommended	Schedule for vaccine administration (any vaccine can be given with another)	Contraindications and precautions (mild illness is not a contraindication)
Influenza Trivalent inactivated influenza vaccine (TIV) Give IM	<ul style="list-style-type: none"> • Anyone wishing to reduce the likelihood of becoming ill with influenza. • Persons age 50yrs and older. • Persons with medical problems (e.g., heart disease, lung disease, diabetes, renal dysfunction, hemoglobinopathy, immunosuppression) and/or people living in chronic care facilities. • Persons with 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). • Persons working or living with at-risk people. • Women who will be pregnant during the influenza season (December–March). • All healthcare personnel and other persons who provide direct care to at-risk people. • Household contacts and out-of-home caregivers of children ages 0–59m. • Travelers at risk for complications of influenza who go to areas where influenza activity exists or who may be among people from areas of the world where there is current influenza activity (e.g., on organized tours). • Persons who provide essential community services. • Students or other persons in institutional settings (e.g., dormitory residents). 	<ul style="list-style-type: none"> • Given every year in the fall or winter. • October and November are the usual months to give TIV. • LAIV may be given as soon as it is available. • Continue to give TIV and LAIV through the influenza season from December through March (including when influenza activity is present in the community) and at other times when the risk of influenza exists. 	<p>Contraindication Previous anaphylactic reaction to this vaccine, to any of its components, or to eggs.</p> <p>Precautions</p> <ul style="list-style-type: none"> • Moderate or severe acute illness. • History of Guillain-Barré syndrome (GBS) within 6wks of previous TIV.
Influenza Live attenuated influenza vaccine (LAIV) Give intranasally	<ul style="list-style-type: none"> • Healthy, non-pregnant persons age 49yrs and younger who meet any of the criteria listed below. - Working or living with at-risk people as listed in the section above. - Healthcare personnel or other persons who provide direct care to at-risk people (except persons in close contact with severely immunosuppressed persons). - Household contacts and out-of-home caregivers of children ages 0–59m. - Travelers who may be among people from areas of the world where there is current influenza activity (e.g., on organized tours). - Persons who provide essential community services. - Students or other persons in institutional settings (e.g., dormitory residents). - Persons who wish to reduce the likelihood of becoming ill with influenza. 	<ul style="list-style-type: none"> • Continue to give TIV and LAIV through the influenza season from December through March (including when influenza activity is present in the community) and at other times when the risk of influenza exists. 	<p>Contraindications</p> <ul style="list-style-type: none"> • Previous anaphylactic reaction to this vaccine, to any of its components, or to eggs. • Pregnancy, asthma, reactive airway disease or other chronic disorder of the pulmonary or cardiovascular system; an underlying medical condition, including metabolic disease such as diabetes, renal dysfunction, and hemoglobinopathy; a known or suspected immune deficiency disease or receiving immunosuppressive therapy; history of GBS. <p>Precaution Moderate or severe acute illness.</p>
Pneumococcal polysaccharide (PPV) Give IM or SC	<ul style="list-style-type: none"> • Persons age 65yrs and older. • Persons who have chronic illness or other risk factors, including chronic cardiac or pulmonary disease, chronic liver disease, alcoholism, diabetes, CSF leak, as well as people living in special environments or social settings (including Alaska Natives and certain American Indian populations). Those at highest risk of fatal pneumococcal infection are persons with anatomic asplenia, functional asplenia, or sickle cell disease; immunocompromised persons including those with HIV infection, leukemia, lymphoma, Hodgkin's disease, multiple myeloma, generalized malignancy, chronic renal failure, or nephrotic syndrome; persons receiving immunosuppressive chemotherapy (including corticosteroids); those who received an organ or bone marrow transplant; and candidates for or recipients of cochlear implants. 	<ul style="list-style-type: none"> • Routinely given as a one-time dose; administer if previous vaccination history is unknown. • One-time revaccination is recommended 5yrs later for persons at highest risk of fatal pneumococcal infection or rapid antibody loss (e.g., renal disease) and for persons age 65yrs and older if the 1st dose was given prior to age 65 and 5yrs or more have elapsed since the previous dose. 	<p>Contraindication Previous anaphylactic reaction to this vaccine or to any of its components.</p> <p>Precaution Moderate or severe acute illness.</p>

*This document was adapted from the recommendations of the Advisory Committee on Immunization Practices (ACIP). To obtain copies of these recommendations, call the CDC-INFO Contact Center at (800) 232-4636; visit CDC's website at www.cdc.gov/nip/publications/ACIP-list.htm; or visit the Immunization Action

Coalition (IAC) website at www.immunize.org/acip. This table is revised periodically. Visit IAC's website at www.immunize.org/adultrules to make sure you have the most current version.

Summary of Recommendations for Adult Immunization (continued)

Vaccine name and route	For whom vaccination is recommended	Schedule for vaccine administration (any vaccine can be given with another)	Contraindications and precautions (mild illness is not a contraindication)
<p>Hepatitis B (Hep B) <i>Give IM</i></p> <p>Brands may be used interchangeably.</p>	<ul style="list-style-type: none"> All persons through age 18yrs. Any adult wishing to obtain immunity against hepatitis B virus infection. High-risk persons, including household contacts and sex partners of HBsAg-positive persons; injecting drug users; sexually active persons not in a long-term, mutually monogamous relationship; men who have sex with men; persons with HIV or a recently diagnosed STD; patients receiving hemodialysis and patients with renal disease that may result in dialysis; recipients of certain blood products; healthcare personnel and public safety workers who are exposed to blood; clients and staff of institutions for the developmentally disabled; inmates of long-term correctional facilities; and certain international travelers. Persons with chronic liver disease. <p>Note: Provide serologic screening for immigrants from endemic areas. If patient is chronically infected, assure appropriate disease management. Screen sex partners and household members; give Hep B at the same visit if not already vaccinated.</p>	<ul style="list-style-type: none"> Three doses are needed on a 0, 1, 6m schedule. Alternative timing options for vaccination include 0, 2, 4m and 0, 1, 4m. There must be 4wks between doses #1 and #2, and 8wks between doses #2 and #3. Overall, there must be at least 16wks between doses #1 and #3. Schedule for those who have fallen behind: If the series is delayed between doses, DO NOT start the series over. Continue from where you left off. 	<p>Contraindication Previous anaphylactic reaction to this vaccine or to any of its components.</p> <p>Precaution Moderate or severe acute illness.</p>
<p>Hepatitis A (Hep A) <i>Give IM</i></p> <p>Brands may be used interchangeably.</p>	<ul style="list-style-type: none"> Anyone wishing to obtain immunity to hepatitis A virus infection. Persons who travel or work anywhere except the U.S., Western Europe, New Zealand, Australia, Canada, and Japan. Persons with chronic liver disease, including persons with hepatitis B and C; injecting and non-injecting drug users; men who have sex with men; people with clotting-factor disorders; persons who work with hepatitis A virus in experimental lab settings (not routine medical laboratories); and food handlers when health authorities or private employers determine vaccination to be appropriate. <p>Note: Prevacination testing is likely to be cost effective for persons older than age 40yrs, as well as for younger persons in certain groups with a high prevalence of hepatitis A virus infection.</p>	<p>For Twinrix® (hepatitis A and B combination vaccine [GSK]) for patients 18yrs and older only: three doses are needed on a 0, 1, 6m schedule. An accelerated schedule can also be used at 0, 7, 21–30d, and a booster at 12m.</p> <ul style="list-style-type: none"> Two doses are needed. The minimum interval between doses #1 and #2 is 6m. If dose #2 is delayed, do not repeat dose #1. Just give dose #2. 	<p>Contraindication Previous anaphylactic reaction to this vaccine or to any of its components.</p> <p>Precautions • Moderate or severe acute illness. • Safety during pregnancy has not been determined, so benefits must be weighed against potential risk.</p>
<p>Td, Tdap (Tetanus, diphtheria, pertussis) <i>Give IM</i></p>	<ul style="list-style-type: none"> All adults who lack a history of a primary series consisting of at least 3 doses of tetanus- and diphtheria-toxoid-containing vaccine. A booster dose of tetanus- and diphtheria-toxoid-containing vaccine may be needed for wound management as early as 5yrs after receiving a previous dose, so consult ACIP recommendations.* Using tetanus toxoid (TT) instead of Td or Tdap is <u>not</u> recommended. In pregnancy, when indicated, give Td or Tdap in 2nd or 3rd trimester. If not administered during pregnancy, give Tdap in immediate postpartum period. <p>For Tdap only:</p> <ul style="list-style-type: none"> All adults younger than age 65yrs who have not already received Tdap. Healthcare personnel who work in hospitals or ambulatory care settings and have direct patient contact and who have not received Tdap. Adults in contact with infants younger than age 12m (e.g., parents, grandparents younger than age 65yrs, childcare providers, healthcare personnel) who have not received a dose of Tdap should be prioritized for vaccination. 	<ul style="list-style-type: none"> For persons who are unvaccinated or behind, complete the primary series with Td (spaced at 0, 1–2m, 6–12m intervals). One dose of Tdap may be used for any dose if ages 19–64yrs. Give Td booster every 10yrs after the primary series has been completed. For adults ages 19–64yrs, a 1-time dose of Tdap is recommended to replace the next Td. Intervals of 2yrs or less between Td and Tdap may be used if needed. <p>Note: The two Tdap products are licensed for different age groups: Adacel™ (sanofi) for use in persons ages 11–64yrs and Boostrix® (GSK) for use in persons ages 10–18yrs.</p>	<p>Contraindications</p> <ul style="list-style-type: none"> Previous anaphylactic reaction to this vaccine or to any of its components. For Tdap only, history of encephalopathy within 7 days following DTP/DTaP. <p>Precautions</p> <ul style="list-style-type: none"> Moderate or severe acute illness. GBS within 6wks of receiving a previous dose of tetanus-toxoid-containing vaccine. Unstable neurologic condition. History of arthus reaction following a previous dose of tetanus- and/or diphtheria-toxoid-containing vaccine, including MCV4. <p>Note: Use of Td/Tdap is not contraindicated in pregnancy. Either vaccine may be given during trimester #2 or #3 at the provider's discretion.</p>
<p>Polio (IPV) <i>Give IM or SC</i></p>	<p>Not routinely recommended for persons age 18yrs and older.</p> <p>Note: Adults living in the U.S. who never received or completed a primary series of polio vaccine need not be vaccinated unless they intend to travel to areas where exposure to wild-type virus is likely (i.e., India, Pakistan, Afghanistan, and certain countries in Africa). Previously vaccinated adults can receive one booster dose if traveling to polio endemic areas.</p>	<ul style="list-style-type: none"> Refer to ACIP recommendations* regarding unique situations, schedules, and dosing information. 	<p>Contraindication Previous anaphylactic or neurologic reaction to this vaccine or to any of its components.</p> <p>Precautions • Moderate or severe acute illness. • Pregnancy.</p>

Summary of Recommendations for Adult Immunization (continued)

Vaccine name and route	For whom vaccination is recommended	Schedule for vaccine administration (any vaccine can be given with another)	Contraindications and precautions (mild illness is not a contraindication)
<p>Varicella (Var) (Chickenpox) <i>Give SC</i></p>	<ul style="list-style-type: none"> All adults without evidence of immunity. <p>Note: Evidence of immunity is defined as a history of two doses of varicella vaccine; born in the U.S. before 1980 (exception: healthcare personnel and pregnant women); a history of varicella disease or herpes zoster based on healthcare provider diagnosis; laboratory evidence of immunity; and/or laboratory confirmation of disease.</p>	<ul style="list-style-type: none"> Two doses are needed. Dose #2 is given 4–8wks after dose #1. If Var and either MMR, LAIV, and/or yellow fever vaccine are not given on the same day, space them at least 28d apart. If the second dose is delayed, do not repeat dose #1. Just give dose #2. 	<p>Contraindications</p> <ul style="list-style-type: none"> Previous anaphylactic reaction to this vaccine or to any of its components. Pregnancy or possibility of pregnancy within 4wks. Persons immunocompromised because of malignancy and primary or acquired cellular immunodeficiency including HIV/AIDS. (See <i>MMWR</i> 1999, Vol. 48, No. RR-6.) Note: For those on high-dose immunosuppressive therapy, consult ACIP recommendations regarding delay time.* <p>Precautions</p> <ul style="list-style-type: none"> If blood, plasma, and/or immune globulin (IG or VZIG) were given in past 11m, see ACIP statement <i>General Recommendations on Immunization*</i> regarding time to wait before vaccinating. Moderate or severe acute illness.
<p>Meningococcal Conjugate vaccine (MCV4) <i>Give IM</i> Polysaccharide vaccine (MPSV4) <i>Give SC</i></p>	<ul style="list-style-type: none"> College freshmen living in dormitories. Persons with anatomic or functional asplenia or with terminal complement component deficiencies. Persons who travel to or reside in countries in which meningococcal disease is hyperendemic or epidemic (e.g., the “meningitis belt” of Sub-Saharan Africa). Microbiologists routinely exposed to isolates of <i>N. meningitidis</i>. 	<ul style="list-style-type: none"> One dose is needed. If previous vaccine was MPSV4, re-vaccinate after 5yrs if risk continues. Revaccination after MCV4 is not recommended. MCV4 is preferred over MPSV4 for persons age 55yrs and younger, although MPSV4 is an acceptable alternative. 	<p>Contraindication</p> <p>Previous anaphylactic or neurologic reaction to this vaccine or to any of its components, including diphtheria toxoid (for MCV4).</p> <p>Precautions</p> <ul style="list-style-type: none"> Moderate or severe acute illness. For MCV4 only, history of GBS.
<p>MMR (Measles, mumps, rubella) <i>Give SC</i></p>	<ul style="list-style-type: none"> Persons born in 1957 or later (especially those born outside the U.S.) should receive at least one dose of MMR if there is no serologic proof of immunity or documentation of a dose given on or after the first birthday. Persons in high-risk groups, such as healthcare personnel, students entering college and other post-high school educational institutions, and international travelers, should receive a total of two doses. Persons born before 1957 are usually considered immune, but proof of immunity (serology or vaccination) may be desirable for healthcare personnel. Women of childbearing age who do not have acceptable evidence of rubella immunity or vaccination. 	<ul style="list-style-type: none"> One or two doses are needed. If dose #2 is recommended, give it no sooner than 4wks after dose #1. If MMR and either Var, LAIV, and/or yellow fever vaccine are not given on the same day, space them at least 28d apart. If a pregnant woman is found to be rubella susceptible, administer MMR postpartum. 	<p>Contraindications</p> <ul style="list-style-type: none"> Previous anaphylactic reaction to this vaccine or to any of its components. Pregnancy or possibility of pregnancy within 4wks. Persons immunocompromised because of cancer, leukemia, lymphoma, immunosuppressive drug therapy, including high-dose steroids or radiation therapy. Note: HIV positivity is NOT a contraindication to MMR except for those who are severely immunocompromised. <p>Precautions</p> <ul style="list-style-type: none"> If blood, plasma, and/or immune globulin were given in past 11m, see ACIP statement <i>General Recommendations on Immunization*</i> regarding time to wait before vaccinating. Moderate or severe acute illness. History of thrombocytopenia or thrombocytopenic purpura. <p>Note: If PPD (tuberculosis skin test) and MMR are both needed but not given on same day, delay PPD for 4–6wks after MMR.</p>
<p>Human-papillomavirus (HPV) <i>Give IM</i></p>	<ul style="list-style-type: none"> All previously unvaccinated women through age 26yrs. 	<ul style="list-style-type: none"> Three doses are needed on a 0, 2, 6m schedule. The minimum interval between doses #1 and #2 is 4wks, and between #2 and #3 is 12wks. 	<p>Contraindication</p> <p>Previous anaphylactic reaction to this vaccine or to any of its components.</p> <p>Precaution</p> <p>Data on vaccination in pregnancy are limited. Vaccination should be delayed until after completion of the pregnancy.</p>
<p>Zoster (shingles) (Zos) <i>Give SC</i></p>	<p>ACIP has voted to recommend herpes zoster (shingles) vaccine for all persons age 60yrs and older who do not have contraindications. Provisional recommendations are online at www.cdc.gov/nip/recs/provisional_rec.</p>		

Recommended Immunization Schedule for Persons Aged 7–18 Years—UNITED STATES • 2007

Vaccine ▼	Age ▶	7–10 years	11–12 YEARS	13–14 years	15 years	16–18 years
Tetanus, Diphtheria, Pertussis ¹	see footnote 1		Tdap		Tdap	
Human Papillomavirus ²	see footnote 2		HPV (3 doses)		HPV Series	
Meningococcal ³		MPSV4	MCV4		MCV4 ⁴	MCV4
Pneumococcal ⁴			PPV			
Influenza ⁵			Influenza (Yearly)			
Hepatitis A ⁶			HepA Series			
Hepatitis B ⁷			HepB Series			
Inactivated Poliovirus ⁸			IPV Series			
Measles, Mumps, Rubella ⁹			MMR Series			
Varicella ¹⁰			Varicella Series			

 Range of recommended ages

 Catch-up immunization

 Certain high-risk groups

This schedule indicates the recommended ages for routine administration of currently licensed childhood vaccines, as of December 1, 2006, for children aged 7–18 years. Additional information is available at <http://www.cdc.gov/nip/recs/child-schedule.htm>. Any dose not administered at the recommended age should be administered at any subsequent visit, when indicated and feasible. Additional vaccines may be licensed and recommended during the year. Licensed combination vaccines may be used whenever any components of the combination are indicated and other components

of the vaccine are not contraindicated and if approved by the Food and Drug Administration for that dose of the series. Providers should consult the respective Advisory Committee on Immunization Practices statement for detailed recommendations. Clinically significant adverse events that follow immunization should be reported to the Vaccine Adverse Event Reporting System (VAERS). Guidance about how to obtain and complete a VAERS form is available at <http://www.vaers.hhs.gov> or by telephone, 800-822-7967.

1. Tetanus and diphtheria toxoids and acellular pertussis vaccine (Tdap).

(Minimum age: 10 years for BOOSTRIX[®] and 11 years for ADACEL[™])

- Administer at age 11–12 years for those who have completed the recommended childhood DTP/DTaP vaccination series and have not received a tetanus and diphtheria toxoids vaccine (Td) booster dose.
- Adolescents aged 13–18 years who missed the 11–12 year Td/Tdap booster dose should also receive a single dose of Tdap if they have completed the recommended childhood DTP/DTaP vaccination series.

2. Human papillomavirus vaccine (HPV). (Minimum age: 9 years)

- Administer the first dose of the HPV vaccine series to females at age 11–12 years.
- Administer the second dose 2 months after the first dose and the third dose 6 months after the first dose.
- Administer the HPV vaccine series to females at age 13–18 years if not previously vaccinated.

3. Meningococcal vaccine. (Minimum age: 11 years for meningococcal conjugate vaccine [MCV4]; 2 years for meningococcal polysaccharide vaccine [MPSV4])

- Administer MCV4 at age 11–12 years and to previously unvaccinated adolescents at high school entry (at approximately age 15 years).
- Administer MCV4 to previously unvaccinated college freshmen living in dormitories; MPSV4 is an acceptable alternative.
- Vaccination against invasive meningococcal disease is recommended for children and adolescents aged ≥ 2 years with terminal complement deficiencies or anatomic or functional asplenia and certain other high-risk groups. See *MMWR* 2005;54(No. RR-7):1–21. Use MPSV4 for children aged 2–10 years and MCV4 or MPSV4 for older children.

4. Pneumococcal polysaccharide vaccine (PPV). (Minimum age: 2 years)

- Administer for certain high-risk groups. See *MMWR* 1997;46(No. RR-8):1–24, and *MMWR* 2000;49(No. RR-9):1–35.

5. Influenza vaccine. (Minimum age: 6 months for trivalent inactivated influenza vaccine [TIV]; 5 years for live, attenuated influenza vaccine [LAIV])

- Influenza vaccine is recommended annually for persons with certain risk factors, health-care workers, and other persons (including household members) in close contact with persons in groups at high risk. See *MMWR* 2006;55(No. RR-10):1–41.
- For healthy persons aged 5–49 years, LAIV may be used as an alternative to TIV.
- Children aged < 9 years who are receiving influenza vaccine for the first time should receive 2 doses (separated by ≥ 4 weeks for TIV and ≥ 6 weeks for LAIV).

6. Hepatitis A vaccine (HepA). (Minimum age: 12 months)

- The 2 doses in the series should be administered at least 6 months apart.
- HepA is recommended for certain other groups of children, including in areas where vaccination programs target older children. See *MMWR* 2006;55(No. RR-7):1–23.

7. Hepatitis B vaccine (HepB). (Minimum age: birth)

- Administer the 3-dose series to those who were not previously vaccinated.
- A 2-dose series of Recombivax HB[®] is licensed for children aged 11–15 years.

8. Inactivated poliovirus vaccine (IPV). (Minimum age: 6 weeks)

- For children who received an all-IPV or all-oral poliovirus (OPV) series, a fourth dose is not necessary if the third dose was administered at age ≥ 4 years.
- If both OPV and IPV were administered as part of a series, a total of 4 doses should be administered, regardless of the child's current age.

9. Measles, mumps, and rubella vaccine (MMR). (Minimum age: 12 months)

- If not previously vaccinated, administer 2 doses of MMR during any visit, with ≥ 4 weeks between the doses.

10. Varicella vaccine. (Minimum age: 12 months)

- Administer 2 doses of varicella vaccine to persons without evidence of immunity.
- Administer 2 doses of varicella vaccine to persons aged < 13 years at least 3 months apart. Do not repeat the second dose, if administered ≥ 28 days after the first dose.
- Administer 2 doses of varicella vaccine to persons aged ≥ 13 years at least 4 weeks apart.

The Recommended Immunization Schedules for Persons Aged 0–18 Years are approved by the Advisory Committee on Immunization Practices (<http://www.cdc.gov/nip/acip>), the American Academy of Pediatrics (<http://www.aap.org>), and the American Academy of Family Physicians (<http://www.aafp.org>).

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Catch-up Immunization Schedule

UNITED STATES • 2007

for Persons Aged 4 Months–18 Years Who Start Late or Who Are More Than 1 Month Behind

The table below provides catch-up schedules and minimum intervals between doses for children whose vaccinations have been delayed. A vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Use the section appropriate for the child's age.

CATCH-UP SCHEDULE FOR PERSONS AGED 4 MONTHS–6 YEARS					
Vaccine	Minimum Age for Dose 1	Minimum Interval Between Doses			
		Dose 1 to Dose 2	Dose 2 to Dose 3	Dose 3 to Dose 4	Dose 4 to Dose 5
Hepatitis B ¹	Birth	4 weeks	8 weeks (and 16 weeks after first dose)		
Rotavirus ²	6 wks	4 weeks	4 weeks		
Diphtheria, Tetanus, Pertussis ³	6 wks	4 weeks	4 weeks	6 months	6 months ³
<i>Haemophilus influenzae</i> type b ⁴	6 wks	4 weeks if first dose administered at age <12 months 8 weeks (as final dose) if first dose administered at age 12–14 months No further doses needed if first dose administered at age ≥15 months	4 weeks ⁴ if current age <12 months 8 weeks (as final dose) ⁴ if current age ≥12 months and second dose administered at age <15 months No further doses needed if previous dose administered at age ≥15 months	8 weeks (as final dose) This dose only necessary for children aged 12 months–5 years who received 3 doses before age 12 months	
Pneumococcal ⁵	6 wks	4 weeks if first dose administered at age <12 months and current age <24 months 8 weeks (as final dose) if first dose administered at age ≥12 months or current age 24–59 months No further doses needed for healthy children if first dose administered at age ≥24 months	4 weeks if current age <12 months 8 weeks (as final dose) if current age ≥12 months No further doses needed for healthy children if previous dose administered at age ≥24 months	8 weeks (as final dose) This dose only necessary for children aged 12 months–5 years who received 3 doses before age 12 months	
Inactivated Poliovirus ⁶	6 wks	4 weeks	4 weeks	4 weeks ⁶	
Measles, Mumps, Rubella ⁷	12 mos	4 weeks			
Varicella ⁸	12 mos	3 months			
Hepatitis A ⁹	12 mos	6 months			
CATCH-UP SCHEDULE FOR PERSONS AGED 7–18 YEARS					
Tetanus, Diphtheria/ Tetanus, Diphtheria, Pertussis ¹⁰	7 yrs ¹⁰	4 weeks	8 weeks if first dose administered at age <12 months 6 months if first dose administered at age ≥12 months	6 months if first dose administered at age <12 months	
Human Papillomavirus ¹¹	9 yrs	4 weeks	12 weeks		
Hepatitis A ⁹	12 mos	6 months			
Hepatitis B ¹	Birth	4 weeks	8 weeks (and 16 weeks after first dose)		
Inactivated Poliovirus ⁶	6 wks	4 weeks	4 weeks	4 weeks ⁶	
Measles, Mumps, Rubella ⁷	12 mos	4 weeks			
Varicella ⁸	12 mos	4 weeks if first dose administered at age ≥13 years 3 months if first dose administered at age <13 years			

- Hepatitis B vaccine (HepB).** (Minimum age: birth)
 - Administer the 3-dose series to those who were not previously vaccinated.
 - A 2-dose series of Recombivax HB[®] is licensed for children aged 11–15 years.
- Rotavirus vaccine (Rota).** (Minimum age: 6 weeks)
 - Do not start the series later than age 12 weeks.
 - Administer the final dose in the series by age 32 weeks. Do not administer a dose later than age 32 weeks.
 - Data on safety and efficacy outside of these age ranges are insufficient.
- Diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP).** (Minimum age: 6 weeks)
 - The fifth dose is not necessary if the fourth dose was administered at age ≥4 years.
 - DTaP is not indicated for persons aged ≥7 years.
- Haemophilus influenzae* type b conjugate vaccine (Hib).** (Minimum age: 6 weeks)
 - Vaccine is not generally recommended for children aged ≥5 years.
 - If current age <12 months and the first 2 doses were PRP-OMP (PedvaxHIB[®] or ComVax[®] [Merck]), the third (and final) dose should be administered at age 12–15 months and at least 8 weeks after the second dose.
 - If first dose was administered at age 7–11 months, administer 2 doses separated by 4 weeks plus a booster at age 12–15 months.
- Pneumococcal conjugate vaccine (PCV).** (Minimum age: 6 weeks)
 - Vaccine is not generally recommended for children aged ≥5 years.
- Inactivated poliovirus vaccine (IPV).** (Minimum age: 6 weeks)
 - For children who received an all-IPV or all-oral poliovirus (OPV) series, a fourth dose is not necessary if third dose was administered at age ≥4 years.
 - If both OPV and IPV were administered as part of a series, a total of 4 doses should be administered, regardless of the child's current age.
- Measles, mumps, and rubella vaccine (MMR).** (Minimum age: 12 months)
 - The second dose of MMR is recommended routinely at age 4–6 years but may be administered earlier if desired.
 - If not previously vaccinated, administer 2 doses of MMR during any visit with ≥4 weeks between the doses.
- Varicella vaccine.** (Minimum age: 12 months)
 - The second dose of varicella vaccine is recommended routinely at age 4–6 years but may be administered earlier if desired.
 - Do not repeat the second dose in persons aged <13 years if administered ≥28 days after the first dose.
- Hepatitis A vaccine (HepA).** (Minimum age: 12 months)
 - HepA is recommended for certain groups of children, including in areas where vaccination programs target older children. See *MMWR* 2006;55(No. RR-7):1–23.
- Tetanus and diphtheria toxoids vaccine (Td) and tetanus and diphtheria toxoids and acellular pertussis vaccine (Tdap).** (Minimum ages: 7 years for Td, 10 years for BOOSTRIX[®], and 11 years for ADACEL[™])
 - Tdap should be substituted for a single dose of Td in the primary catch-up series or as a booster if age appropriate; use Td for other doses.
 - A 5-year interval from the last Td dose is encouraged when Tdap is used as a booster dose. A booster (fourth) dose is needed if any of the previous doses were administered at age <12 months. Refer to ACIP recommendations for further information. See *MMWR* 2006;55(No. RR-3).
- Human papillomavirus vaccine (HPV).** (Minimum age: 9 years)
 - Administer the HPV vaccine series to females at age 13–18 years if not previously vaccinated.

Information about reporting reactions after immunization is available online at <http://www.vaers.hhs.gov> or by telephone via the 24-hour national toll-free information line 800-822-7967. Suspected cases of vaccine-preventable diseases should be reported to the state or local health department. Additional information, including precautions and contraindications for immunization, is available from the National Center for Immunization and Respiratory Diseases at <http://www.cdc.gov/nip/default.htm> or telephone, 800-CDC-INFO (800-232-4636).

Summary of Recommendations for Childhood and Adolescent Immunization

Adapted from the recommendations of the Advisory Committee on Immunization Practices (ACIP)* by the Immunization Action Coalition, November 2006

Vaccine name and route	Schedule for routine vaccination and other guidelines (any vaccine can be given with another)	Schedule for catch-up vaccination and other related issues	Contraindications and precautions (mild illness is not a contraindication)
Hepatitis B <i>Give IM</i>	<ul style="list-style-type: none"> Vaccinate all children ages 0 through 18yrs. Vaccinate all newborns with monovalent vaccine prior to hospital discharge. Give dose #2 at 1–2m and the final dose at 6–18m (the last dose in the infant series should not be given earlier than age 24wks). After the birth dose, the series may be completed using 2 doses of single-antigen vaccine or up to 3 doses of Comvax (ages 2m, 4m, 12–15m) or Pediarix (ages 2m, 4m, 6m), which may result in giving a total of 4 doses of hepatitis B vaccine. If mother is HBsAg-positive: give the newborn HBIG + dose #1 within 12hrs of birth; complete series at age 6m or, if using Comvax, at 12–15m. If mother's HBsAg status is unknown: give the newborn dose #1 within 12hrs of birth. If mother is subsequently found to be HBsAg positive, give infant HBIG within 7d of birth and follow the schedule for infants born to HBsAg-positive mothers. 	<ul style="list-style-type: none"> Do not restart series, no matter how long since previous dose. 3-dose series can be started at any age. Minimum spacing between doses: 4wks between #1 and #2, 8wks between #2 and #3, and at least 16wks between #1 and #3 (e.g., 0-, 2-, 4m; 0-, 1-, 4m). <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <p>Special Notes on Hepatitis B Vaccine (HepB) Dosing of HepB: Vaccine brands are interchangeable. For persons ages 0 through 19yrs, give 0.5 mL of either Engerix-B or Recombivax HB. Alternative dosing schedule for unvaccinated adolescents ages 11 through 15yrs: Give 2 doses Recombivax HB 1.0mL (adult formulation) spaced 4–6m apart. (Engerix-B is not licensed for a 2-dose schedule.) For preterm infants: Consult ACIP hepatitis B recommendations (<i>MMWR</i> 2005; 54 [RR-16]).</p> </div>	<p>Contraindication: Previous anaphylaxis to this vaccine or to any of its components.</p> <p>Precaution Moderate or severe acute illness.</p>
DTaP, DT (Diphtheria, tetanus, acellular pertussis) <i>Give IM</i>	<ul style="list-style-type: none"> Give to children at ages 2m, 4m, 6m, 15–18m, 4–6yrs. May give dose #1 as early as age 6wks. May give #4 as early as age 12m if 6m have elapsed since #3 and the child is unlikely to return at age 15–18m. Do not give DTaP/DT to children age 7yrs and older. If possible, use the same DTaP product for all doses. 	<ul style="list-style-type: none"> #2 and #3 may be given 4wks after previous dose. #4 may be given 6m after #3. If #4 is given before 4th birthday, wait at least 6m for #5 (age 4–6yrs). If #4 is given after 4th birthday, #5 is not needed. 	<p>Contraindications</p> <ul style="list-style-type: none"> Previous anaphylaxis to this vaccine or to any of its components. For DTaP/Tdap only: encephalopathy within 7d after DTP/DTaP. <p>Precautions</p> <ul style="list-style-type: none"> Moderate or severe acute illness. Guillain-Barré syndrome within 6wks after previous dose of tetanus toxoid-containing vaccine.
Td, Tdap (Tetanus, diphtheria, acellular pertussis) <i>Give IM</i>	<ul style="list-style-type: none"> Give Tdap booster dose to adolescents age 11–12yrs if 5yrs have elapsed since last dose DTaP/DTP; boost every 10yrs with Td. Give 1-time Tdap to all adolescents who have not received previous Tdap. Special efforts should be made to give Tdap to persons age 11yrs and older who are <ul style="list-style-type: none"> in contact with infants younger than age 12m. healthcare workers with direct patient contact. In pregnancy, when indicated, give Td or Tdap in 2nd or 3rd trimester. If not administered during pregnancy, give Tdap in immediate postpartum period. 	<ul style="list-style-type: none"> If never vaccinated with tetanus- and diphtheria-containing vaccine: give Td dose #1 now, dose #2 4wks later, and dose #3 6m after #2, then give booster every 10yrs. A 1-time Tdap may be substituted for any dose in the series. Intervals of 2yrs or less between Td and Tdap may be used if needed. 	<ul style="list-style-type: none"> For DTaP only: Any of these occurrences following a previous dose of DTP/DTaP: 1) temperature of 105°F (40.5°C) or higher within 48hrs; 2) continuous crying for 3hrs or more within 48hrs; 3) collapse or shock-like state within 48hrs; 4) convulsion with or without fever within 3d. For DTaP/Tdap only: Unstable neurologic disorder. <p>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.</p>
Polio (IPV) <i>Give SC or IM</i>	<ul style="list-style-type: none"> Give to children at ages 2m, 4m, 6–18m, 4–6yrs. May give #1 as early as age 6wks. Not routinely recommended for those age 18yrs and older (except certain travelers). 	<ul style="list-style-type: none"> All doses should be separated by at least 4wks. If dose #3 is given after 4th birthday, dose #4 is not needed. 	<p>Contraindication Previous anaphylaxis to this vaccine or to any of its components.</p> <p>Precautions</p> <ul style="list-style-type: none"> Moderate or severe acute illness. Pregnancy.
Human Papillomavirus (HPV) <i>Give IM</i>	<ul style="list-style-type: none"> Give 3-dose series to girls at age 11–12yrs on a 0, 2, 6m schedule. May be given as early as age 9yrs. Vaccinate all older females (through age 26yrs) not previously vaccinated. 	<ul style="list-style-type: none"> Dose #2 may be given 4wks after dose #1. Dose #3 may be given 12wks after dose #2. 	<p>Contraindication Previous anaphylaxis to this vaccine or to any of its components.</p> <p>Precautions</p> <ul style="list-style-type: none"> Moderate or severe acute illness. Pregnancy.

*For specific ACIP recommendations, refer to the official ACIP statements published in *MMWR*. To obtain copies of these statements, call the CDC-INFO Contact Center at (800) 232-4636; visit CDC's website at www.cdc.gov/nip/publications/ACIP-list.htm; or visit the Immunization Action Coalition (IAC) website at www.immunize.org/acip.

This table is revised periodically. Visit IAC's website at www.immunize.org/childrules to make sure you have the most current version. IAC thanks William Atkinson, MD, MPH, from CDC's National Center for Immunization and Respiratory Diseases for his assistance. For more information, contact IAC at 1573 Selby Avenue, St. Paul, MN 55104, (651) 647-9009, or email admin@immunize.org.

Summary of Recommendations for Childhood and Adolescent Immunization

Vaccine name and route	Schedule for routine vaccination and other guidelines (any vaccine can be given with another)	Schedule for catch-up vaccine administration and other related issues	Contraindications and precautions (mild illness is not a contraindication)
Varicella (Var) (Chickenpox) <i>Give SC</i>	<ul style="list-style-type: none"> • Give dose #1 at age 12–15m. • Give dose #2 at age 4–6yrs. Dose #2 may be given earlier if at least 3m since dose #1. • Give a routine second dose to all older children and adolescents with history of only 1 dose. • MMRV may be used in children 12m through 12yrs. 	<ul style="list-style-type: none"> • If younger than age 13yrs, space dose #1 and #2 at least 3m apart. If age 13yrs or older, space 4–8wks apart. • May use as postexposure prophylaxis if given within 3–5d. • If Var and either MMR, LAIV, and/or yellow fever vaccine are not given on the same day, space them at least 28d apart. 	<p>Contraindications</p> <ul style="list-style-type: none"> • Previous anaphylaxis to this vaccine or to any of its components. • Pregnancy or possibility of pregnancy within 4wks. • Children immunocompromised because of high doses of systemic steroids, cancer, leukemia, lymphoma, or immunodeficiency. Note: For patients with humoral immunodeficiency, HIV infection, or leukemia, or for patients on high doses of systemic steroids, see ACIP recommendations*. <p>Precautions</p> <ul style="list-style-type: none"> • Moderate or severe acute illness. • If blood, plasma, and/or immune globulin (IG or VZIG) were given in past 11m, see ACIP statement <i>General Recommendations on Immunization*</i> regarding time to wait before vaccinating.
MMR (Measles, mumps, rubella) <i>Give SC</i>	<ul style="list-style-type: none"> • Give dose #1 at age 12–15m. • Give dose #2 at age 4–6yrs. Dose #2 may be given earlier if at least 4wks since dose #1. • If a dose was given before age 12m, it doesn't count as the first dose, so give #1 at age 12–15m with a minimum interval of 4wks between the invalid dose and dose #1. • MMRV may be used in children 12m through 12yrs. 	<ul style="list-style-type: none"> • If MMR and either Var, LAIV, and/or yellow fever vaccine are not given on the same day, space them at least 28d apart. • When using MMR (not MMRV) for both doses, minimum interval is 4wks. 	<p>Contraindications</p> <ul style="list-style-type: none"> • Previous anaphylaxis to this vaccine or to any of its components. • Pregnancy or possibility of pregnancy within 4wks. • Severe immunodeficiency (e.g., hematologic and solid tumors; congenital immunodeficiency; long-term immunosuppressive therapy, or severely symptomatic HIV). <p>Precautions</p> <ul style="list-style-type: none"> • Moderate or severe acute illness. • If blood, plasma, or immune globulin given in past 11m or if on high-dose immunosuppressive therapy, see ACIP statement <i>General Recommendations on Immunization*</i> regarding delay time. • History of thrombocytopenia or thrombocytopenic purpura. <p>Note: MMR is not contraindicated if a PPD (tuberculosis skin test) was recently applied. If PPD and MMR not given on same day, delay PPD for 4–6wks after MMR.</p>
Influenza Trivalent inactivated influenza vaccine (TIV) <i>Give IM</i> Live attenuated influenza vaccine (LAIV) <i>Give intranasally</i>	<ul style="list-style-type: none"> • On an annual basis, vaccinate all children ages 6–59m, as well as all siblings and household contacts of children ages 0–59m. • Vaccinate persons 5yrs and older who <ul style="list-style-type: none"> - have a risk factor (e.g., pregnancy, heart disease, lung disease, diabetes, renal dysfunction, hemoglobinopathy, immunosuppression, on long-term aspirin therapy, or have a condition that compromises respiratory function or the handling of respiratory secretions or that can increase the risk of aspiration) or live in a chronic-care facility. - live or work with at-risk people as listed above. • Vaccinate any person wishing to reduce the likelihood of becoming ill with influenza. • LAIV may be given to healthy, non-pregnant persons ages 5–49yrs. • Give 2 doses to first-time vaccinees ages 6m through 8yrs. For TIV, space 4wks apart; for LAIV, space 6wks apart (no younger than age 5yrs). • For TIV, give 0.25 mL dose to children ages 6–35m and 0.5 mL dose if age 3yrs and older. 		<p>Contraindications</p> <ul style="list-style-type: none"> • Previous anaphylaxis to this vaccine, to any of its components, or to eggs. • For LAIV only: Pregnancy, asthma, reactive airway disease, or other chronic disorder of the pulmonary or cardiovascular systems; an underlying medical condition, including metabolic diseases such as diabetes, renal dysfunction, and hemoglobinopathies; a known or suspected immune deficiency disease or receiving immunosuppressive therapy; history of Guillain-Barré syndrome. <p>Precautions</p> <ul style="list-style-type: none"> • Moderate or severe acute illness. • For TIV only: History of Guillain-Barré syndrome within 6wks of previous TIV.
Rotavirus (Rota) <i>Give orally</i>	<ul style="list-style-type: none"> • Give a 3-dose series at ages 2m, 4m, 6m. • May give dose #1 as early as age 6wks. • Give dose #3 no later than age 32wks. 	<ul style="list-style-type: none"> • Do not begin series in infants older than age 12wks. • Dose #2 and #3 may be given 4wks after previous dose. 	<p>Contraindication</p> <p>Previous anaphylaxis to this vaccine or to any of its components.</p> <p>Precautions</p> <ul style="list-style-type: none"> • Moderate or severe acute illness. • Altered immunocompetence. • Moderate to severe acute gastroenteritis or chronic gastrointestinal disease. • History of intussusception.

Summary of Recommendations for Childhood and Adolescent Immunization

Vaccine name and route	Schedule for routine vaccination and other guidelines (any vaccine can be given with another)	Schedule for catch-up vaccination and other related issues	Contraindications and precautions (mild illness is not a contraindication)
<p>Hib (<i>Haemophilus influenzae</i> type b) Give IM</p>	<ul style="list-style-type: none"> HibTITER (HbOC) and ActHib (PRP-T): give at 2m, 4m, 6m, 12–15m (booster dose). PedvaxHIB or Comvax (containing PRP-OMP): give at 2m, 4m, 12–15m. Dose #1 of Hib vaccine may be given no earlier than age 6wks. The last dose (booster dose) is given no earlier than age 12m and a minimum of 8wks after the previous dose. Hib vaccines are interchangeable; however, if different brands of Hib vaccines are administered, a total of three doses are necessary to complete the primary series in infants. Any Hib vaccine may be used for the booster dose. Hib is not routinely given to children age 5yrs and older. 	<p>All Hib vaccines:</p> <ul style="list-style-type: none"> If #1 was given at 12–14m, give booster in 8wks. Give only 1 dose to unvaccinated children from age 15m to 5yrs. <p>HibTITER and ActHib:</p> <ul style="list-style-type: none"> #2 and #3 may be given 4 wks after previous dose. If #1 was given at 7–11m, only 3 doses are needed; #2 is given 4–8wks after #1, then boost at 12–15m (wait at least 8wks after dose #2). <p>PedvaxHIB and Comvax:</p> <ul style="list-style-type: none"> #2 may be given 4wks after dose #1. 	<p>Contraindication Previous anaphylaxis to this vaccine or to any of its components.</p> <p>Precaution Moderate or severe acute illness.</p>
<p>Pneumo. conjugate (PCV) Give IM</p>	<ul style="list-style-type: none"> Give at ages 2m, 4m, 6m, 12–15m. Dose #1 may be given as early as age 6wks. Give 1 dose to unvaccinated healthy children ages 24–59m. Give 2 doses at least 8wks apart to unvaccinated high-risk** children ages 24–59m. PCV is not routinely given to children age 5yrs and older. <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <p>**High-risk: Those with sickle cell disease; anatomic/functional asplenia; chronic cardiac, pulmonary, or renal disease; diabetes; cerebrospinal fluid leaks; HIV infection; immunosuppression; or who have or will have a cochlear implant.</p> </div>	<ul style="list-style-type: none"> For ages 7–11m: If history of 0–2 doses, give additional doses 4wks apart with no more than 3 total doses by age 12m; then give booster 8wks later. For ages 12–23m: If 0–1 dose before age 12m, give 2 doses at least 8wks apart. If 2–3 doses before age 12m, give 1 dose at least 8wks after previous dose. For ages 24–59m: If patient has had no previous doses, or has a history of 1–3 doses given before age 12m but no booster dose, or has a history of only 1 dose given at 12–23m, give 1 dose now. 	<p>Contraindication Previous anaphylaxis to this vaccine or to any of its components.</p> <p>Precaution Moderate or severe acute illness.</p>
<p>Pneumo. polysacch. (PPV) Give IM or SC</p>	<ul style="list-style-type: none"> Give 1 dose at least 8wks after final dose of PCV to high-risk children age 2yrs and older. For children who are immunocompromised or have sickle cell disease or functional or anatomic asplenia, give a 2nd dose of PPV 3–5yrs after previous PPV (consult ACIP PPV recommendations [MMWR 1997;46 [RR-8] for details*). 		<p>Contraindication Previous anaphylaxis to this vaccine or to any of its components.</p> <p>Precaution Moderate or severe acute illness.</p>
<p>Hepatitis A Give IM</p>	<ul style="list-style-type: none"> Give 2 doses to all children at age 1yr (12–23m) spaced 6m apart. Vaccinate all children and adolescents age 2 years and older who <ul style="list-style-type: none"> Live in a state, county, or community with a routine vaccination program already in place for children ages 2yrs and older. Travel anywhere except U.S., W. Europe, N. Zealand, Australia, Canada, or Japan. Wish to be protected from HAV infection. Have chronic liver disease, clotting factor disorder, or are MSM adolescents. 	<ul style="list-style-type: none"> Minimum interval between doses is 6m. Consider routine vaccination of children ages 2yrs and older in areas with no existing program. 	<p>Contraindication Previous anaphylaxis to this vaccine or to any of its components.</p> <p>Precaution Moderate or severe acute illness.</p>
<p>Meningococcal conjugate (MCV4) Give IM</p> <p>polysaccharide (MPSV4) Give SC</p>	<ul style="list-style-type: none"> Give 1-time dose of MCV4 to adolescents ages 11–12yrs, to adolescents at high school entry (approximately age 15yrs), and to college freshmen living in dormitories. Vaccinate all children age 2yrs and older who have any of the following risk factors (use MPSV4 if age younger than 11yrs and MCV4 if age 11yrs and older): <ul style="list-style-type: none"> Anatomic or functional asplenia, or terminal complement component deficiencies. Travel to, or reside in countries in which meningococcal disease is hyperendemic or epidemic (e.g., the “meningitis belt” of Sub-Saharan Africa). <p>Note: Other adolescents who wish to decrease their risk of meningococcal disease may be vaccinated with MCV4.</p>	<p>If previously vaccinated with MPSV4 and risk continues, give MCV4 5yrs after MPSV4.</p>	<p>Contraindication Previous anaphylaxis to this vaccine or to any of its components, including diphtheria toxoid (for MCV4).</p> <p>Precaution Moderate or severe acute illness.</p> <p>Note: MCV4 is not licensed for use in children younger than age 11 yrs.</p>

Attachment 3

*Proposed Legislation to Authorize the
Licensing of Mobile Locations by the
Board of Pharmacy for Emergencies*

4062. (a) Notwithstanding Section 4059 or any other provision of law, a pharmacist may, in good faith, furnish a dangerous drug or dangerous device in reasonable quantities without a prescription during a federal, state, or local emergency, to further the health and safety of the public. A record containing the date, name, and address of the person to whom the drug or device is furnished, and the name, strength, and quantity of the drug or device furnished shall be maintained. The pharmacist shall communicate this information to the patient's attending physician as soon as possible. Notwithstanding Section 4060 or any other provision of law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

(b) During a declared federal, state, or local emergency, the board may waive application of any provisions of this chapter or the regulations adopted pursuant to it if, in the board's opinion, the waiver will aid in the protection of public health or the provision of patient care.

(c) During a declared federal, state, or local emergency the board will allow for the deployment of a mobile pharmacy to impacted areas to ensure the continuity of patient care if all of the following conditions are met:

(1) The mobile pharmacy shares common ownership with at least one currently licensed pharmacy in good standing.

(2) The mobile pharmacy retains records of dispensing as required in subdivision (a);

(3) A licensed pharmacist is on the premises, and the mobile pharmacy is under the control and management of a pharmacist while the drugs are being dispensed;

(4) Reasonable security measures are taken to safeguard the drug supply maintained in the mobile pharmacy.

(5) The mobile pharmacy is located within the declared disaster area or affected areas; and

(6) The mobile pharmacy ceases the provision of services within forty-eight (48) hours following the termination of the declared emergency.

4110. (a) No person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the board. A license shall be required for each pharmacy owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a pharmacy in more than one location. The license shall be renewed annually. The board may, by regulation, determine the circumstances under which a license may be transferred.

(b) The board may, at its discretion, issue a temporary permit, when the ownership of a pharmacy is transferred from one person to another, upon the conditions and for any periods of time as the board determines to be in the public interest. A temporary permit fee shall be established by the board at an amount not to exceed the annual fee for renewal of a permit to conduct a pharmacy. When needed to protect public safety, a temporary permit may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary permit was issued by mistake or denies the application for a permanent license or registration, the temporary license or registration shall terminate upon either personal service of the notice of termination upon the permit-holder or service by certified mail, return receipt requested, at the permit-holder's address of record with the board, whichever comes first. Neither for purposes of retaining a temporary permit nor for purposes of any disciplinary or license denial proceeding before the board shall the temporary permit-holder be deemed to have a vested property right or interest in the permit.

(c) The board may allow the temporary use of a mobile pharmacy, when a pharmacy is destroyed or damaged and when needed to protect the health and safety of the public and the following conditions are met:

(1) The mobile pharmacy shall provide services only on or immediately contiguous to the site of the damaged or destroyed pharmacy.

(2) The mobile pharmacy is under the control and management of the Pharmacist-in-Charge of the pharmacy that was destroyed or damaged

(3) A licensed pharmacist is on the premises while drugs are being dispensed;

(4) Reasonable security measures are taken to safeguard the drug supply maintained in the mobile pharmacy;

(5) The pharmacy operating the mobile pharmacy provides the board with records of the destruction or damage and an expected restoration date;

(6) Within three (3) calendar days of restoration of the pharmacy services, the board is provided with notice of the restoration to the permanent pharmacy;

(7) The mobile pharmacy is not operated for more than forty-eight (48) hours following the restoration of the pharmacy.



GROCERY COMPANY

GENERAL OFFICES

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July 25, 2007

Virginia Herold
Executive Officer
California State Board of Pharmacy
1625 North Market Blvd, Suite N219
Sacramento, CA 95834

Ms. Herold,

Ralphs Grocery Co., a division of the Kroger Co., is seeking guidance from the CA Board of Pharmacy. We have invested in two mobile pharmacy trailers to provide prescription drugs and/or devices during a state of emergency. We intend to use these trailers temporarily to replace an existing Ralphs Pharmacy that has been lost or damaged. Our plan is to operate these mobile trailers under the license of that location. Examples regarding deployment of the mobile pharmacies are listed below:

Example 1: An existing licensed Ralphs Pharmacy is damaged and closed.

Ralphs would deploy a mobile pharmacy to the parking lot of the closed store, activate the generator, and operate under the current license of the damaged pharmacy.

Example 2: An existing licensed Ralphs Pharmacy is completely destroyed, and the current license location is not available to park the mobile pharmacy.

We would park the mobile pharmacy as close as possible to the original location of the store. However, the street address may be different and we would operate under the license of the destroyed pharmacy.

In addition, I am also seeking guidance from the DEA.

We are planning to be ready for deployment (if needed) by September 1, 2007.

Please send your response to me at: Ralphs Grocery Co.
Attn: Rebecca Cupp
1100 W. Artesia Blvd.
Compton, CA 90220

Any assistance you can offer regarding this matter would be greatly appreciated. I can be reached at (310) 884-4722 or by email at rebecca.cupp@ralphs.com. Thank you for your time.

Sincerely,

Rebecca Cupp
Director of Pharmacy

Attachment 4

Recent Articles on Emergency Response

DRUG TOPICS

100 Years of Dedication to Pharmacy

Pharmacies are ready for the next natural disaster

May 21, 2007

By: Reid Paul

Drug Topics

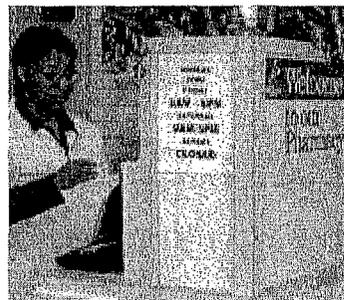
Hurricane Charley slammed into Port Charlotte, Fla., in August 2004, packing winds of 150 miles an hour and causing more than \$13 billion in damages to the state. The year before Hurricane Katrina would set a new standard for death, destruction, and chaos, Charley sent more than one million people on the Gulf Coast fleeing from the path of the storm and healthcare officials scurrying to make sure evacuees were able to receive adequate care.



The destructive power of storms like Charley and Katrina as well as the threat of earthquakes, tornados, and floods have heightened the awareness of healthcare officials to the importance of developing emergency response systems. One of the responses has been the development of the recently announced ICERx (In Case of Emergency Rx, www.icerx.org) prescription database.

And efforts have not stopped there. The California Board of Pharmacy has developed a disaster preparation policy, and pharmacy chains such as Winn-Dixie have created mobile pharmacies that can quickly respond to areas hit by disasters. In addition, a National Association of Boards of Pharmacy task force recently issued 11 guidelines for state boards of pharmacy that address issues ranging from emergency dispensing to compliance with federal laws under emergency conditions.

David Medvedeff, Pharm.D., president of Informed Decisions, a subsidiary of Gold Standard, was instrumental in the development of the ICERx system. Medvedeff was recently named the 2007 Albert B. Prescott Pharmacy Leadership Award winner by the Pharmacy Leadership & Education Institute. While helping Hurricane Charley evacuees, he realized the need for emergency responders to have access to Rx records. Informed Decisions had a contract with the state of Florida to develop a system that would give healthcare practitioners access to Medicaid prescription data. Despite the storm, the system helped Medicaid patients get their medications.



A Winn-Dixie R.Ph. working in one of the chains new mobile pharmacies

Even before the storm had passed, Medvedeff recognized the system provided a good basis for a true emergency response system. "We realized we could do the same thing on a larger scale," he said. "We learned a lot about what to do."

A year later when Hurricane Katrina hit, Medvedeff was asked by David Brailer, M.D., the national coordinator for health information technology at the Department of Health & Human Services, to join a group to help Katrina evacuees who had fanned out across the country. In addition to Informed Decisions, the team included SureScripts and RxHub. With little notice, the group developed the Katrinahealth.org Web site, which provided a prescription database that was accessed by 25,000 pharmacies nationwide.

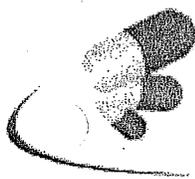
"We were able to look at the largest retail chains that had pharmacies in the impacted zip codes and pull prescription data going back 90 days," Medvedeff recalled. "We were able to get Medicaid claims from Louisiana and Mississippi. And for the first time, Veterans Affairs gave access to its claims data to an outside group for the database."

The Katrinahealth.org site was, in essence, the test version of the ICERx. Like its predecessor, ICERx pools outpatient prescription medication history information from a variety of sources, including pharmacy benefit managers, community pharmacies, and participating state Medicaid programs. Although the system will not

include records from independent pharmacies, Medvedeff estimates that it should have about 75% to 80% of prescription records in most areas. And, like the Katrina site, ICERx brings together Informed Decisions, SureScripts, and RxHub, and it will also include support from the American Medical Association, National Association of Chain Drug Stores, and the National Community Pharmacists Association.

The system is ready to go live in June in time for the hurricane season. "We have the plumbing in the pipes," Medvedeff said about the ICERx system. "Right now, nothing is flowing through the pipe, but if the unfortunate does happen, we can have data flowing through right away."

ICERx is not the only step pharmacists are taking for disaster preparation. When the Americus, Ga., Winn-Dixie store was destroyed March 1 by a tornado, the company deployed a mobile pharmacy operation to the town within days. In California, the pharmacy board has developed a disaster preparation policy, which waives requirements that may be "implausible to meet under [emergency] circumstances." According to Virginia Herold, the board's executive director, the agency is "spending a great deal of time in emergency preparedness."



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In the event of a severe public health emergency, one of the many critical factors in preserving and protecting public health will be continued access to essential medicines – for treatment of injuries or illness caused by the event, as well as continued supply of medicines for patients.

Rx Response partners are committed to working together with local, state and federal officials as well as volunteer organizations to help support the continued delivery of medicines to people who need them in the event of such an emergency – whether it is caused by a natural disaster, terrorist incident or health emergency such as a pandemic.

Rx Response partners include the drug and biotechnology manufacturing and distribution industries as well as hospitals and community pharmacies. Rx Response has worked with the American Red Cross, and the Departments of Health and Human Services and Homeland Security to share information to help support the continuing provision of medicines to patients during a severe public health emergency.

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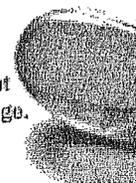
August 15, 2007

Healthcare Organizations Launch Disaster Response Initiative

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Kaiser Daily Health Policy Report

Thursday, August 16, 2007

Prescription Drugs

Industry Groups Create Program To Coordinate Delivery of Medications During Public Health Emergencies

Several health care industry organizations on Wednesday announced a program that will coordinate the delivery of medications during public health emergencies, such as Hurricane Katrina, *CQ HealthBeat* reports.

RxResponse will provide state and local officials a phone number and Web site to make their pharmaceutical needs known during emergency situations. Program organizers said RxResponse will serve as a way for the private sector and government to monitor disasters, identify risks to medication supplies and be a forum for problem solving, according to *CQ HealthBeat*. The program will not be a place for patients to go for medications during an emergency, according to organizers.

Rich Umbdenstock -- president of the American Hospital Association, a sponsor of the program -- said, "In times of crisis, people turn to hospitals to help and heal. In extraordinary situations, we've learned that we need a better way to help provide hospital caregivers with the tools they need to do their job. This effort will help do just that."

During Hurricane Katrina, people were unable to quickly identify medication needs, and there was no alternative drug distribution system in place. Billy Tauzin -- president of the Pharmaceutical Research and Manufacturers of America, another program sponsor -- said, "During a disaster, it is vital that systems are in place to assist with the coordinated delivery of medicines to hospitals, health care providers and patients in need."

Other program sponsors include the Biotechnology Industry Organization, the Healthcare Distribution Management Association and the American Red Cross, as well as pharmacy groups, HHS, the Department of Homeland Security, and state and local governments (Reichard, *CQ HealthBeat*, 8/15).



NEWSROOM

The latest news from Rx Response.

BE PREPARED



Are you prepared for an emergency?

PARTNERS



Effective emergency response is a team effort.

NEWSROOM



The latest news from Rx Response.

LEARN MORE



Our mission is to get medication to patients in emergencies.

Healthcare Organizations Launch Disaster Response Initiative

Rx Response Platform Allows Companies, Volunteers and Government Agencies To Work Together to Help Support Continued Medicines Delivery in Times of Emergency

New Orleans, LA – Health care organizations involved in the manufacturing, distribution and dispensing of pharmaceutical products came together today to announce the creation of Rx Response – a program designed to support the continued delivery of medicines during a severe public health emergency. The partnership includes the American Hospital Association, American Red Cross, Biotechnology Industry Organization, Healthcare Distribution Management Association, National Association of Chain Drug Stores, National Community Pharmacists Association and the Pharmaceutical Research and Manufacturers of America.

"During a disaster, it is vital that systems are in place to assist with the continued delivery of medicines to hospital healthcare providers and patients in need," said Billy Tauzin, president and CEO, Pharmaceutical Research and Manufacturers of America (PhRMA). "Rx Response is a partnership dedicated to assist with the delivery of critical medicines to patients whose health is threatened during a crisis."

The Rx Response program includes the pharmaceutical and biotechnology manufacturing industries as well as distribution companies, community pharmacies and hospitals – all of whom play a role in delivering medicines to patients. The group also includes the American Red Cross – and all of the partners worked with the U.S. Department of Health and Human Services and Homeland Security to develop this program. Additionally, the partnership is working with state emergency agencies to further develop the program to help support the continued delivery of medications to patients whose health may be threatened during a crisis.

"Disasters can strike at any time and the American Red Cross encourages all families and individuals to be Red Cross Ready by taking three simple steps – get a kit, make a plan, and be informed," said Joe Becker, senior vice president Preparedness and Response. "An important part of any disaster kit is the inclusion of any vital medications, in addition to at least three days supplies of food and water and other essential items. This initiative can be vital in helping people plan for the possibility of disaster."

In the past, when the pharmaceutical supply chain was disrupted, there was no single forum for suppliers to connect and share information. Now, Rx Response will help support information sharing among partners, community volunteer relief organizations and local, state and federal agencies responding to major disasters by helping to

support the continued delivery of critical medicines and, where possible, addressing challenges.

"During and in times of crisis, HDMA's primary healthcare distributors are prepared and on the front lines delivering billions of prescription medicines and healthcare products to 144,000 local pharmacies, hospitals, doctors offices, clinics and nursing homes across the United States. As a partner in Rx Response we continue our commitment to emergency preparedness and coordinated response efforts on behalf of patients," said John M. Gray, president and CEO, Healthcare Distribution Management Association (HDMA).

The program will be activated when responding to severe domestic public health emergencies – when existing emergency relief plans and service programs are disrupted – to help assist partner organizations in their individual response activities. For example, a disaster declared by a U.S. Governor or the President of the United States, may initiate Rx Response program engagement. Other situations warranting initiation, as determined by Rx Response, may also activate the program. While public health emergencies will be determined on a case-by-case basis, there are a number of existing mechanisms that will be used to help guide decision-making:

- Disaster declaration by a U.S. Governor or the U.S. President
- American Red Cross Level V+ Event
- Department of Homeland Security Severe Classification
- World Health Organization Phase IV+ Event
- Health and Human Services Stage 2+ Event
- Other situations warranting a response as determined by the respective decision-making bodies within the represented industry groups

"In times of crisis, people turn to hospitals to help and heal. To do our jobs, the men and women of America's hospitals need important resources such as medicines," said Rich Umbdenstock, president and CEO, American Hospital Association. "In extraordinary situations, we've learned that we need a better way to help provide hospital caregivers with the tools they need to do their job. This effort will help do just that."

In addition, Rx Response partners emphasized the important role patients play in emergency preparedness. The consumer website, www.RxResponse.org, offers visitors the opportunity to print a convenient wallet card – in English or Spanish – where they can include a personal list of medications and other relevant medical information in case of an emergency.

"As leaders in the production of existing therapies and the development of new treatments for patients, biotech companies are proud to participate in Rx Response," said Jim Greenwood, CEO of Bio. "We know this program, in tandem with government efforts, will be extremely valuable in a severe public health emergency to improve access for patients to life-saving biotech medicines."

"Retail community pharmacy has a strong track record in maintaining essential prescription services during times of disasters. In fact, a just-released Department of Health and Human Services Office of the Inspector General report suggests that community pharmacy did just that after Hurricane Katrina," said Steven C. Anderson, IOM, CAE, president and CEO of the National Association of Chain Drug Stores (NACDS). "The new RxResponse program is a natural extension of the capabilities of pharmacists, as front-line health care providers, in serving the public in critical circumstances."

"The National Community Pharmacists Association is pleased to participate in an effort to help facilitate collaboration between the private and government sectors. Many of the 23,300 community pharmacies in the U.S. are located in rural and underserved areas where patients have the greatest medication needs—especially in the event of a disaster. We look forward to working with the Rx Response groups in concert with federal initiatives," said Bruce T. Roberts, R. Ph, executive vice president and CEO, National Community Pharmacists Association (NCPA).

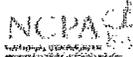
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Rx Response is comprised of healthcare organizations recognizing that access to medicines during times of severe public health emergencies requires a broad public effort and close communication among the many public and private sector stakeholders involved. This includes responding agencies such as government agencies, as well as private relief groups.

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Attachment 5

- *Proposed Competencies for Pharmacist Interns Completing their Basic Level of Experience in Schools of Pharmacy*
- *Letter from Dr. Koda-Kimble*

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

I. Communication and Professional Behavior

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.

II. The Practice of Pharmacy

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.

Co-Chairs: Barbara Sauer, PharmD (UCSF), Kathy Besinque, PharmD (USC), Eric Boyce, PharmD (UOP)

Participants: Sarang Aranke, PharmD (Target), Melvin Baron, PharmD (USC), Elizabeth Boyd, PhD (UCSF), Sian Carr-Lopez, PharmD (UOP), James Colbert, PharmD (UCSD), Robin Corelli, PharmD (UCSF), Larry Drechsler, PharmD (Target), Jeff Goad, PharmD (USC), William Gong, PharmD (USC), Steven Gray, PharmD, JD (Kaiser), Virginia Herold (California Board of Pharmacy), Donald Hsu, PharmD (Western), Gamal Hussein, PharmD (Loma Linda), LaDonna Jones, PharmD (Loma Linda), Linh Lee, PharmD (Ralphs), Paul Lofholm, PharmD (CPhA), Susan Ravnar, PharmD (California Board of Pharmacy), Debra Sasaki-Hill, PharmD (Touro), Sam Shimomura, PharmD (Western), Anne Sodergren (California Board of Pharmacy), Rick Sylvies, PharmD (Western), Reza Taheri, PharmD (Loma Linda), Dianne Tobias, PharmD (Medpin), David Williams (Safeway), Sharon Youmans, PharmD, MPH (UCSF), Keith Yoshizuka, PharmD, MBA, JD (Touro)

May 2007



School of Pharmacy
Office of the Dean

BOARD OF PHARMACY

2007 AUG 20 PM 4: 18

Mary Anne Koda-Kimble, Pharm.D.
Professor and Dean
Thomas J. Long Chair in
Community Pharmacy Practice

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August 14, 2007

California State Board of Pharmacy
Attn: Virginia G. Herold, Executive Officer
1625 North Market Boulevard, Suite N219
Sacramento, CA 95834-1924

Dear Members of the Licensing Committee:

The first phase of the California Pharmacy IPPE-OSCE Initiative has been completed. Representatives of the pharmacy schools, the Board, and practitioners reached consensus on the basic knowledge, skills, and attitudes that students should achieve through early practice exposure and experiences. We now seek your endorsement.

You may recall that the California pharmacy schools developed this initiative to address our concerns with a new accreditation standard mandating 300 hours of experiential training early in the curriculum. While we are in agreement in concept with early practice experiences, we prefer that the focus of introductory practice experiences (IPPEs) be on achievement of competencies rather than on time spent in practice experiences. The competencies developed through this collaboration will provide much needed guidance to pharmacy interns and their preceptors, which represents a significant contribution to the education and training of pharmacists in the state.

As one of our partners in this initiative, we must be sure that the Board is in agreement with the IPPE Competencies that were developed. In fact, we are requesting that all of our schools and collaborators review the document and, if appropriate, suggest revisions. We are now in the process of developing cases to test these competencies via an objective simulated competency examination (OSCE). This is a performance-based exam.

I encourage you to carefully review the proposed IPPE Competencies and affirm that the Board agrees with this document. Please let us know if you feel any significant revision is necessary.

With best regards,

Mary Anne Koda-Kimble, PharmD
Professor and Dean
Thomas J. Long Chair in Community Pharmacy Practice

Attachment 6

*Examination Statistics from April 1,
2007 through August 31, 2007*

**California State Board of Pharmacy
CPJE Statistics 4/1/07 – 8/31/07**

The charts below display data for all candidates who took the CPJE examination between 4/1/07 – 8/31/07, inclusive.

The board also displays NAPLEX scores associated with any candidate who took the CPJE during this six-month period and was reported to the board, regardless of when the NAPLEX may have been taken (it could have occurred outside the five-month reporting period noted above).

Typically, the board reports CPJE performance data at six month intervals. However, due to quality assurance assessment requirements, this report contains data for five months. The next report will cover performance data for 9/1/07 – 3/31/08.

Overall Pass Rates

CPJE

		Frequency	Percent
Valid	F	143	14.5
	P	845	85.5
	Total	988	100.0

NAPLEX

		Frequency	Percent
Valid	F	41	4.3
	P	918	95.7
	Total	959	100.0

Location of School

CPJE

			JPE		JPE Total	NAPLEX		NAPLEX Total
			Fail	Pass		Fail	Pass	
School	California	Count	22	534	556	4	546	550
		% within PF	4.0	96.0		0.7	99.3	
	Other US	Count	77	255	332	20	294	314
		% within PF	23.2	76.8		6.4	93.6	
	Foreign	Count	44	56	100	17	78	95
		% within PF	44.0	56.0		17.9	82.1	
Total	Count	143	845	988	41	918	959	
	% within PF	14.5%	85.5%		4.3%	95.7%		

Gender

			JPE pass fail status		JPE Total	NAPLEX pass fail status		NAPLEX Total
			Fail	Pass		Fail	Pass	
gender	F	Count	94	548	642	26	603	629
		% within PF	14.6	85.4		4.1	95.9	
	M	Count	49	297	346	15	315	330
		% within PF	14.2	85.8		4.5	95.5	
Total		Count	143	845	988	41	918	959
		% within PF	14.5%	85.5%		4.3%	95.7%	

Degree

			JPE pass fail status		JPE Total	NAPLEX pass fail status		NAPLEX Total
			Fail	Pass		Fail	Pass	
degree awarded	BS Pharmacy	Count	56	84	140	21	110	131
		% within PF	40.0	60.0		16.0	84.0	
	Pharm D.	Count	87	761	848	20	808	828
		% within PF	10.3	89.7		2.4	97.6	
Total		Count	143	845	988	41	918	959
		% within PF	14.5%	85.5%		4.3%	95.7%	

California Schools

			JPE pass fail status		JPE Total	NAPLEX pass fail status		NAPLEX Total
			Fail	Pass		Fail	Pass	
school	UCSF	Count	4	102	106	0	106	106
		% within PF	3.8	96.2		0	100.0	
	UOP	Count	8	137	145	0	143	143
		% within PF	5.5	94.5		0	100.0	
	USC	Count	8	154	162	2	158	160
		% within PF	4.9	95.1		1.3	98.7	
	Western	Count	1	103	104	2	101	103
		% within PF	1.0	99.0		1.9	98.1	
	Loma Linda	Count	0	21	21	0	20	20
		% within PF	0	100.0		0	100	
	UCSD	Count	1	17	18	0	18	18
		% within PF	5.6	94.4		0	100.0	
Total		Count	22	534	556	4	546	550
		% within PF	4.0%	96.0%		0.7%	99.3%	

US Schools of Pharmacy

	JPE pass fail status		Total
	F	P	
U of AZ	1	2	3
UCSF	4	102	106
U of Pacific	8	137	145
USC	8	154	162
U of CO	1	1	2
U of Conn	1	4	5
Howard DC	2	2	4
FL A&M	1	2	3
U of FL	0	3	3
U of GA	0	3	3
Idaho SU	0	3	3
U of IL Chi	2	5	7
Butler U	1	1	2
Purdue	0	5	5
Drake	1	6	7
U of IA	0	2	2
U of KS	1	2	3
U of KY	0	1	1
NE LA U	0	1	1
Xavier	1	1	2
U of MD	4	10	14
MA Col Pharm	12	36	48
NE-MA	3	2	5
Ferris	2	1	3
U of MI	0	2	2
Wayne SU	1	0	1
U of MN	0	2	2
U of MS	0	1	1
St. Louis Col of PH	2	4	6
UMKC	1	2	3
U of MT	0	1	1
Creighton	4	19	23
U of NE	0	3	3
Rutgers	0	1	1
U of NM	2	4	6
Western	1	103	104
Midwestern U Chicago	2	5	7
A&M Schwartz	3	12	15
St. Johns	1	3	4
SUNY-Buff	3	3	6
Union U	1	3	4

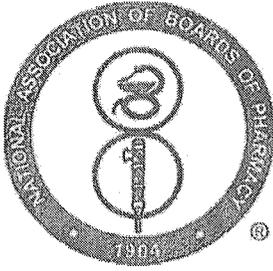
	JPE pass fail status		Total
	F	P	
ND SU	1	2	3
OH Nrthrn U	0	1	1
OH State U	0	2	2
U of Cinn	1	1	2
U of Toledo	0	3	3
Phl C of Pharm	2	5	7
Temple	3	10	13
U of Pitt	0	3	3
U of PR	0	1	1
U of RI	0	2	2
U of SC	2	2	4
U of TN	0	1	1
TX SO U	1	2	3
U of Hous	0	4	4
U of TX	1	2	3
U of UT	0	3	3
Med C of VA	1	3	4
U of WA	1	6	7
WA State U	1	6	7
WV U	1	0	1
U of WI-Mad	0	3	3
Nova Southeastern	2	2	4
Wilkes University	0	1	1
Texas Tech	0	1	1
Bernard J Dunn	0	1	1
Midwestern AZ	2	5	7
Nevada College of Pharmacy	4	20	24
Loma Linda University	0	21	21
UCSD	1	17	18
MA School of Pharmacy - Worcester	0	4	4
Palm Beach Atlantic University	1	0	1
Lake Erie Col	0	1	1
Other/FG	44	56	100
Total	143	845	988

Country

	JPE pass fail status		Total
	F	P	F
Armenia	0	1	1
Australia/Ashmore/Coral Sea Is/Cartier Is	0	1	1
Bangladesh	1	2	3
Canada	0	1	1
Germany	0	1	1
Egypt	0	4	4
Spain	0	1	1
France	1	2	3
United Kingdom	0	2	2
India	10	17	27
Iran	0	2	2
Japan	0	1	1
Jordan	0	2	2
Kenya	1	1	2
Korea (N&S)	1	2	3
S. Korea	1	0	1
Nigeria/New Guinea	1	1	2
New Zealand	0	1	1
Philippines	11	8	19
Pakistan	3	1	4
Seychelles	0	21	21
USSR	4	0	4
Syria	3	0	3
Taiwan	1	1	2
Ukranian	0	1	1
USA	101	769	870
Venezuela	1	0	1
South Africa	3	2	5
Total	143	845	988

Attachment 7

*Information on the NAPLEX
Compromise*



National Association of Boards of Pharmacy

1600 Feehanville Drive • Mount Prospect, IL 60056-6014

Tel: 847/391-4406 • Fax: 847/391-4502

Web Site: www.nabp.net

nabp

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TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY
FROM: Carmen A. Catizone, Executive Director/Secretary
DATE: September 13, 2007
RE: Reactivation of the NAPLEX and Georgia MPJE Examinations

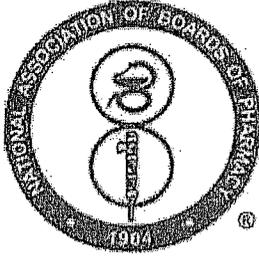
NABP is continuing its efforts to reactivate the North American Pharmacist Licensure Examination (NAPLEX) and Georgia Multistate Pharmacy Jurisprudence Examination (MPJE) as quickly as possible. Candidates who were scheduled to sit for the NAPLEX from the date the examinations were suspended, on August 25, until approximately mid October 2007 are being and have been rescheduled for new dates beginning in early November. It is our intent to meet and far exceed the original target date of November 1, 2007. As soon as the reinstatement date is finalized, the state boards will be immediately notified via e-mail.

Reactivation of the Georgia MPJE may take slightly more time. NABP Competency Assessment staff completed the review of the uncompromised items to support the relaunch of the Georgia MPJE; however, the delivery of the Georgia MPJE, as well as other states' MPJE, depends upon a sophisticated software driver and NABP is working closely with our testing vendor to coordinate such software with reactivation of the Georgia MPJE. NABP cautiously estimates that reinstatement of the Georgia MPJE will occur in late November or early December.

NABP understands that the suspension has caused difficulties for candidates who were scheduled to sit for the examinations. Our Customer Service and Executive Office staff are responding to each and every inquiry and using their best efforts to assist candidates who have been placed in this unfortunate circumstance by factors outside of the control of NABP. The number of candidates contacting NABP has decreased significantly since the examinations were first suspended. If there is any assistance we can provide to you in this regard, please do not hesitate to contact me at 847/391-4400 or via e-mail at exec-office@nabp.net.

We truly appreciate your support and assistance in this matter.

cc: NABP Executive Committee



nabp
National Association of Boards of Pharmacy
1600 Feehanville Drive • Mount Prospect, IL 60056
Tel: 847/391-4406 • Fax: 847/391-4502
Web Site: www.nabp.net

TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY
DEANS – SCHOOLS AND COLLEGES OF PHARMACY

FROM: Carmen A. Catizone, Executive Director/Secretary

DATE: August 6, 2007

RE: Materials Seized from University of Georgia College of Pharmacy Following
Allegations of Breaches of National Pharmacy Licensure Examination

Today, Monday, August 6, United States' Marshals seized materials and computers from the University of Georgia College of Pharmacy and the offices and home of Flynn Warren, Jr, clinical professor and assistant dean for student affairs, pursuant to an ex parte temporary restraining order and seizure order from a federal court in the Middle District of Georgia Athens Division.

The action by the federal court follows investigations and complaints by NABP into alleged breaches of the North American Pharmacist Licensure Examination (NAPLEX) and the Multistate Pharmacy Jurisprudence Examination (MPJE) and outline activities of faculty, students, and the University of Georgia College of Pharmacy. NABP is disappointed and appalled that the public trust and health were victimized, the security of the NAPLEX and MPJE breached, and the integrity of the licensure process compromised with the knowledge and at the direction of individuals responsible for educating and preparing students to become competent and ethical pharmacists.

The NABP Executive Committee is evaluating how the actions noted in the findings of the federal court impact the NAPLEX and MPJE and what changes need to occur to ensure the integrity of the NAPLEX and MPJE.

NABP will move aggressively to hold accountable, legally and financially, any and all individuals, colleges and schools of pharmacy, and organizations involved in and responsible for the compromise of the NAPLEX and MPJE examinations. The petitions filed and granted in federal court last week will be amended and expanded to name and act against any and all individuals, colleges and schools of pharmacy, and organizations that have engaged or engage in activities adversely impacting the integrity and security of the NAPLEX and MPJE and violate state and federal laws. NABP will take any action possible to ensure that the public health is protected.

If you have any questions, please contact me via e-mail at exec-office@nabp.net or via phone at 847/391-4400 or 1-800/774-6227. Thank you.

cc: NABP Executive Committee
Advisory Committee on Examinations

TO: EXECUTIVE OFFICERS - STATE BOARDS OF PHARMACY

FROM: Carmen A. Catizone, Executive Director/Secretary

DATE: August 30, 2007

RE: Update on Suspension of the NAPLEX and Georgia MPJE

The National Association of Boards of Pharmacy (NABP) appreciates all of the support you have provided following the suspension last week of the North American Pharmacist Licensure Examination (NAPLEX) and the Georgia Multistate Pharmacy Jurisprudence Examination (Georgia MPJE). NABP knows this is a challenging time for all of you and apologizes for the additional workload you have faced in responding to candidate inquiries. NABP fully understands the issues some candidates are facing as a result of the suspension of these examinations. This decision was one of the most difficult decisions in the history of NABP, but it was the only one that could be made in the interest of protecting the integrity of the examinations, state licensure processes, and, ultimately, the public health.

The NAPLEX and Georgia MPJE will be reactivated as soon as possible when NABP is confident that both examinations are able to validly assess the entry-level competence of pharmacists to safely practice pharmacy. NABP cautiously estimates that the examinations will be reinstated by early November 2007, following review and approval by NABP. I can assure you that, upon reactivation, the NAPLEX and Georgia MPJE programs will provide valid, psychometrically sound assessments of candidate competence and will embody the highest standards of testing that characterize and define NABP and its programs. This rapid reactivation timeline is possible thanks to the strength of the programs and processes that NABP has in place and is despite these programs having sustained significant damage that may have completely destroyed other programs.

To support you and your staff in responding to e-mails and calls regarding this matter, NABP has created the attached script, which we hope will assist you in your responses. The script addresses the following four categories of inquiries:

- inquiries from candidates with appointments to sit for the NAPLEX and/or Georgia MPJE;
- inquiries from candidates who have applied to sit for examinations, but have not yet scheduled appointments to test;
- inquiries from candidates who have not applied for the examinations; and
- non-candidate inquiries.

NABP requests that any media inquiries be forwarded to NABP's executive office by calling 847/391-4405.

For your information and to provide you with some background, following

suspension of the NAPLEX and Georgia MPJE, NABP's testing vendor, Prometric, immediately began contacting candidates who had appointments to test between August 25, 2007 and mid-October 2007 to inform them about the examination suspensions and to offer them the opportunity to reschedule their appointments.

As soon as we are legally able to do so, we will provide a more detailed explanation regarding the suspension of the examinations. We will also continue to provide regular updates to you and alert you immediately when there is significant information to report.

Once again, NABP recognizes that this matter has resulted in additional work for you and your staff. We sincerely thank you for your support.

If you have any questions, please feel free to contact me at 847/391-4400 or exec-office@nabp.net.

cc: NABP Executive Committee

The Board of Pharmacy announces that the National Association of Boards of Pharmacy has suspended administration of the NAPLEX examination until it can fully investigate a serious security breach of the examination. The suspension also affects the Georgia MPJE. NABP is not aware how long the suspension will last.

For more information about the NAPLEX exam: here is a link to the NABP Web site:
<http://www.nabp.net>

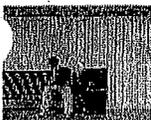
The California Board of Pharmacy fully supports the efforts of the NABP to secure its examination from possible compromise, and to fully investigate the matter before resuming administration of the examination. This is essential for California to have trust in the examination and one key process the board uses to determine the minimal competency of applicants for pharmacist licenses. This is a public safety issue.

Please note that this suspension does NOT affect the California Pharmacist Jurisprudence Examination, which is developed by the California Board of Pharmacy solely for administration to applicants seeking pharmacist licensure in California. This examination will continue to be administered to candidates who meet required standards at test centers in California and throughout the US by Psychological Services, Inc.

Also, the board will release the NAPLEX scores of all applicants who took the examination before administration was suspended on August 25.

More information will be shared about the NAPLEX as it becomes available.

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Pharmacy student Robert Ko sits outside the Pharmacy Building Wednesday.

Conversations show students received help

Scandal prevents pharmacy students from taking current exam

By: BRIAN HUGHES

Posted: 8/31/07

Katie Barnett flew more than halfway across the country to attend a review class taught by Flynn Warren Jr., a University pharmacy professor accused of giving out test questions to students, according to court documents.

Now a pharmacist in Seattle, a graduate from the Wisconsin School of Pharmacy raved in an e-mail about the class she took from Warren in South Carolina and wrote that the pharmacy community would be enhanced with more teachers like him.

As part of her gratitude, court documents show she then supplied Warren with general topics from her North American Pharmacist Licensure Examination, a test used by each state's boards of pharmacy, as well as exact questions to the test.

"What does- p-value mean if $p=0.04$ does that mean 4% due to chance? - had this twice," she writes.

In the same document, Jeff Bruce, a pharmacy student from Creighton University, cites Warren's guidance for his "inflated score." He wrote that he scored a 130 out of 150 on the NAPLEX, which requires a score of 75 to pass.

"About one-third of the questions were either word-for-word, or very similarly worded to those in the practice test you went over with us in Athens," he wrote to the professor in the document.

Warren retired from the University this July but still teaches elective classes at the College of Pharmacy.

The National Association of Boards of Pharmacy has accused him of copyright infringement, alleging that he asked students to memorize test questions and share what they could remember with him.

And now students who have never met Warren are unable to take their licensure tests, at least for the foreseeable future.

The NABP suspended administration of both the NAPLEX nationally and Georgia MPJE on Saturday.

The organization has not revealed when students will be able to take the test again.

The Red & Black scheduled a meeting for Thursday afternoon with Svein Oie, dean of the College of Pharmacy, but the appointment was cancelled that day by college officials.

Tom Jackson, vice president for public affairs, said no plans have been made to keep Warren from teaching this fall. He is scheduled to instruct in the spring, Jackson added.

Alan Ray Spies, an assistant pharmacy professor at Samford University, said in an affidavit that he learned in May 2007 Warren was giving NAPLEX questions to students.

A senior administrator at Samford's School of Pharmacy, who did not want to be named due to the pending investigation, said he was aware students at the school used Warren's review course.

The news began to reverberate at universities nationwide this week.

Michael McKenzie, a senior associate dean for professional affairs at the University of Florida's College of Pharmacy, said to his knowledge none of the college's students had participated in Warren's review course. He said he recognized the potential effect of the investigation.

"I would suspect they'll have to make new questions and throw out ones that may have been compromised," he said.

Authorities seized materials from Warren's computers Aug. 6 and found a copy of an electronic receipt used to purchase electronic shredding software, which is used to purge files from a computer so they cannot be recovered forensically. The court documents state the software was purchased just before the seizure.

A recent graduate from the pharmacy school at The University of Colorado at Boulder, who requested not to be identified, was unable to take the licensure test he scheduled for Monday. He said he has \$130,000 in student loans and a baby due in November.

"I'm just a pawn in the game," the graduate said. "My career and profession hang in the balance."

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Attachment 8

*Proposed Language to Amend
Sections 1721 and 1723.1 of Title 16
of the California Code of Regulations*

**Board of Pharmacy
Specific Language**

Amend Section 1721 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1721. Dishonest Conduct During Examination.

An applicant for examination as a pharmacist who engages in dishonest conduct during the examination shall not have that examination graded, shall not be approved to take the examination for ~~twelve months~~ three years from the date of the incident, and shall surrender his or her intern card license until eligible to take the examination. The applicant may not be issued a pharmacy technician license until the applicant is again eligible to take the examination.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4200, Business and Professions Code.

Amend Section 1723.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1723.1. Confidentiality of Examination Questions.

Examination questions are confidential. Any applicant for any license issued by the board who removes all or part of any qualifying examination from the examination room or area, or who conveys or exposes all or part of any qualifying examination to any other person may be disqualified as a candidate for a license. The applicant shall not be approved to take the examination for three years from the date of the incident and shall surrender his or her intern license until again eligible to take the examination. The applicant may not be issued a pharmacy technician license until the applicant is again eligible to take the examination.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 123 and 496, Business and Professions Code.

Attachment 9

*Information about Creighton
University's On-line PharmD Program*

Creighton Search Creighton Creighton Medical

Home | Programs | Prospective Students | Current Students | Faculty and Staff | Alumni

Pharmacy

INFORMATION FOR:
 Alumni
 Faculty & Staff
 Office of Academic and Student Affairs
 Office of Information Technology and
 Learning Resources

Entry Level Doctor of Pharmacy Program (Web-Based)

Navigation: Home -
 > Entry-Level
 Pharmacy Program



Home

- ✦ [School](#)
- ✦ [Pharmacy](#)

Entry Level Pharmacy Program (Web-Based)

- ✦ [Overview/Curriculum](#)
- ✦ [Entry Requirements](#)
- ✦ [How to Apply](#)
- ✦ [Admission FAQs](#)
- ✦ [Application Checklist](#)
- ✦ [2006 Entering Class Profile](#)
- ✦ [Cost/Tuition](#)
- ✦ [Financial Aid](#)
- ✦ [Housing](#)
- ✦ [International Students](#)
- ✦ [Goals & Objectives](#)
- ✦ [AACP Article](#)
- ✦ [Accreditation](#)
- ✦ [Graduation Requirements](#)
- ✦ [Clinical Rotation Requirements](#)
- ✦ [Pharmacy Technical Standards](#)
- ✦ [Elective Requirements](#)
- ✦ [Technology Requirements](#)
- ✦ [Travel Requirements](#)
- ✦ [Sample class](#)
- ✦ [Success Tips](#)

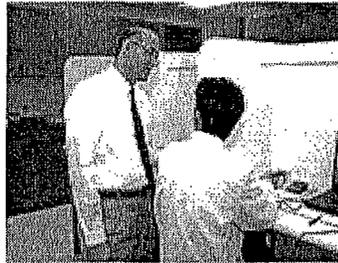
Other Information

- ✦ [Why Pharmacy?](#)
- ✦ [Campus Life](#)
- ✦ [Housing](#)
- ✦ [Message from the Dean](#)
- ✦ [School Mission](#)

Links

- ✦ [Faculty & Research Information](#)

Program Overview



Pharmacy is consistently ranked as one of the most respected professions in the nation, and the Creighton pharmacy program is considered one of the best pharmacy programs in the country. Creighton believes that pharmacists must be responsive to patient needs by providing a level of patient care that focuses on disease state management, prevention of disease, patient outcomes and wellness.

Creighton University offers the first and only accredited **Doctor of Pharmacy Program Distance Pathway (Online Pharmacy Program)** providing a full-time educational method to obtain a Doctor of Pharmacy degree. This innovative pathway covers the same material as the traditional on-campus pathway, but allows students to take didactic coursework using distance mechanisms, which include the Internet and CD-ROMs, from wherever they live. Interactions with faculty and mentors occur via Internet chat rooms, e-mail, fax, and telephone.

The didactic portion of the Distance pathway is taught on a semester basis. Students complete the laboratory courses in a condensed manner during the summers. The on-campus laboratory sessions last for 1-2 weeks.

The Doctor of Pharmacy degree requires a minimum of two years of pre-pharmacy and four years of professional education. Many students complete three years or a baccalaureate degree before beginning professional education.

Creighton's program has changed to reflect changes in the practice of pharmacy that focuses on pharmaceutical care. Pharmaceutical care is the direct, responsible provision of medication-related care for the purpose of achieving definitive outcomes that improve a patient's quality of life. Today's pharmacy education focuses on:

- Patient data collection
- Medication therapy assessment and delivery
- Pharmacy care plan
- Patient counseling
- Patient monitoring and compliance
- Patient outcomes evaluation and documentation



The clinical component of the online pharmacy program requires eight five-week clinical rotations. Five clinical rotations are in required subject areas. The remaining clinical rotations are in elective subject areas. These unpaid clinical rotations provide experience in actual pharmacy practice. Sites for clinical rotations are in a variety of locations throughout the country, with some international sites. New sites are being constantly identified and developed. It may be necessary for students to travel to sites during at least a portion of the last year, depending on the availability of suitable clinical rotation in their

location.

Graduates enter practice with strong basic knowledge, communication skills, critical thinking abilities and an empathic attitude toward their patients. Specialized clinical and internship programs are available to students who have particular interests in fields ranging from critical care to family medicine, pediatrics to gerontology, cardiology to home care and neurology to psychiatry. Graduates find ready employment at excellent salaries in a wide range of health service settings including private businesses, hospitals, clinics, government, military, and academic and research institutions.

Information is provided by current students regarding online pharmacy program benefits, curriculum/design, and self-reported personal attributes is available.

Nationally Recognized

The Creighton pharmacy program has taken the lead to address the shortage of pharmacists by offering a distance based pharmacy pathway in addition to its campus pathway. In an innovative move in 2001, Creighton started the first web-based distance pharmacy pathway in which students can take all didactic courses on the Internet. The distance pathway is the only one of its kind in the United States and is accredited by the American Council on Pharmacy Education. [Read More Here](#).

Curriculum for Doctor of Pharmacy Program Distance Pathway ([Class of 2008](#), [Class of 2009](#))

Curriculum

Doctor of Pharmacy Program (Beginning with the 2006 entering class)

Distance Pathway (4 years) (Online Pharmacy Program)

First Professional Year

Summer on CU campus	Fall Semester	Hrs	Spring Semester
Orientation (6 days)	PHA 304 Human Anatomy	2	BMS 404 Physiology
Technology Training	BMS 301 Biochemistry	4	PTG 105 Introduction to Pathology of Human Disease
	PHA 313 Pharmacy Calculations	2	PHA 325 Dosage Forms and Drug Delivery Systems
	PHA 315 Physical Pharmacy	3	PHA 444 Biostatistics and Research Design I
	PHA 316 Health Care Systems	3	PHA 442 Pharmacy Practice Management
	PHA 329 Introduction to Drug information & Pharmaceutical Care	1	PHA 402 Early Practice Experience I*
	PHA 320 Communication Skills*	2	Electives
	Total	17	Total

Second Professional Year

Summer Lab Session July - 12 days on CU Campus (Not registered for Summer Term)	Fall Semester	Spring Semester
Parenterals Communications	MIC 541 Microbiology 4	PHR 242 Pharmacology II
EPE 1	PHR 241 Pharmacology I 5	PHA 447 Chemical Basis of Drug Action II
	PHA 337 Chemical Basis of Drug Action I 3	PHA 324 Nonprescription Therapeutics
	PHA 334 Parenteral Drug Products* 3	PHA 443 Basic Pharmacokinetics
	Electives 3	PHA 412 Early Practice Experience II*
		PHA 326 Patient Assessment*
	Total 18	Total

Third Professional Year

Summer Lab Session July - 6 days on CU Campus (Not registered for Summer Term)	Fall Semester	Spring Semester
Patient Assessment	PHA 450 Pharmacotherapeutics I 7	PHA 460 Pharmacotherapeutics II
EPE II	PHA 459 Immunopharmacology 2	PHA 464 Clinical Pharmacokinetics
	PHA 458 Drug Literature Evaluation 3	PHA 456 Ethics in the Health Care Professions
	PHA 454 Pharmacy Practice Law 3	PHA 485 Dispensing and Pharmaceutical Care Lecture
	Electives 3	PHA 422 Early Practice Experience III*
		Electives
	Total 18	Total

Fourth Professional Year

Summer Lab Session May - 12 days on	Summer Semester Hrs	Fall Semester Hrs	Spring Semester
--	---------------------	-------------------	-----------------

CU Campus					
Dispensing	Dispensing and Pharmaceutical Care Lab	1	Clinical Rotation #3	5	Clinical Rotation #6
EPE III	Clinical Rotation #1	5	Clinical Rotation #4	5	Clinical Rotation #7
	Clinical Rotation #2	5	Clinical Rotation #5	5	Clinical Rotation #8
Total		11	Total 15		Total

* Courses requiring on-campus components at Creighton University during the summer lab sessions.

The Doctor of Pharmacy degree requires nine semesters of professional course work (thirteen semesters including the two years of pre-pharmacy courses). Students are required to attend clinical rotations during the summer prior to the last year of the program. **A full semester of tuition is charged for the summer clinical rotation experience.**

Elective Requirements

The elective didactic requirements for the pharmacy program are as follows:

- Electives do not need to be taken as shown. As of August 15, 2002, elective course requirements for pharmacy students has changed. A total of ten (10) elective hours is required; of these, the new requirements state that:
 - a. Five (5) semester hours of electives are required of all entry-level pharmacy students, regardless of pre-pharmacy academic history. These five elective hours must be taken at an accredited, four-year school, college or university while enrolled in Creighton's Doctor of Pharmacy program.
 - b. Five (5) semester hours of unrestricted electives are also required of all entry level pharmacy students. These unrestricted hours may be taken while enrolled in Creighton's Doctor of Pharmacy program, but credit hours earned in pre-professional coursework that are above and beyond those hours required for matriculation may also count against this requirement*. If pre-professional coursework is used to satisfy the requirement, a grade of C or better must have been earned. Unrestricted electives can be completed at any post-secondary institution of higher learning.
- The unrestricted electives required of pharmacy students may be taken at any four year accredited college or university. Prior approval of the elective course by the Assistant Dean of Academic Affairs is required. A syllabus may need to be submitted to the Assistant Dean for Academic Affairs for review and approval. The advisor's recommendation will be an important part of the decision whether to allow the course to count against the requirements for graduation.
- All elective courses must be taken for a grade unless the instructor has elected to use the Satisfactory/Unsatisfactory grading system. The Pass/No Pass option is not allowed for courses that will be applied toward the degree. As D grades do not transfer, elective courses taken for a letter grade at other institutions must be completed with a grade of C or better. Students should be advised that, while they will receive academic credit for the electives taken at institutions outside of Creighton University, the grades earned in these elective courses will NOT be

calculated into their pharmacy grade point average. Credit transfers, but grades do not. If electives are taken at a school or college outside of Creighton an official transcript which documents the grade earned in the elective course must be submitted to the Assistant Dean for Academic Affairs. An elective course cannot be considered to have been successfully completed until an official transcript is in the student's file.

- In order for a course to count against the elective course requirements for graduation, the student must **NOT** have taken a similar course that covered the same content, during their pre-professional studies (i.e., they should not take astronomy if they have taken a similar astronomy course in their pre-professional studies).
- If a student wishes to apply for transient study, the form entitled "Application Transient Study" must be completed and approved before registering for the course. The student must obtain his/her advisor's signature on the form before submitting the form to the Office of Academic and Student Affairs for approval. A copy will be placed in the student's and advisor's mailbox after the final decision has been made.

Clinical Rotation Requirements

The Clinical Rotation requirements for the pharmacy program are as follows:

In the last three semesters of the program, five credits are given for each five week clinical rotation experience. Five (5) rotations are required:

PHA 510 Community Pharmacy Practice Clinical Rotation
PHA 511 Inpatient Hospital Pharmacy Practice Clinical Rotation
PHA 512 Adult Acute Pharmaceutical Care Clinical Rotation
PHA 515 Drug Information Clinical Rotation
PHA 516 Ambulatory Care Clinical Rotation

The remaining three (3) clinical rotations are elective but must be selected so as to provide a variety of professional experiences. Students are encouraged to enroll in clinical rotations that will expose them to direct patient contact and clinical service, distributive functions, and nontraditional practices. The experiential year has been designed to graduate a generalist practitioner who is highly qualified to enter practice or pursue advanced study in the clinical, administrative, or basic pharmaceutical sciences.

The elective clinical rotations available to Pharm.D. students currently include:

PHA 520 Elective Community Pharmacy Practice Clinical Rotation
PHA 521 Elective Community Pharmacy Management Clinical Rotation
PHA 523 Elective Long Term Care Clinical Rotation
PHA 524 Elective Ambulatory Care Clinical Rotation
PHA 526 Elective Ambulatory Home Care Clinical Rotation
PHA 528 Elective Third World Cultures and Health Care (ILAC)
PHA 529 Elective International Clinical Rotation
PHA 533 Elective Pharmacy Organization Management Clinical Rotation
PHA 535 Elective Academic Clinical Rotation
PHA 536 Elective Pharmacoeconomics Clinical Rotation
PHA 540 Elective Inpatient Hospital Pharmacy Practice Clinical Rotation
PHA 541 Elective Hospital Pharmacy Management Clinical Rotation
PHA 542 Elective Drug Information Clinical Rotation
PHA 543 Elective Poison Center Clinical Rotation
PHA 544 Elective Drug Utilization Review Clinical Rotation
PHA 545 Elective Nuclear Medicine Clinical Rotation
PHA 546 Elective Veterinary Pharmaceuticals Clinical Rotation
PHA 550 Elective Industrial Pharmacy Clinical Rotation

PHA 551 Elective Clinical Research Clinical Rotation
PHA 560 Elective Adult Acute Pharmaceutical Care Clinical Rotation I
PHA 561 Elective Adult Acute Pharmaceutical Care Clinical Rotation II
PHA 562 Elective Clinical Pharmacokinetics Clinical Rotation
PHA 563 Elective Infectious Disease Clinical Rotation I
PHA 564 Elective Infectious Disease Clinical Rotation II
PHA 565 Elective AIDS Clinical Rotation
PHA 566 Elective Oncology-Hematology Clinical Rotation I
PHA 567 Elective Oncology-Hematology Clinical Rotation II
PHA 568 Elective Critical Care/Surgery Clinical Rotation
PHA 569 Elective Cardiology Clinical Rotation
PHA 570 Elective Psychiatry Clinical Rotation I
PHA 571 Elective Psychiatry Clinical Rotation II
PHA 572 Elective Pediatrics Clinical Rotation
PHA 573 Elective Clinical Nutrition Support Clinical Rotation

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Creighton Addresses Pharmacist Shortage Through Technology

By Mary Zagoda

The Creighton pharmacy program has taken the lead to address the shortage of pharmacists by offering a distance based pharmacy pathway in addition to its campus pathway. In an innovative move in 2001, Creighton started the first web-based pharmacy pathway in which students can take all didactic courses on the Internet. The web-based pathway is the only one of its kind in the United States and is accredited by the American Council on Pharmacy Education.

The shortage of pharmacists – and other health professionals – and ways to deal with the shortage continue to be a concern for academic health science centers around the country, Dean Chris Bradberry said. A new study recently released indicates that the U.S. pharmacy profession could face a worsening shortage of pharmacists in the next decade as more pharmacists prepare to retire and more men and women opt for part-time work. The study, called the National Pharmacist Workforce Study, was done by the Pharmacy Manpower Project and is due to be published in the May/June 2006 issue of the Journal of the American Pharmacists Association.

Dr. Bradberry attributes the pharmacy shortage to multiple factors beginning with the baby boomer generation. "As our population ages, people begin to take more and more medications, often times for multiple health problems. This creates a stress on pharmacists to provide more services, more prescriptions and more healthcare services as people get older."

Other factors he contributes to the shortage are a maldistribution of healthcare professionals, mostly affecting rural areas; the increased responsibilities that have been given to pharmacists; and more women entering the health professions who want a career and a family and men are choosing to work part time.

Another factor affecting the shortage is the expansion in numbers of pharmacies across the country, mostly corporate community pharmacies and also pharmacies available in chain food stores. "A larger network requires more pharmacists to staff it."

Also part of the shortage issue is faculty to educate students. "Our faculties are aging also. We have to be concerned with not only providing manpower but replacing faculty as well," said Dr. Bradberry.

Creighton started the web-based pathway as a creative and different way to educate pharmacists that would focus on students who might not have accessibility to an on-site university program. The pathway allows students to obtain an entry-level Doctor of Pharmacy (Pharm.D) degree while spending a minimum of time away from home. The web-based pathway, developed in-part through a grant from the Institute for the Advancement of Community Pharmacy, was viewed as a way to address the manpower shortage issues by expanding class size and increasing accessibility for those students who are cannot make it to campus.

Students take their classes from home via course websites with audio and video feeds on the Internet and CD-ROM. They correspond with faculty and fellow students through e-mail, chat rooms, instant messaging and by telephone. Each student has a faculty advisor as well as an instructional mentor for basic biomedical and pharmaceutical science courses.

In addition to a week-long Orientation on the Creighton campus, students attend an intense two-week to three-week laboratory session for three summers at Creighton, which fulfills their hands-on laboratory requirements. Students may also do clinical rotations near their home provided the School has approved affiliations with clinical sites in the area, otherwise students will return to Omaha for the fourth (P4) year.

The pathway is predominantly self study in which the student can review the audio materials from the classes according to their own schedules; however, there is a schedule of classes and tests. The curriculum is the same as the campus pathway but some classes may vary slightly in the order they are given. Testing is done at approved testing sites with students using specific testing software provided for student use at the approved testing site.

The current enrollment across all four professional years of web students is 226, 149 females and 80 males, who represent

38 states. The average age of the web-based student is 33 years of age compared to 28 years of age in the campus program.

Enrollment in both pharmacy programs at Creighton have had a steady increase over the last three years and application pools are strong, Dr. Bradberry said. There are openings each year for 110 students in the campus pathway and 55 in the web-based pathway. For those 165 seats, Creighton will receive approximately 1,500 applications.

Students in both pathways have been tested on three levels of assessment and show statistically equivalent performance achievements. Students are rated on their classroom studies, clinical performance and pharmacy licensure or board exams. "Our assessments show there are no statistical differences between the two pathways. The web-based students learn differently, but they learn just as well as the campus students," Dr. Bradberry said.

For students like for Katie McConkey, a second year student in the web-based pathway, pharmacy school may not have been possible except for Creighton's program. The nearest pharmacy school is 80 miles from her home in Cuyahoga Falls, Ohio, where her husband is completing his residency in emergency medicine.

Katie, whose parents live in Lincoln, Neb., will be moving back to Omaha at the end of May. She said she has no intention of switching to the campus program. She said she has really connected with her classmates and has made many close friends.

Although it may seem that the web-based students are isolated because of the way they take their classroom studies, the students are actually very involved, she said. Creighton encourages participation and socialization amongst the students. Katie is president of her class and is involved in both Phi Lambda Sigma leadership society and Rho Chi honor society.

She says the best thing about the Creighton program is the flexibility it allows her to study. She cites the support from professors, administrators and fellow students to the success she feels about the program.

In the future, Dr. Bradberry said, Creighton will continue to address the pharmacy shortage by enhancing both the web and campus pathways. He said that by developing the web-pathway, Creighton has also created a model for other schools and colleges of pharmacy to follow.

Attachment 10

*Minutes of the Licensing Committee
Meeting of September 5, 2007*



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
LICENSING COMMITTEE MEETING
MINUTES**

DATE: September 5, 2007

LOCATION: Department of Consumer Affairs
First Floor Hearing Room
1625 N. Market Boulevard
Sacramento, CA 95834

BOARD MEMBERS

PRESENT: Ruth Conroy, PharmD, Chairperson
Clarence Hiura, PharmD
Susan L. Ravnan, PharmD
Henry Hough, Public Member
Robert Gaul, RPh

STAFF

PRESENT: Virginia Herold, Executive Officer
Karen Cates, Assistant Executive Officer
Joshua Room, Deputy Attorney General
Spencer Walker, DCA Staff Counsel
Robert Ratcliff, Supervising Inspector
Anne Sodergren, Legislation and Regulation Manager
Christine Soto, Licensing Manager
Karen Abbe, Public and Licensee Education Analyst

CALL TO ORDER

Chairperson Conroy called the meeting to order on September 5, 2007 at 9:34 a.m.

**1. Proposed Regulation Requirements for Pharmacies that Compound Medication –
Amendments to 16 CCR Sections 1716.1 and 1716.2 and Adoption of Sections 1735 - 1735.8 –
Self-Assessment Form**

Dr. Conroy advised that at the July 2007 Board Meeting, the board voted to initiate the rulemaking process for the compounding regulations. To finalize the regulations, the self-assessment form needed to be developed.

She stated that the revised language and the draft self-assessment form were provided in the meeting materials for committee review and comment.

Deputy Attorney General Joshua Room stated that in addition to the self-assessment form, staff meshed the proposed compounding requirements with the existing sterile injectable compounding regulation. Compounding requirements as a general category are promulgated in proposed Article 4.5 and sterile injectable compounding in Article 7.

Article 7 is layered on top of Article 4.5, and provides the additional requirements for sterile injectable compounding.

Mr. Room noted key changes in section 1735(d). That subdivision makes explicit that the parameters and requirements stated by Article 4.5 (Section 1735 et seq) apply to all compounding practices; additional parameters and requirements applicable solely to sterile injectable compounding are stated in Article 7 (Section 1751 et seq).

Mr. Room said that revisions to Section 1735.1(c) addressed the presence of decomposed substances and other harmful contaminants to be excluded from quality compounded products.

Steven Gray, from Kaiser, commented that wording in section 1735.1(c) should reflect “quantitative” and “qualitative” and he suggested that “harmful amounts” be used in the language.

Mr. Room added that in Section 1735.3(a)(6), the word “supplier” was replaced by “manufacturer or supplier” because of the inability in some circumstances to get the name of a manufacturer. Some suppliers are unable or unwilling to get the name of a manufacturer.

Supervising Inspector Bob Ratcliff asked how e-pedigree would affect compounding.

Mr. Room responded that e-pedigree only deals with finished products.

Mr. Room said that most revisions to Article 7 reflect renumbering; for example, numbering of .01 and .02 was confusing, so these sections were renumbered to .1 and .2. The general idea of the revisions to Article 7 was to make it a subset for specialty compounding exceeding requirements of Article 4.5. Mr. Room added that all duplications should have been removed, and he welcomed comments if any items are still duplicative.

Mr. Hough noted the requirement to maintain records for at least three years had been deleted from Article 7 section 1751.1. He said that from an administrative standpoint, there should be some kind of time limit.

Mr. Room stated that the three-year retention would apply to all sterile compounding records as well. He added that section 1751.1 hadn't changed much, other than the numbering.

Mr. Graul asked about Article 4.5 section 1735.2(c) as listed on the self-assessment form. He stated that he believed the intent under subsection (c) is that (1), (2), and (3) are all to be followed.

Mr. Room responded that yes, all three criteria must be satisfied.

Mr. Room responded that it wouldn't hurt to put another "and" in the language. It's general statutory process to put it in only before the last item in a series.

Mr. Graul said he wants to ensure that everyone knows that all three must be satisfied.

Ms. Herold added that the boxes would be deleted from that portion of the self-assessment form.

Dr. Ravnan noted that federal requirements break it down into sterile compounding and non-sterile compounding.

Mr. Room responded that Article 7 is an additional step of sterile compounding, lying on top of Article 4.5.

Dr. Ravnan asked whether a pharmacy that is doing sterile compounding still needs to fill out the self-assessment form for nonsterile compounding.

Mr. Room responded, yes.

Dr. Gray added that there are three categories – compounding, sterile injectible compounding, and nonsterile injectible compounding. There may need to be more regulatory sections. When the regulations were first developed, stakeholders were not ready to take on all aspects of compounding.

Mr. Room responded that another option would be to have entirely duplicative regulations having all the same baseline. We want to set a baseline for all compounding, and set additional requirements for sterile injectible compounding. Any ideas about the best way to do that are welcomed.

Mr. Room also noted that variation in pharmacy practice is another reason to have this layered system. Individual pharmacists must have an additional license to do sterile injectible compounding or have specified accreditation and still comply with California's requirements.

Ms. Herold added that if the board wants to add another subsection, they could do so by adding regulatory language. She said she appreciated the time that Mr. Room spent developing this new language.

Phillip Swanger, Director of Governmental Affairs for the California Society of Health-System Pharmacists, said they sent a letter to Ms. Herold on the issue of sterile and non-sterile compounding. They believe Mr. Room's revised language resolves issues, but they suggest requiring just one self-assessment form.

Ms. Herold responded that for pharmacy operations, the self-assessment form should be completed. For sterile injectable compounding, there is a separate self-assessment form to be completed.

Mr. Room added that we can have one self-assessment form with an appendix for sterile injectable compounding, rather than two separate forms, which will have duplication.

Ms. Herold emphasized that she wanted to thank Mr. Room again for working on this regulatory language.

Ms. Herold added that the committee could decide whether to further refine the language, and then bring it to the full board for consideration. She suggested bringing the regulation to the board in October to hear additional comments at that point. Then the proposed language could go out to public notice, and the board could take action in January 2008.

MOTION: That the proposed language and self-assessment form regarding Pharmacies that Compound Medication (amendments to 16 CCR Sections 1716.1 and 1716.2, adoption of Sections 1735-1735.8, and amendments to sections 1751-1751.8) be presented at the October 2007 Board Meeting with the recommendation to release for the formal rulemaking process.

M/S: HIURA/RAVNAN

SUPPORT: 5 OPPOSE: 0

2. Update: Request to add the Exam for the Certification of Pharmacy Technicians (ExCPT) developed by the Institute for the Certification of Pharmacy Technicians as a qualification method for Pharmacy Technician Registration

Dr. Conroy summarized the background information in the meeting materials. In California, individuals may become qualified for registration as pharmacy technicians by one of four means:

- 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 recognized by the board
- Being certified by the Pharmacy Technician Certification Board (PTCB)

At the October 2006 Board Meeting, the board directed a review of a new exam, the ExCPT, to determine if it is job-related. The ExCPT is a relatively new computer-based test used to assess the knowledge of pharmacy technicians. The Institute for the Certification of Pharmacy Technicians developed the ExCPT, and made a presentation to the board in October 2006.

Section 139 of the Business and Professions Code requires a periodic assessment of all licensure examinations used by a regulatory agency for job-relatedness. Initially, board staff had hoped to use professional staff in the Department of Consumer Affairs Office of Examination Resources (OER) to conduct this assessment. However, the Department of Consumer Affairs was having a difficult time with recruitment of a PhD-level expert to oversee the office.

As a result, board staff met with the department to identify the appropriate means by which to contract with a consultant to provide a review of the documentation for both the PTCB and ExCPT exams to ensure they are job-related and meet California's requirements.

Ms. Herold added that in order to do an adequate assessment of both exams, we need someone specifically trained to do it. This type of specialized staff is in very short supply. The DCA no longer has a PhD to perform this task, and state agencies cannot contract it out until everyone in state service is exhausted. Ms. Herold asked whether the committee wished to continue with this effort.

Dr. Ravnan added that California's pharmacist associations are looking at qualifications of pharmacy technicians, and asked if the committee could table the matter until we get their recommendation.

MOTION: That the committee table the matter of reviewing the ExCPT exam pending the recommendation for changes in pharmacy technicians training currently underway.

M/S: GRAUL/RAVNAN

SUPPORT: 5 OPPOSE: 0

3. California Schools of Pharmacy Proposal to Identify and Agree on the Professional Competencies that Should Be Achieved by the End of Basic Internship Experiences

Chairperson Conroy summarized the background on this issue. The board participated in a project initiated by California's schools of pharmacy, who are working together with other stakeholders to evaluate the components of ACPE approved intern experience at both the basic (IPPE) and advanced (APPE) levels. The project is called the California Pharmacy IPPE/OSCE Initiative.

This initiative is in response to new ACPE accreditation standards that spell out how much time students must spend in IPPEs and APPEs rather than what they should learn (outcomes). Board Member Ravnan, Legislative Coordinator Anne Sodergren, and Ms. Herold attended three meetings, which resulted in a list of basic competencies that students should achieve by the end of the IPPE.

The second phase of this effort began in June 2007 and involves developing a reliable and valid performance-based exam. An objective structured clinical exam (OSCE) would assess student

achievement of these competencies. The timeline aims for incorporation of the standards during academic year 2007-08.

Dr. Conroy stated that the meeting materials included a copy of the competencies developed under this project, as well as a request from Mary Anne Koda-Kimble, who represents the UCSF School of Pharmacy. Dr. Koda-Kimble asks that the board affirm its agreement with this document.

Dr. Ravnan said that without clarification about the board's role, she is concerned that we do not have the authority to approve curriculum.

Dr. Conroy commented about Dr. Koda-Kimble's letter and whether she is asking for board approval.

Mr. Room clarified that this is the type of thing that is affirmed by silence. It would be more appropriate for individual board members to communicate their concerns about deficiencies, rather than the board to affirm the document.

Ms. Herold added that affirming the document has little effect unless the board makes a regulation. At the last meeting, it was suggested that the board look through the guidelines and if something rings untrue, we should call attention to it.

Dr. Gray commented that one of the original concepts of the OSCE program was concern by the school that the required number of hours would interfere with pharmacists' education. The 300-hour requirement was somewhat arbitrary. He suggested a list of competencies that must be obtained, and if they achieved the competencies in 100 hours, should satisfy the ACPE. The arbitrariness of 1500 hours or 500 hours or 2,000 hours doesn't serve the industry or the public safety well. Dr. Gray stressed that we still have students that come out that meet requirements for a license, but do not have these competencies.

Dr. Ravnan commented that we could consider changing the licensing requirements, and entertain the idea of offering a licensing exam similar to the Medical Board. We need to have control over the quality of the exams.

Dr. Conroy asked if there were any comments about the board existing requirements for 900 hours of the 1,500 intern hours be earned inside a pharmacy. She said that some board members felt that 900 hours inside a pharmacy was necessary.

Dr. Hiura stated that he has always had a problem with determining the level of competency of students practicing today. He would like to ask universities what they are lacking and how to correct those deficiencies.

Dr. Gray spoke about the objective of the project, which is that students will come out with experience. He asked whether Dr. Koda-Kimble's objective was that she just wanted

acknowledgement from the board without an official endorsement. He suggested taking it to the full board for discussion.

Mr. Graul stated that there are three issues at hand – basic versus advanced intern training as imposed by ACPE schools, whether or not the board’s requirement for 1,500 hours is appropriate, and whether or not the 900 hours needs to be done as a subset.

Dr. Conroy stated that we tabled the discussion regarding the 900-hours about one year ago pending the ACPE project. She recommended that Dr. Koda-Kimble’s letter be referred to the board in October for discussion.

4. Creighton University School of Pharmacy Program's Web-Based Pathway to PharmD Degrees

Chairperson Conroy stated that the American Council on Pharmacy Education (ACPE) has approved its first online PharmD program, which is being offered by Creighton University. They also offer a traditional PharmD program.

Ms. Herold added that this program has been accredited for a while, and it is innovative. She added that the item was provided to the committee only for information.

Ms. Sodergren added that this program began in 2000, and falls under the same accreditation standards as traditional schools.

Dr. Ravnan asked if any of their students had taken California’s exam.

Ms. Herold responded that she did not know.

5. Update: Disaster Response/California Department of Health Services – Healthcare Surge Project

- Request from San Diego County to Exempt Prescription Container Labeling Requirements for First Responders and Their Families as Part of Emergency Preparedness

The board received a request from San Diego County to provide up to 500,000 bottles of a 7-14 day dosing regiment 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 elsewhere. The county was seeking an exemption from patient-specific labeling because it would be “difficult, if not impossible” to label these containers.

Board staff was unaware under what authority the board could grant such an exemption in advance of a disaster unless the board promulgated a regulation or obtained statutory approval to authorize this.

Dr. Conroy advised that San Diego County withdrew their request, in order to gather more information.

- Request from Ralphs to Deploy Mobile Pharmacies After Declared State of Emergency

Chairperson Conroy advised that the board had received a request for guidance from Ralphs Grocery Co. about the appropriate use of mobile pharmacy trailers. Ralphs would like to use these trailers under emergency conditions or in the event an existing pharmacy is damaged or closed. A copy of the request was provided in the meeting materials packet for committee discussion and recommendation.

Dr. Conroy stated that there are two different situations – damage to a pharmacy, where you would put an RV in the parking lot, or 2) if an entire area is destroyed.

Ms. Herold added that she would defer to Supervising Inspector Ratcliff, and that the NABP recommended that pharmacies have mobile units available.

Mr. Room asked whether they meant a disaster to Ralphs was a disaster to an entire region.

Dr. Ratcliff responded that there are two examples. Example 1 would apply to an existing licensed Ralphs Pharmacy that is damaged and closed. Ralph's would deploy a mobile pharmacy to the parking lot of the closed store, activate the generator, and operate under the current license of the damaged pharmacy.

Mr. Ratcliff clarified that the law currently allows that practice for pharmacies. If there's a fire, or they want to do a remodel – they can operate out of a trailer. We tell them that the wheels must be removed from the trailer so it can't be towed away in the night.

Example 2 would apply to an existing licensed Ralph's Pharmacy that is completely destroyed, and the current license location is not available to park the mobile pharmacy.

Dr. Ratcliff clarified that the drugs ordered must be delivered to the address of record for the licensed entity under California Business and Professions Code section 4059.5. Example 2 creates problems for a supplier, and statutorily, they can't do it, unless a change of address has been approved.

Ms. Herold asked if there were any thoughts on whether we can promote this.

Mr. Graul said the concern is licensing. They can only use the license to replace that pharmacy. If there's a disaster in Sante Fe, from a bigger perspective, trailers could be deployed to bring them in to where the emergency is. Mr. Graul said he was not sure of what is the best way to handle this.

Dr. Conroy added that many chain stores have RVs for this purpose. She gave MEDCO as an example of a chain store that came in to the areas affected by Hurricane Katrina.

Mr. Room stated that the board could certainly issue a temporary license for some fixed location in that area, saying in the interest of an emergency, it has waived provisions. However, you do need to have fixed addresses or locations to issue a license.

Dr. Conroy asked how fast a temporary license could be provided. If it was provided in a matter of weeks or months, that would be of no use during an emergency.

Mr. Hough stated that, as a matter of principle and general policy, the board should be on record encouraging these kinds of trailers. Obviously, in terms of disaster preparedness, it is essential that this would be a matter of policy to encourage Walgreens and others to consider this kind of thing. Mr. Hough stressed that we have got to prepare, and that September 11th showed a need for preparedness.

Mr. Room responded that there are two possible ways to do this. There could be an amendment to the disaster preparedness statement on the Web site to specifically mention and encourage the use of trailers. Another way to do it would be to preload a temporary trailer license procedure that could be expedited in the event of an emergency.

Mr. Walker stated that a statutory or regulatory change could be made, and that the Board of Optometry addressed the matter in their regulations. The Board of Optometry specified how the trailers are to be used, and in what circumstance. Mr. Walker added that he did not think it would be wise to amend the board's emergency preparedness statement at this time prior to an investigation about whether it can be done without regulatory change.

Dr. Hiura added that he felt that during an emergency, anything goes as far as he's concerned. As far as regulations and paperwork, tons of people affected by Katrina got their medications. If you're a professional, you can do as much as possible to help people.

Mr. Graul said that trailers will exist ahead of time, and that having a regulation on the books that addresses those specific trailers makes sense.

Dr. Ravnan added that she liked the concept of trailers as well, but she would rather see one in person and consider the security issues and other factors.

Dr. Conroy added that during Hurricane Katrina, some pharmacies were wiped out and the National Guard was guarding them.

Ms. Herold asked how many trailers Walgreens has.

Dr. Conroy responded that she doesn't know how many trailers they have, but they have RVs ready to respond as needs arise, like in fires.

Ms. Herold said that it appears they drive an RV to a site, and take care of patients, but they are not necessarily licensed at that location. She agreed with Mr. Ratcliff that in the event of a disaster, we don't want to get in the way of doing the right thing. To plan for disaster, we can encourage the use of trailers and develop a regulatory framework for it. Possibly temporary permits may be a solution.

Dr. Conroy added that she served on the NABP committee.

Doug Hillblom, from Prescription Solutions, commented that there are a number of issues as we go into this. For example, what happens to the supplies in the pharmacies that are destroyed? How are pharmacies licensed? What about moving stock from semi-destroyed pharmacies to other pharmacies?

Dr. Gray asked that the board not stray too far. He said that Examples 1 and 2 are taken care of already because the board has recognized those situations in the past. For example, taking the wheels off a trailer. Another example being getting a temporary address change quickly, and the pharmacy is still under a local licensed entity. But there is an "Example 3" which would be an entity wanting to help, but not having a local address. Kaiser has a contingency contract with a mobile home/trailer company that promises, on 12 hours notice, to deliver a unit with security, air conditioning, inside toilets, and washing stations to meet health requirements. The units will be readily available, and they have the same contract with suppliers of generators that run on diesel oil.

Ms. Herold asked whether "immediate" meant within 24 hours.

Dr. Gray responded that he had experience during the Northridge earthquake. During a short period of time, just 48 hours, they had a mobile unit set up in a parking lot.

Mr. Graul asked whether the board has a subcommittee looking at the regulations.

Dr. Conroy responded, no.

Mr. Graul suggested that a subcommittee review the regulation and statutes, looking at disaster preparedness.

Ms. Herold added that the Office of Emergency Services (OES), and part of the Department of Health Services, understand that without medication during an emergency, patient care is compromised. In *The Script*, the board encouraged the flow of medicine so that people can be treated. The board got so far out in front on this issue, the DHS thought the board would waive all of its requirements. To be clear, the board would not waive all requirements -- we just want pharmacists to be there taking care of patients. Ms. Herold emphasized that the board wants to be better prepared to perform its role during an emergency.

Dr. Conroy stated that she sat on the NABP panel. It has since disbanded, but in two days, they came up with guidelines. We should continue to look at licensure issues, and specifically mobile pharmacies that aren't tied to a specific pharmacy.

Dr. Gray added that, as we proceed, we should bring DHS in for discussion because there will be a problem for patients that need Medi-Cal and other indigent patients that can't pay. If medications can't be provided for free, our most disadvantaged patients cannot pay the money and be reimbursed later. He said that, especially in isolated areas, there would be problems because of transportation services. Dr. Gray encouraged the board to ask that DHS participate in this discussion.

Dr. Conroy added that in Hurricane Katrina, FEMA didn't require payment. FEMA later did pay, but you must have had a contract or agreement with FEMA to get that.

Dr. Gray responded that many pharmacies never got paid by FEMA.

Dr. Hiura stated that payments to pharmacies will not be an issue during an emergency.

- Rough and Ready 2007

Dr. Conroy stated that she recently attended "Rough and Ready 2007," a joint civilian-military disaster field training and demonstration. The scenario presented was a Southern California disaster causing mass casualties. She said it was quite interesting, and the event included participation by three mobile field hospitals. The field hospitals were set up, and a number of different organizations were also there. The California National Guard, among other agencies, participated. The California National Guard can put 82 gurneys on one plane.

Dr. Conroy emphasized that the different programs that participated talked about how they all linked together. Emergency personnel, from fire fighters to nurses, provided better understanding about how they all work together. The Governor has emphasized emergency preparedness during the last couple of years.

Dr. Conroy added that the communication capabilities are impressive, and a plan is in place outlining which entity comes in first second, second, and third, to provide care.

- California Medical Volunteers

Dr. Conroy advised that board staff recently participated in the evaluation of proposals for the implementation and operation of California's Emergency System for the Advanced Registration (ESAR) of Volunteer Health Professionals. This system, known as the California Medical Volunteers, will play an instrumental role in the deployment of registered health care professionals in response to disasters and terrorist events.

The board will continue to highlight this in upcoming newsletters to encourage pharmacist participation.

Ms. Herold added that it was an honor to be asked to participate in this, which is due to the board's efforts in disaster response. Anne Sodergren sat on the panel.

Ms. Herold said that the board would continue to promote it in *The Script*. She emphasized that the importance of training and drills. She said that pharmacists have not been well represented in the planning stages, until recently.

6. Legislative Proposal: Establishment of State Protocols for Immunizations

Dr. Conroy summarized the history of this issue. She stated that at the July 2007 Board Meeting, the board voted to adopt the proposed state protocols to allow pharmacists to administer immunizations. At the last Licensing Committee Meeting, Dr. Jeff Goad, a professor from USC, made a presentation to the committee about establishing state protocols for immunizations by pharmacists. Dr. Goad stated that pharmacists can administer immunizations in 44 states. California is one of these states.

Business and Professions Code Section 4052(a)(9) allows a pharmacist to administer immunizations pursuant to a protocol with a prescriber. According to testimony provided by Dr. Goad, physicians are reluctant to accept the liability for this action, even though it has wide support. Additionally, Health and Safety Code Section 1261.3 allows for a pharmacist to administer both the influenza and pneumococcal immunizations for a certain patient population in a skilled nursing facility pursuant to standing orders.

Since the July 2007 Board Meeting, the proposed language has been revised to detail more specific training requirements, continuing education requirements, as well as recordkeeping and reporting requirements.

The meeting materials contained a draft of the proposed language for committee consideration as follows:

Business and Professions Code Section 4052.8

- (a) A pharmacist may order and administer immunizations pursuant to a protocol with a prescriber or pursuant to the current Recommended Adult and Adolescent Immunization Schedules provided by the Centers for Disease Control and Prevention consistent with the published recommendations of the Advisory Committee on Immunization Practices.
- (b) Any pharmacist administering vaccines pursuant to this section may administer epinephrine by injection for severe allergic reactions.
- (c) Prior to performing any procedure authorized by this section, a pharmacist shall have completed the American Pharmacists Association pharmacy-based immunization

- certificate program or another pharmacy-based immunization training program endorsed by Centers for Disease Control and Prevention within the last four years.
- (d) A pharmacist administering immunizations pursuant to this section must complete 2.5 hours of immunization related continuing education coursework annually.
 - (e) Any pharmacist administering vaccines pursuant to this section shall maintain current Basic Life Support certification.
 - (f) Any adverse event must be reported to the Vaccine Adverse Event Reporting System within the U.S. Department of Health and Human Services.
 - (g) The patient or patient's agent must receive the appropriate Vaccine Information Sheet for each vaccine administered.
 - (h) A pharmacist who administers vaccines pursuant to this section shall provide documentation of vaccine administration to a specified provider as directed by the patient or patient's agent.
 - (i) The pharmacist must maintain a vaccine administration record that includes the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, vaccine information statement date, and the name and title of the person administering the vaccine

Dr. Conroy asked whether item “c” relating to a pharmacist completing a certification program within the last four years was an additional requirement.

Ms. Herold responded, yes, that is an additional requirement.

Mr. Room said that vaccination records would be kept for three years, and medical records would be kept longer. He said that another possibility would be that vaccination records be transmitted to a patient’s primary care physician.

Ms. Sodergren noted that subdivision “h” might not be clear. The language needs to be reworked if a pharmacist is to provide the records to a specific provider.

Orriette Quandt, Longs Drugs, said that pharmacists who do immunizations keep the records for four years.

Dr. Gray said the requirements may not be exactly applicable to community pharmacy programs because most vaccines are pediatric. They keep the medical records until the age of majority plus one year, because that’s the law regarding minors. With new vaccines for pre-teens and teenage girls, they keep records often longer than the three or four years, the traditional period for record keeping. They keep records for a national fund set up to cover costs for patients harmed from the vaccine. They must have records to reference.

Dr. Gray added that the liability of providing these vaccines is so high, a fund was set up for kids harmed by a vaccine. He also added that people who come in saying “give me a shot,” usually don’t have a doctor.

Mr. Room responded that the best option is to have cascading requirements. If a patient's provider can be identified, then keep the records for three, four, or five years, or age of majority plus one year. That could be a possibility.

Dr. Gray responded that for vaccines covered under Medicare Part D, there's a ten-year record-keeping requirement.

Medical records are required to be kept for seven years. An immunization would qualify as treatment or service provided by a medical provider, so it would fall under that requirement.

Dr. Gray said that, here again, we need to engage DHS' campaign to provide vaccines to children. DHS has a program, which is trying to get indigents, American Indians, and everyone vaccinated. They are putting together a database to feed into. With those populations, patients themselves don't keep good records, or complete inoculations if a series of inoculations is needed. He suggested that the board ask DHS what they do. He offered to get the name of the DHS person who is interested in increasing their outreach program.

Dr. Conroy said that there's a lot of talk about a statewide registry for childhood vaccinations. If that was in existence, we would want pharmacists to report into it. She asked if there were any thoughts or comments on that.

Mr. Graul suggested that the board ask Dr. Goad because he's been running a travel clinic for many years. Dr. Goad may have insight into this issue. Mr. Graul said he agreed with Mr. Walker that seven years is the requirement for keeping records on adults. For minors, it is the age of majority, plus one year.

Dr. Gray suggested considering a requirement that a pharmacy give a patient a record of their vaccinations. He said that patients get confused on where they're at in a series.

Dr. Conroy responded that pharmacies are required to give patients a vaccine information sheet, but not a record of their vaccines.

Following a discussion about the age for adolescents, staff agreed to refine the regulation.

Dr. Gray added that immunizations are not necessarily an injection. For example, flu mists.

Dr. Ratcliffe noted that under subdivision "d" a pharmacist administering immunizations must complete 2.5 hours of immunization-related continuing education coursework annually. Other than emergency contraception, this is the only carve-out. He asked whether 2.5 hour requirements was going to be maintained, other than being sent to the board.

Dr. Gray added, that as a practical matter, you don't receive continuing education for a half hour. It would be either two or three hours, and it should be from an accredited provider.

Ms. Sodergren noted that Dr. Goad said that information is contained in the CDC recommendations.

Ms. Herold said that this is a piece of legislation we want to sponsor next year. We should get the language in good shape, and we are seeking comments and legislative proposals so we can refine it. The board needs professionals to support this as a coalition.

Dr. Conroy asked if there were any additional comments on this issue. There were none.

7. Competency Committee Report and Update on Transition to a New Test Administration Company for the California Pharmacist Jurisprudence Examination

Conversion to New Examination Vendor

Dr. Conroy referred to the information in the meeting materials. On June 1, 2007, the board converted to a new vendor to administer the CPJE. The new firm is Psychological Services, Inc. (PSI). Board staff is working to resolve the issues that have arisen as a result of the transition to the new vendor.

Examination scores from tests administered at PSI were released on August 27. Part of the delay was due to the conversion, but also there was slow test taking since June 1, 2007 by the applicants. Another quality assurance check is scheduled to begin September 1, 2007.

Ms. Herold stated that the overall pass rate so far is 80 percent. Quality assurance reviews are built in, and they are important to ensure the integrity of the CPJE. Ms. Herold emphasized that the board's priority is to license those who have passed the exam.

Competency Committee

The Competency Committee held a two-day meeting in August to discuss exam-related issues and work on future questions. One issue discussed was the compromise of exam questions and cheating on the exam, which led the committee to request that the board seek higher penalties from those applicants who compromise the exam discussed below. There are two meetings scheduled this fall; one in September 2007 and one in October.

NAPLEX Compromised

Dr. Conroy stated that on August 6, 2007, the NABP issued a notice to all state boards of pharmacy that US Marshals seized materials and computers from the University of Georgia College of Pharmacy after allegations of breaches of the National Pharmacy Licensure Examination (NAPLEX). As such, the NABP was suspending administration of the NAPLEX until the matter could be investigated. A process that could take months.

Dr. Conroy noted that the meeting materials contained recent updates by the NABP, as well as the information posted on the board's Web site and news articles.

The board supports the efforts by the NABP to secure its examination from possible compromise and to fully investigate the matter before resuming administration of the examination. Failure on the part of NABP to take such action could result in compromised public safety.

Dr. Conroy added that applicants should continue to apply for the NAPLEX, so that once the exam is ready, they can take it.

Regulation Proposal to Strengthen Penalty for Dishonest Conduct by Applicants

Dr. Conroy referred to the meeting materials, which contained draft regulatory language for the committee's consideration. The language strengthens the penalty an applicant would incur for dishonest conduct during an examination, as well as further clarify the penalty an applicant would incur for conveying or exposing any part of the licensing examination.

This recommendation is generated from the board's Competency Committee, which is responsible for the development of the CPJE examination. According to the board's current exam psychometrician, the cost to generate a new test item is \$2,000 per test item (there are 90 test items on any test). Compromised test items pose not only a financial loss to the board, but also inhibit the board's ability to test for minimum competency and if an otherwise incompetent applicant passes the exam because the exam has been compromised, such a breach is a public safety issue.

As recently as September 2005, the board disciplined two licensees for compromising the board examination and is currently working with the NABP to address allegations of a recent candidate who allegedly cheated on the NAPLEX while attempting to qualify for a pharmacist license in California.

Ms. Herold noted that the proposed language in the meeting materials was developed prior to the recent compromise of the exam. The recent compromise involved an applicant who was caught in her car while taking the exam. Dr. Hiura and Dr. Ravnan were prior members of the Competency Committee, and they were aware of the hard work of this committee because the integrity of the exam is important.

Dr. Ravnan asked whether penalties are in place for applicant found cheating, after they have already received a license.

Mr. Room responded, yes; however, it became a formal disciplinary process.

Dr. Gray stated that in Georgia, there was confusion among faculty about whether they could ask a licensed pharmacist about the exam experience. If faculty asked a pharmacist if this was on the exam or that was on the exam, would that be considered cheating? He added that it happens all the time.

Ms. Herold responded that, technically yes. And if you are specific about the questions and possible answers, you are reconstructing the exam. The agreement candidates must sign before taking the exam says they agree with this policy. This is a licensing exam, and the board spends a lot of money validating whether a person has the knowledge to perform safely. Generally helping students prepare is different than crossing the line by memorizing questions and answers. Ms. Herold recommended that applicants just don't talk about the exam.

Dr. Conroy suggested that there is a difference between confirming that there are questions about hypoglycemia on the exam, as opposed to memorizing a specific question and then sharing it.

Dr. Gray stated that he knows there are dinner meetings where faculty are general interested in whether they gave them the help and information they needed for the exam. They may ask if the exam went into a pharmacodynamic. Well meaning people may mislead a student down a wrong path. Education and outreach may be needed, so this issue should go to the Communication and Public Education Committee. Dr. Gray added that he's familiar with an exam prep course that went over the line, but there is ordinary faculty discussion that coursework is pertinent to what students need to know. He considers cheating as writing on a cup or going out to their car.

Mr. Room added that he was fine if we want to provide public education, but we shouldn't engage too much in hypotheticals as far as what would constitute a violation for fear of compromising future cases. It comes down to discretion – when it crosses the line into “teaching to the exam,” it should be left in the hands of enforcement staff as to when that becomes an enforcement case. Don't be so specific as to say you can ask three questions about the exam, but not four questions. The general message is that the exam is confidential. Don't repeat items on the exam, and don't convey how many questions about this or that are on the exam. They may be innocent questions, but they endanger the confidentiality of those exam questions.

Ms. Herold added the members of the Competency Committee are sworn not to discuss the exam, and not to tell people that they're on the committee. Members of faculty sometimes put pressure on people to reveal what's on the exam.

MOTION: That the committee approve the proposed language to strengthen the penalty for dishonest conduct by applicants, amending Sections 1721 and 1723.1 of Division 17 of Title 16 of the California Code of Regulations from one year to three years.

1721. Dishonest Conduct During Examination.

An applicant for examination as a pharmacist who engages in dishonest conduct during the examination shall not have that examination graded, shall not be approved to take the examination for ~~twelve months~~ three years from the date of the incident, and shall surrender his or her intern ~~and~~ license until eligible to take the examination. The applicant may not be issued a pharmacy technician license until the applicant is again eligible to take the examination.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4200, Business and Professions Code.

1723.1. Confidentiality of Examination Questions.

Examination questions are confidential. Any applicant for any license issued by the board who removes all or part of any qualifying examination from the examination room or area, or who conveys or exposes all or part of any qualifying examination to any other person may be disqualified as a candidate for a license. The applicant shall not be approved to take the examination for three years from the date of the incident and shall surrender his or her intern license until again eligible to take the examination. The applicant may not be issued a pharmacy technician license until the applicant is again eligible to take the examination.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 123 and 496, Business and Professions Code.

M/S: GRAUL/HIURA

SUPPORT: 5 OPPOSE: 0

ADJOURNMENT

There being no additional business, Chairperson Conroy adjourned the meeting at 11:55 a.m.

Attachment 11

Licensing Statistics

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
APPLICATIONS													
Received													
Pharmacist (exam applications)	169	115	108										392
Pharmacist (initial licensing applications)	205	42	361										608
Intern pharmacist	52	287	316										655
Pharmacy technician	604	590	634										1828
Pharmacy	49	48	25										122
Sterile Compounding	11	3	11										25
Clinics	13	5	8										26
Hospitals	5	0	0										5
Nonresident Pharmacy	8	6	6										20
Licensed Correctional Facility	0	0	0										0
Hypodermic Needle and Syringes	1	3	0										4
Nonresident Wholesalers	9	10	6										25
Wholesalers	3	5	4										12
Veterinary Food-Animal Drug Retailer	0	0	0										0
Designated Representatives	54	33	24										111
Issued													
Pharmacist	195	58	359										612
Intern pharmacist	82	287	268										637
Pharmacy technician	684	629	267										1580
Pharmacy	27	53	34										114
Sterile Compounding	1	5	8										14
Clinics	7	10	5										22
Hospitals	2	6	0										8
Nonresident Pharmacy	1	3	11										15
Licensed Correctional Facility	0	0	1										1
Hypodermic Needle and Syringes	1	0	1										2
Nonresident Wholesalers	6	4	11										21
Wholesalers	6	2	9										17
Veterinary Food-Animal Drug Retailer	0	0	0										0
Designated Representatives	41	26	36										103

u/a - Information not available for July and August. Effective September 2007, dated collected through Department's Application Tracking System and will be available for future reports.

*Calstars reports not available

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Pending*													
Pharmacist Examination	u/a	u/a	1086										1086
Intern pharmacist	u/a	u/a	109										109
Pharmacy technician	u/a	u/a	739										739
Pharmacy	u/a	u/a	172										172
Sterile Compounding	u/a	u/a	60										60
Clinics	u/a	u/a	77										77
Hospitals	u/a	u/a	22										22
Nonresident Pharmacy	u/a	u/a	58										58
Licensed Correctional Facility	u/a	u/a	0										0
Hypodermic Needle and Syringes	u/a	u/a	7										7
Nonresident Wholesalers	u/a	u/a	129										129
Wholesalers	u/a	u/a	37										37
Veterinary Food-Animal Drug Retailer	u/a	u/a	2										2
Designated Representatives	u/a	u/a	160										160
Change of Pharmacist-in-Charge													
Received	74	165	88										327
Processed	148	128	92										368
Pending	33	70	66										0
Change of Exemptee-in-Charge													
Received	5	14	11										30
Processed	13	21	7										41
Pending	21	56	60										0
Change of Permits													
Received	37	191	11										239
Processed	18	0	1										19
Pending	119	310	320										0
Discontinuance of Business													
Received	17	19	19										55
Processed	28	22	19										69
Pending	3	0	0										0

u/a - Information not available for July and August. Effective September 2007, dated collected through Department's Application Tracking System and will be available for future reports.

*Calstars reports not available

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Renewals Received													
Pharmacist	1429	3074											4503
Pharmacy technician	1724	4015											5739
Pharmacy	609	636											1245
Sterile Compounding	9	63											72
Hospitals	27	28											55
Clinics	46	184											230
Nonresident Pharmacy	18	40											58
Hypodermic Needle and Syringes	12	44											56
Nonresident Wholesalers	19	65											84
Wholesalers	19	108											127
Veterinary Food-Animal Drug Retailer	0	5											5
Designated Representatives	74	410											484

u/a - Information not available for July and August. Effective September 2007, data collected through Department's Application Tracking System and will be available for future reports.

*Calstars reports not available

Attachment 12

*First Quarterly Report on Committee
Goals for 2007/08*

LICENSING COMMITTEE

Goal 2: Ensure the qualifications of licensees.

Outcome: Qualified licensees

Objective 2.1	Issue licenses within 3 working days of a completed application by June 30, 2011.								
Measure:	Percentage of licenses issued within 3 work days.								
Tasks:	1. Review 100 percent of all applications within 7 work days of receipt.								
		Apps. Received:				Average Days to Process:			
		Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4
	Pharmacist (exam applications)	392				15			
	Pharmacist (initial licensing)	608				10			
	Pharmacy Intern	655				30			
	Pharmacy Technician	1828				16			
	Pharmacies	127				18			
	Non-Resident Pharmacy	20				17			
	Wholesaler	12				20			
	Veterinary Drug Retailers	0				10			
	Designated Representative	111				10			
	Out-of-state distributors	25				20			
	Clinics	26				21			
	Hypodermic Needle & Syringe Distributors	4				10			
	Sterile Compounding	25				10			
	2. Process 100 percent of all deficiency documents within 5 work days of receipt.								
		Average Days to process deficiency:							
		Qtr 1	Qtr 2	Qtr 3	Qtr 4				
	Pharmacist (exam applications)	15							
	Pharmacist (initial licensing)	7							
	Pharmacy Intern	15							
	Pharmacy Technician	15							
	Pharmacies	4							
	Non-Resident Pharmacy	10							
	Wholesaler	10							
	Veterinary Drug Retailers	2							
	Designated Representative	5							
	Out-of-state distributors	10							
	Clinics	1							
	Hypodermic Needle & Syringe	2							

3. Make a licensing decision within 3 work days after all deficiencies are corrected.

	Average Days to Determine to Deny/Issue License:			
	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist (exam applications)	1			
Pharmacist (initial licensing)	1			
Pharmacy Intern	1			
Pharmacy Technician	3			
Pharmacies	4			
Non-Resident Pharmacy	5			
Wholesaler	4			
Veterinary Drug Retailers	1			
Designated Representative	1			
Out-of-state distributors	4			
Clinics	1			
Hypodermic Needle & Syringe	1			

4. Issue professional and occupational licenses to those individuals and firms that meet minimum requirements.

	Licenses Issued:			
	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist	612			
Pharmacy Intern	637			
Pharmacy Technician	1580			
Pharmacies	123			
Non-Resident Pharmacy	15			
Wholesaler	17			
Veterinary Drug Retailers	0			
Designated Representative	103			
Out-of-state distributors	21			
Clinics	22			
Hypodermic Needle & Syringe	2			
Sterile Compounding	14			

5. Withdrawn licenses to applicants not meeting board requirements.

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacy Technician	1			
Pharmacies	4			
Non-Resident Pharmacy	1			
Clinics	0			
Sterile Compounding	0			
Designated Representative	0			
Hypodermic Needle & Syringe	0			
Out-of-state distributors	1			
Wholesaler	2			

6. Deny applications to those who do not meet California standards.

7. Responding to email status requests and inquiries to designated email addresses.

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist/Pharmacist Intern	1,863			
Pharmacy Technicians	1,092			
Site licenses (pharmacy, clinics)	1,156			
Site licenses (wholesalers, nonresident pharmacies)	1,103			

8. Responding to telephone status request and inquiries.

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist/Pharmacist Intern	671			
Pharmacy Technicians	150			
Site licenses (pharmacy, clinics)	243			
Site licenses (wholesalers, nonresident pharmacies)	370			

Objective 2.2	Cashier 100 percent of all application and renewal fees within two working days of receipt by June 30, 2011.
Measure:	Percentage of cashiered application and renewal fees within 2 working days.
Tasks:	<ol style="list-style-type: none"> <li data-bbox="370 247 1529 646">1. Cashier application fees. <ul style="list-style-type: none"> <li data-bbox="440 279 1529 342"><i>1st Qtr 06/07: The average processing time for processing new application fees is 2-3 working days.</i> <li data-bbox="440 352 1529 415"><i>2nd Qtr 06/07: The average processing time for processing new application fees is 2-3 working days.</i> <li data-bbox="440 426 1529 489"><i>3rd Qtr 06/07: The average processing time for processing new application fees is 3 working days.</i> <li data-bbox="440 499 1529 562"><i>4th Qtr 06/07: The average processing time for processing new application fees is 2-3 working days.</i> <li data-bbox="440 573 1529 636"><i>1st Qtr 07/08: The average processing time for processing new application fees is 2-3 working days.</i> <li data-bbox="370 657 1529 877">2. Cashier renewal fees. <ul style="list-style-type: none"> <li data-bbox="440 688 1529 720"><i>1st Qtr 06/07: The average processing time for cashiering is 2-3 working days.</i> <li data-bbox="440 730 1529 762"><i>2nd Qtr 06/07: The average processing time for cashiering is 2-3 working days.</i> <li data-bbox="440 772 1529 804"><i>3rd Qtr 06/07: The average processing time for cashiering is 2-3 working days.</i> <li data-bbox="440 814 1529 846"><i>4th Qtr 06/07: The average processing time for cashiering is 2-3 working days.</i> <li data-bbox="440 856 1529 877"><i>1st Qtr 07/08: The average processing time for cashiering is 2-3 working days.</i> <li data-bbox="370 888 1529 1058">3. Secure online renewal of licenses. <ul style="list-style-type: none"> <li data-bbox="440 919 1529 982"><i>1st Qtr 06/07: Board meets with programmers to initiate parameters for board licensing programs to convert to DCA Applicant Tracking Program.</i> <li data-bbox="440 993 1529 1058"><i>Jan. 2007: Board converts all application programs to DCA's Applicant Tracking Program. See Objective 2.4, Task 7 below.</i>

Objective 2.3	Update 100 percent of all information changes to licensing records within 5 working days by June 30, 2011.
Measure:	Percentage of licensing records changes within 5 working days.
Tasks:	<ol style="list-style-type: none"> 1. Make address and name changes. <ul style="list-style-type: none"> <i>1st Qtr 06/07: Processed 1,832 address changes.</i> <i>2nd Qtr 06/07: Processed 1,322 address changes.</i> <i>3rd Qtr 06/07: Processed 1,613 address changes.</i> <i>4th Qtr 06/07: Processed 1,857 address changes.</i> <i>1st Qtr 07/08: Processed 1,990 address changes.</i> 2. Process discontinuance of businesses forms and related components. <ul style="list-style-type: none"> <i>1st Qtr 06/07: Processed 41 discontinuance-of-business forms. Processing time is 46 days.</i> <i>2nd Qtr 06/07: Processed 0 discontinuance-of-business forms.</i> <i>3rd Qtr 06/07: Processed 72 discontinuance-of-business forms. Processing time is 30 days.</i> <i>4th Qtr 06/07: Processed 38 discontinuance-of-business forms. Processing time is 30 days.</i> <i>1st Qtr 07/08: Processed 69 discontinuance-of-business forms. Processing time is 30 days.</i> 3. Process changes in pharmacist-in-charge and designated representative-in-charge. <ul style="list-style-type: none"> <i>1st Qtr 06/07: Processed 247 pharmacist-in-charge changes. Average processing time is 30 days. Processed 0 designated representative-in-charge changes.</i> <i>2nd Qtr 06/07: Processed 382 pharmacist-in-charge changes. Average processing time is 30 days. Processed 5 designated representative-in-charge changes. Average processing time is 10 days.</i> <i>3rd Qtr 06/07: Processed 358 pharmacist-in-charge changes. Average processing time is 30 days. Processed 0 designated representative-in-charge changes.</i> <i>4th Qtr 06/07: Processed 544 pharmacist-in-charge changes. Average processing time is 30 days. Processed 14 designated representative-in-charge changes. Average processing time is 14 days.</i> <i>1st Qtr 07/08: Processed 368 pharmacist-in-charge changes. Average processing time is 30 days. Processed 30 designated representative-in-charge changes. Average processing time is 30 days.</i> 4. Process off-site storage applications. <ul style="list-style-type: none"> <i>1st Qtr 06/07: Processed and approved 42 off-site storage applications. Average processing time is 30 days.</i> <i>1st Qtr 07/08: Processed and approved 42 off-site storage applications. Average processing time is 30 days.</i> 5. Transfer of intern hours to other states. <ul style="list-style-type: none"> <i>1st Qtr 06/07: Processed 76 applications. Average processing time is 30 days.</i> <i>2nd Qtr 06/07: Processed 45 applications. Average processing time is 30 days.</i> <i>1st Qtr 07/08: Processed 76 applications. Average processing time is 30 days.</i>

Objective 2.4	Implement at least 25 changes to improve licensing decisions by June 30, 2011.
Measure:	Number of implemented changes.
Tasks:	<ol style="list-style-type: none"> <li data-bbox="363 210 1487 273">1. Determine why 26 states do not allow the use of a CA license as the basis for transfer a pharmacist license to that state. <i>Jan. 2007: Survey of some states indicate misunderstanding of why California cannot accept NAPLEX scores earned before January 1, 2004. Educational efforts, on a state by state basis, initiated.</i> <i>March 2007: Pennsylvania agrees to accept California NAPLEX scores.</i> <i>May 2007: At National Association of Boards of Pharmacy meeting several states agree to reconsider their position against accepting California scores.</i> <li data-bbox="363 504 1487 567">2. Work with the University of California to evaluate the drug distribution system of its clinics and their appropriate licensure. <li data-bbox="363 577 1487 714">3. Work with the Department of Corrections on the licensure of pharmacies in prisons. <i>June 2007: Meet with the Department of Corrections Receiver to discuss possible regulatory structures for drug dispensing and distribution within correctional facilities.</i> <li data-bbox="363 724 1487 1470">4. Work with local and state officials on emergency preparedness and planning for pandemic and disasters. Planning to include the storage and distribution of drugs to assure patient access and safety. <i>Sept. 2006: Committee hears presentation by DHS on emergency preparedness.</i> <i>Oct. 2006: Presentation by Orange County and LA emergency response staff at NABP District 7 & 8 meeting. Board meeting has presentation by DHS and board develops policy statement for licensees in responding to declared emergencies.</i> <i>Jan. 2007: Board publishes disaster response policy statement.</i> <i>Feb. & March 2007: Board attends seven-day DHS-hosted training session on surge emergency response as part of the state's disaster response.</i> <i>April - June 2007: Board continues to participate in SURGE planning activities and in a joint public/private partnership project envisioned by the Governor.</i> <i>June 2007: Board staff aids in contract evaluation to select a consultant to provide pre-emergency registration of health care providers.</i> <i>Sept. 2007: Board attends Rough & Ready Demonstration in Orange County.</i> <i>Oct. 2007: Board considers legislative proposal to license mobile pharmacies for deployment during declared disasters.</i> <i>Staff resume attendance at ESAR VHPs meeting of EMSA.</i> <li data-bbox="363 1480 1487 1507">5. Evaluate the need to issue a provisional license to pharmacy technician trainees.

6. Evaluate use of a second pharmacy technician certification examination (ExCPT) as a possible qualifying route for registration of technicians.
- Sept. 2006: Committee hears presentation on ExCPT exam approved for certification of technicians by five states. Committee directs staff to evaluate exam for possible use in California.*
- Dec. 2006: DCA recruiting for Chief of Examination Resources Office; review postponed. Additional methods to accomplish review considered.*
- March 2007: DCA recruiting for Chief of Examination Resources Office; review postponed. Additional methods to accomplish review considered.*
- May 2007: Board seeks private contractor to evaluate both ExCPT and PTCB exams for job validity.*
- Sept. 2007: Board required to check with other state agencies to ensure that state-employed PhD psychometricians are not able to perform this review before the board can contract for services. Committee recommends delay until CSHP and CPhA complete their review of pharmacy technician training and knowledge.*
7. Implement the Department of Consumer Affairs Applicant Tracking System to facilitate implementation of I-Licensing system, allowing online renewal of licenses by 2008.
- July 2006: Board executive officer becomes executive sponsor of program.*
- Nov. 2006: Board completes system identification of parameters for each licensing program.*
- Dec. 2006-Jan. 2007: Preparatory work and pilots completed; Board Staff initiates transfer to ATS system as sole platform for applicant tracking for all licensing programs.*
- March 2007: Work on securing vendors for I-Licensing continues. Staff changes at DCA may delay implementation.*
- June 2007: DCA hires additional staff for I-Licensing project. Implementation for board programs delayed until mid-2009.*
- Aug. 2007: Executive Officer still on executive steering committee.*
8. Participate with California's Schools of Pharmacy in reviewing basic level experiences required of intern pharmacists, in accordance with new ACPE standards.
- 3rd Qtr 06/07: Board attends 3 day-long working sessions convened by California's schools of pharmacy to develop list of skills students should possess by end of basic intern level experience (about 300 hours).*
- Oct. 2007: Board considers basic internship competencies developed under the program.*
9. Implement new test administration requirements for the CPJE.
- March 2007: Board advised about new exam vendor for CPJE effective June 1, 2007. Board notifies all CPJE eligible candidates of pending change, advises California schools of pharmacy graduating students and applicants in general.*
- June 2007: Shift to new exam vendor, PSI, takes place. New Candidates Guide is printed and distributed. Some transition issues to new vendor exist and are being worked on.*
- Oct. 2007: Transition efforts to PSI continue.*