



California State Board of Pharmacy

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

NOTICE OF MEETING and AGENDA Licensing Committee

DATE: SEPTEMBER 5, 2007

TIME: 9:30 a.m. – 1 p.m.

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

This committee meeting is open to the public and will be held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Karen Abbe (916) 574-7946, at least five working days before the meeting.

Opportunities are provided for public comment on each agenda item. Board members who are not on the committee may also attend and comment.

Note: Pharmacists and pharmacy technicians who attend the full committee meeting can be awarded two hours of CE, in accordance with the board's CE policy. A maximum of four CE hours can be earned each year by attending the meetings of two different board committees.

Call to Order

9:30 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
2. Update: Request to Add the Exam for the Certification of Pharmacy Technicians Developed by the Institute for the Certification of Pharmacy Technicians as a Qualification Method for Pharmacy Technician Registration
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
4. Creighton University School of Pharmacy Program's Web-Based Pathway to PharmD Degrees
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
 - Request from Ralph's to Deploy Mobile Pharmacies After Declared State of Emergency
 - California Medical Volunteers
6. Legislative Proposal: Establishment of State Protocols for Immunizations
7. Competency Committee Report and Update on Transition to a Test Administration Company for the California Pharmacist Jurisprudence Examination

Adjournment

1 p.m.

Meeting materials will be available from the board's Web site by August 31, 2007

Agenda Item 1

Compounding Regulation Proposal

- Background Memo
- Draft language
- Comment from McGuff
Compounding Pharmacy
Services, Inc.
- Draft Self-Assessment Form

Memorandum

To: Licensing Committee

Date: August 30, 2007

From: Board of Pharmacy

Subject: Compounding by Pharmacies

Background:

At the January 2007 Board Meeting, the board moved to regulation hearing proposed regulations for pharmacies that compound medication, providing patient protections when they receive medication compounded by a pharmacy. These regulations were developed during 2004 while the board was convening its Work Group on Compounding with stakeholders and other regulatory agencies.

At the January Board Meeting, noting that some individuals may wish to comment on the regulations before they are noticed, the board also asked that those individuals with comments to provide these comments to the Licensing Committee.

At and after the March Licensing Committee, comments were received from several interested parties.

Staff has reviewed these comments, looked to the proposed language from the federal bill associated with Senator Kennedy and made several modifications to the language.

At the July Board Meeting, the board voted to move forward this language and initiate the rulemaking process. Board staff has now developed the referenced self-assessment form. This form, which will be incorporated by reference in the regulation language, requires board approval to be included as part of the regulation package.

Staff received one additional comment (attached) requesting further refinement to the language. The enclosed draft language incorporates the change and is indicated with double strikeout and double underline.

This Meeting:

The revised language and the draft self-assessment form are provided for committee review and comment and will then be presented at the October Board Meeting with the intent of obtaining board approval and moving forward with the formal rulemaking process after the October Board Meeting.

§1716.1. Compounding Unapproved Drugs for Prescriber Office Use.

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

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

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

§1716.2. Record Requirements—Compounding for Future Furnishing.

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

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

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

Article 4.5 General Compounding

§1735. Compounding in Licensed Pharmacies

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

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

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

§1735.1. Compounding Definitions

- (a) “Integrity” means retention of potency until the expiration date noted on the label.
- (b) “Potency” means active ingredient strength within +/- 10% of the labeled amount.
- (c) “Quality” means the absence of harmful contaminants, 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: Section 4005, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, and 4052, Business and Professions Code.

§1735.2. Compounding Limitations and Requirements

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

¹ Moved from 1716.1

- (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 8/07). The self assessment shall subsequently be performed before July 1 of each year, within 30 days of the designation of a new pharmacist-in-charge, or within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

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

§1735.3. Records of Compounded Drug Products

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

- (9) The expiration date of the final compounded drug product.
- (10) The quantity or amount of drug product compounded.²

- (a) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.
- (b) 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.
- (c) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.

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

§1735.4. Labeling of Compounded Drug Products

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

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

§1735.5. Compounding Policies and Procedures

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

² Imported in modified form from 1716.2

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

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

§1735.6. Compounding Facilities and Equipment

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

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

§1735.7. Training of Compounding Staff

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

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

§1735.8. Compounding Quality Assurance

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

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

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

§1751.3. Recordkeeping Requirements.

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

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

August 6, 2007

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



Dear Ms. Herold,

Please ask the Board of Pharmacy to consider revising one section of the Proposed Regulation Requirements for Pharmacies that Compound.

Proposed:
§1735.3. Records of Compounded Drug Products

(6) The manufacturer and lot number of each component.

Recommended Change:
§1735.3. Records of Compounded Drug Products

(6) The manufacturer or supplier and lot number of each component.

Rationale: Some suppliers will not provide the name of the manufacturer of the raw material (component). I suspect they do this so the pharmacy will not bypass the supplier by purchasing directly from the manufacturer if the name of the manufacturer is divulged.

Unless a provision is made to use the name of the supplier (if one cannot obtain the name of the manufacturer) many raw materials (components) will not be available. This may deny the patient a compounded preparation that may be critical to that patient.

Please have the Committee call me if there are any questions.

Very best wishes,

McGuff Compounding Pharmacy Services, Inc.

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

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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.

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)

Yes No N/A

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

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 to as defined.

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.

Is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice.

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.

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

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.

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):
 - 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 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 finale 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 he drugs are placed in a secure storage facility in the same building as the pharmacy 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 required information required in B&PC 4076.
- The container or receipt contains a statement that the drug the drug has been compounded by the pharmacy. (CCR 1735.4(b))
- Drug products compounded into unit-dose containers 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, 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.

CORRECTIVE ACTION OR ACTION PLAN: _____

7. Training of Compounded 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 developed 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.

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: (CCR 1735.8)

Verification, monitoring and review of the adequacy of the compounding processes as well as documentation of review of those processes by qualified pharmacy personnel.

Qualitative and quantitative integrity, potency, quality and labeled strength analysis of compounded drug products.

Such reports are retained by the pharmacy and collated with the compounding record and master formula.

Scheduled action in the event any compounded drug product is ever discovered to be below minimum standards for integrity, potency, quality or labeled strength.

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 _____ Date _____
(Pharmacist-in-Charge)

Agenda Item 2

ExCPT Examination as a
Qualifying Method for
Pharmacy Technicians

Memorandum

To: Licensing Committee

Date: August 30, 2007

From: Board of Pharmacy

Subject: Exam for the Certification of Pharmacy Technicians (ExCPT)

In California, individuals may become qualified for registration as pharmacy technicians by one of four means:

1. Possessing an associate's degree in pharmacy technology.
2. 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).
3. Graduating from a school of pharmacy recognized by the board.
4. Being certified by the Pharmacy Technician Certification Board.

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

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.

Board staff was recently advised that this review must be completed by DCA staff within the OER or by specialized staff employees of another agency (e.g., Department of Education). We hope to initiate this review in the coming months and provide a report to the Licensing Committee in the next six months.

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

Agenda Item 3

- Update on OSCE Assessment for Beginning Intern Pharmacist Competencies
- Request from Dr. Mary Anne Koda-Kimble
- Proposed IPPE Competencies

Memorandum

To: Licensing Committee

Date: August 30, 2007

From: Board of Pharmacy

Subject: Pharmacist Intern Competencies

The Board of Pharmacy 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.

The California pharmacy schools are collaborating on this new initiative to determine and assess the competencies that students should achieve by the end of their introductory pharmacy practice experiences (IPPEs) prior to starting their advanced pharmacy practice experiences (APPEs). 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). The ACPE believes that there should be 300 hours of this basic experience.

Board Member Ravnan, Legislative Coordinator Anne Sodergren and I attended three day-long meetings – January 26, February 28 and March 27, which resulted in a list of basic competencies that students should achieve by the end of the IPPE.

The second phase, which began in June and involves developing a reliable and valid performance-based exam (i.e., objective structured clinical exam, OSCE) to assess student achievement of these competencies.

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

Attached, for your information, are the competencies developed under this project as well as a request from Dr. Mary Anne Koda-Kimble that the board affirm its agreement with this document.



School of Pharmacy
Office of the Dean

2007 AUG 30 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

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 Ravnan, 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

Agenda Item 4

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

Memorandum

To: Licensing Committee

Date: August 23, 2007

From: Board of Pharmacy

Subject: Creighton University – Online PharmD program

Recently 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.

Following is some information provided on Creighton University's Web site.

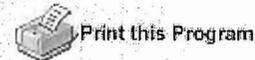


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Entry Level Doctor of Pharmacy Program (Web-Based)

Navigation: Home -
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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 I	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

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.

Agenda Item 5

Disaster Response for Pharmacy

- Memo
- Request from Ralphs
- Recent articles discussing disaster response

Memorandum

To: Licensing Committee

Date: August 30, 2007

From: Board of Pharmacy

Subject: Emergency Preparedness for California

Emergency Preparedness continues to be an important initiative of this Administration.

1. County of San Diego Request for Dispensing Doxycycline or Ciprofloxacin

The board received a request from San Diego County to provide an unspecified number of up to 500,000 bottles of a 7-14 day dosing 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 somewhere (unmentioned) else. They county was seeking an exemption from patient-specific labeling because it would be "difficult, if not impossible" to label these containers.

Whereas the board could exempt such labeling after an emergency had been declared, 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.

Staff was just advised that San Diego County is withdrawing this request and will be submitting a new request after further refinement of the proposal.

2. Request for Ralphs Grocery Co.

The board received a request for guidance from Ralphs Grocery Co. about the appropriate use of mobile pharmacy trailers. Raplphs 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 is provided for committee discussion and recommendation.

3. Rough and Ready 2007.

Board Member Conroy 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. Dr. Conroy will provide a summary of the event.

4. California Medical Volunteers

Board staff recently participated in the evaluation of proposals 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 highlight this in upcoming newsletters to encourage pharmacist participation.



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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



*Licensing/
Disaster
Response*

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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Rx RESPONSE PREPAREDNESS PLAN

Every health-related company has a part to play when disaster strikes.



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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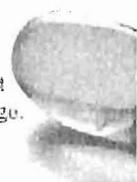
August 15, 2007

Healthcare Organizations Launch Disaster Response Initiative

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Disaster
Response

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).

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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

(E

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 of 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 convene 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.

"Daily 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 emergency.

"As leaders in the production of existing therapies and the development of new treatments for patients, biotechnology 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).

#

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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Agenda Item 6

Immunization Proposal

- Background Memo
- Draft language
- Immunization Schedules
- Article from *Pharmacist's Letter*

Memorandum

To: Licensing Committee**Date: August 23, 2007****From: Board of Pharmacy****Subject: Immunizations**

At the July 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. At the April 2007 board meeting the board voted to develop a statutory modification to allow pharmacists to administer immunizations pursuant to a state adopted protocol.

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.

At the July Board Meeting, the board voted to adopt the proposed state protocols to allow pharmacists to administer immunizations. Since that time, the language has been revised to detail more specific training requirements, continuing education requirements as well as recordkeeping and reporting requirements.

Provided with this memo are:

- A draft of proposed language for committee consideration.
- A copy of the recommendations for the Adult and Adolescent Immunization Schedules.
- Copy of recent article from *Pharmacist's Letter* detailing new CDC recommendations for immunizations.

The committee needs to review the proposed language in this packet.

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

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 ³ 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 Reconvivax 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 ¹	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			

1. 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.

2. 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.

3. 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.

4. *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.

5. Pneumococcal conjugate vaccine (PCV). (Minimum age: 6 weeks)

- Vaccine is not generally recommended for children aged ≥5 years.

6. 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.

7. 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.

8. 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.

9. 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.

10. 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).

11. 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). 	<p>Contraindication: Previous anaphylaxis to this vaccine or to any of its components.</p> <p>Precaution Moderate or severe acute illness.</p>
<p>Special Notes on Hepatitis B Vaccine (HepB)</p> <p>Dosing of HepB: Vaccine brands are interchangeable. For persons ages 0 through 19yrs, give 0.5 mL of either Engerix-B or Recombivax HB.</p> <p>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.)</p> <p>For preterm infants: Consult ACIP hepatitis B recommendations (<i>MMWR</i> 2005; 54 [RR-16]).</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 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. Note: MCV4 is not licensed for use in children younger than age 11 yrs.</p>

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		
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)

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 ►	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 ¹¹	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 (0, 4–8 wks)						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 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

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-1st.htm]. Consult the ACP statement for recommendations for administering Td as prophylaxis in wound management (www.cdc.gov/mmwr/preview/mmwrftml/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 $\mu\text{g}/\text{mL}$ (Recombinax 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)
<p>Influenza Trivalent inactivated influenza vaccine (TIV) <i>Give IM</i></p>	<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.
<p>Influenza Live attenuated influenza vaccine (LAIV) <i>Give intranasally</i></p>	<ul style="list-style-type: none"> • Healthy, non-pregnant persons age 49yrs and younger who meet any of the criteria listed below. <ul style="list-style-type: none"> - 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. 	<p>(Same as above)</p>	<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>
<p>Pneumococcal poly-saccharide (PPV) <i>Give IM or SC</i></p>	<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</p> <ul style="list-style-type: none"> Moderate or severe acute illness. Safety during pregnancy has not been determined, so benefits must be weighed against potential risk.
<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</p> <ul style="list-style-type: none"> Moderate or severe acute illness. Pregnancy.

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. 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. 	<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>		

PHARMACIST'S LETTER



Unbiased Evidence and Advice for the Pharmacist on New Developments in Drug Therapy

Vol. 23, No. 9

September 2007

Dear Pharmacist:

More patients will be getting vaccines for meningitis, hepatitis A, varicella, pertussis, and influenza.

This is due to new CDC recommendations...and it's an opportunity for pharmacists to expand more into immunization.

Meningitis. ALL adolescents age 11 to 18 should now be vaccinated...not just those in high-risk groups. More kids are eligible now that there's enough vaccine to go around.

Recommend vaccination any time...not just before school entry.

Hepatitis A. ALL toddlers from 12 to 23 months should now get hepatitis A vaccine...not just those in high-risk areas like before.

Suggest "catch-up" vaccination for older, unvaccinated kids.

CDC may also soon recommend hepatitis A vaccine for people under 41 to prevent hep A after exposure...instead of using immune globulin.

Varicella. Two doses are now recommended for children under 13. Many providers already do this...but now it's official.

Most kids will get their first dose at 12 to 15 months...and a second dose at age 4 to 6 before they start school. Kids over 6 should get a catch-up dose if they haven't had their second dose yet.

Pertussis. Recommend one dose of a tetanus, diphtheria, and pertussis vaccine for adolescents and adults...usually when their next tetanus and diphtheria booster is due.

Influenza. Kids under 9 should get TWO doses of flu vaccine the first time they're vaccinated. If they did not get the second dose, recommend two doses the next season for adequate immunity.

The nasal flu vaccine (*FluMist*) is now reformulated. The dose volume is smaller...and it is now refrigerated instead of frozen.

FluMist might also get approved for kids as young as 2 years... instead of just down to age 5.

Avian flu. The government is stockpiling the new vaccine to use in case of an outbreak. Researchers are also trying to anticipate future mutations to design a vaccine for use BEFORE an outbreak.

To get CE credit on vaccines and learn about immunization programs, changes, and billing, go to our *Detail-Document*.²³⁰⁹⁰¹

OSTEOPOROSIS

Women will be hearing about *Reclast*, the first once-a-YEAR bisphosphonate for treating postmenopausal osteoporosis.

It can be given as a 15-minute infusion in a doctor's office.

Reclast is zoledronic acid. It's already approved for Paget's disease...and is the same drug that's in *Zometa* for cancer patients.

Reclast reduces spinal fractures 70% and hip fractures 41%.

This works out to be 76 fewer spinal fractures and 11 fewer

Agenda Item 7

Competency Committee Report

- Update on Transition to new test vendor for CPJE
- NAPLEX Exam Compromise
- Regulation Proposal to amend 16 CCR 1721 and 16 CR 1723.1

Memorandum

To: Licensing Committee

Date: August 31, 2007

From: Board of Pharmacy

Subject: Competency Committee Report

Conversion to New Examination Vendor

On June 1, 2007, the board converted to a new vendor to administer the CPJE. The new firm is Psychological Services, Inc (or simply PSI).

The new firm is expected to offer better service, online registration, the scheduling an exam within two weeks, more tests sites and a lower fee (\$33).

However, the transition to the new vendor has had some bumps. Staff works to resolve the issues as they arise. The department's executive office has been helpful in resolving the more complex issues.

Examination scores from tests administered at PSI were released on August 27. Part of the delay was due to the conversion, but the greater issue is that there was slow test taking since June 1 by the applicants.

Another quality assurance check is scheduled to begin September 1.

NAPLEX Compromised

As discussed elsewhere in this tab section, questions from the NAPLEX have purportedly been compromised.

Competency Committee

The board 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.

There are two meetings scheduled this fall – one in September and one in October.

Memorandum

To: Licensing Committee

Date: August 30, 2007

From: Board of Pharmacy

Subject: NAPLEX Compromise

On August 6, 2007, the NABP issued a notice to all State Boards of Pharmacy as well Deans of Schools and Colleges of Pharmacy. This notice stated 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).

Included for your review are 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.



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

nabp

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

Board Script for Candidates Inquiring About Suspension of NAPLEX and Georgia MPJE

NABP prepared the following script in order to guide Board staff who may be answering phone or e-mail inquiries related to the suspension of the North American Pharmacist Licensure Examination (NAPLEX) and the Georgia Multistate Pharmacy Jurisprudence Examination (Georgia MPJE). **Please forward media inquiries related to this matter to NABP's executive office at 847/391-4405.**

Affected Candidates Who Are Already Scheduled for NAPLEX and/or Georgia MPJE

- Thank you for your call/e-mail.
- We apologize for any inconvenience.
- NABP suspended the NAPLEX in all jurisdictions and suspended the MPJE in Georgia effective Saturday, August 25, 2007, in order to maintain the integrity and validity of the examinations.
- NABP cautiously estimates that the examinations will be reinstated in the early part of November following review and approval by NABP.
- If you have an appointment scheduled for the NAPLEX or Georgia MPJE between August 25, 2007, until approximately mid October 2007, we understand that NABP's testing vendor, Prometric, will contact you to reschedule your appointment based upon the availability of appointments at the testing center that you select and the estimated time period in which the exams will be reinstated.
- Non-Georgia MPJE candidates who already made appointments for the MPJE examination will be able to sit for the exam as previously scheduled.
- The determination of eligibility to sit for the examination is solely the decision of the Board of Pharmacy.
- Candidate eligibility (for example, extend the eligibility period), will be adjusted as appropriate and as permitted by the Board, in accordance with the date that the exam is reinstated.
- If you have additional questions, please contact NABP's customer service department at 847/391-4406 or custserv@nabp.net.

Affected Candidates Who Applied, But Have Not Scheduled an Appointment to Test

- Thank you for your call/e-mail.
- We apologize for any inconvenience.
- NABP suspended the NAPLEX in all jurisdictions and suspended the MPJE in Georgia effective Saturday, August 25, 2007, in order to maintain the integrity and validity of the examinations. The MPJE is available in all other jurisdictions.
- NABP cautiously estimates that the examinations will be reinstated in the early part of November following review and approval by NABP.
- If the Board has not yet deemed you eligible to sit for the examinations, then your application file is currently under review by the Board. The determination of eligibility to sit for the examination is solely the decision of the Board and we will notify you in the event that we need more information.
- Once your eligibility is verified by the Board, NABP's testing vendor, Prometric, will issue you an authorization to test (ATT).
- You may call Prometric to schedule your appointment, which will be based upon the availability of appointments at the testing center that you select and NABP's cautious estimate that the examinations will be reinstated in early November 2007.
- Candidate eligibility (for example extend the eligibility period), will be adjusted as appropriate and permitted by the Board, in accordance with the date the exam is reinstated.
- As soon as the examination is reactivated, NABP will immediately publish information on its Web site, www.nabp.net. Please check NABP's Web site for updates.
- If you have additional questions, please contact NABP's customer service department at 847/391-4406 or custserv@nabp.net.

Candidates Who Have Not Yet Applied

- Thank you for your call/e-mail.
- We apologize for any inconvenience.
- NABP suspended the NAPLEX in all jurisdictions, and suspended the MPJE in Georgia effective Saturday, August 25, 2007, in order to maintain the integrity and validity of the examinations. The MPJE is available in all other jurisdictions.
- NABP cautiously estimates that the examinations will be reinstated in the early part of November following review and approval by NABP.
- You may register for the examinations following the standard registration process. Please visit NABP's Web site, www.nabp.net, to review the NAPLEX and MPJE registration bulletin, which contains information regarding the registration procedure.
- Upon receipt of your completed application, NABP will verify your eligibility with the Board.
- Once your eligibility is verified by the Board, NABP's testing vendor, Prometric, will issue you an authorization to test (ATT).
- You may call Prometric to schedule your appointment, which will be based upon the availability of appointments at the testing center that you select and NABP's cautious estimate that the examinations will be reinstated in early November 2007.
- As soon as the examination is reactivated, NABP will immediately publish information on its Web site, www.nabp.net. Please check NABP's Web site for updates.
- If you have additional questions, please contact NABP's customer service department at 847/391-4406 or custserv@nabp.net.

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- As soon as the examinations are reactivated, NABP will publish the information on its Web site, www.nabp.net. Please check NABP's Web site for updates.
- If you have additional questions, please contact NABP's customer service department at 847/391-4406 or custserv@nabp.net.

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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UGA professor caught in exam scandal

Test suspended nationwide; teacher accused of giving students answers

By [BILL RANKIN](#), [ANDREA JONES](#)

The Atlanta Journal-Constitution

Published on: 08/30/07

Recent pharmacy school graduates nationwide are putting their careers on hold because of allegations that a University of Georgia professor shared questions with students for their board's licensing exam.

The National Association of Boards of Pharmacy suspended indefinitely the licensing exam.

Earlier this month, the organization filed a lawsuit accusing Flynn Warren Jr. of copying exam questions and distributing them in his course materials for students who were about to take the test.

The national test is taken by pharmacy graduates across the country, and they must pass the exam before they can become practicing professionals.

The decision to suspend the national exam "in the wake of the allegations against Warren" has had devastating consequences for some graduates.

Lori Riney, who graduated from St. Louis College of Pharmacy last May and is now an intern at a CVS pharmacy, called the situation "a terrible mess."

Riney, newly pregnant, said postponing the exam could cost her maternity leave because she won't be licensed for long enough for her benefits to kick in.

"This is just unacceptable," she said.

Neither UGA nor the National Association of the Boards of Pharmacy would comment on the case.

Warren, a popular and recently retired UGA pharmacy school professor, did not return telephone phone calls Thursday.

But in the federal lawsuit filed earlier this month in Athens, the pharmacy association said it is seeking damages from Warren, UGA and the Board of Regents.

The lawsuit alleges copyright infringement, misappropriation of trade secrets and breach of contract.

Shortly after the lawsuit was filed, U.S. Marshals seized materials and computers from the College of Pharmacy and Warren's home.

The materials were seized in connection to an investigation into Warren's use of questions on the exam, the North American Pharmacist Licensure Examination, also known as NAPLEX.

In a statement, the agency's executive director, Carmen A. Catizone, said the tests were suspended "to ensure that the integrity of the examinations is maintained."

No decision has been made on when the tests would resume, Catizone said in his statement, which was first reported by the independent UGA student newspaper, The Red and Black.

Previous problem

This isn't the first time the pharmacy association has investigated Warren.

In the summer of 1994, the association was told Warren had asked students to remember questions from the exam so he could put them in his course materials, according to the lawsuit.

This led to a settlement agreement in which Warren and UGA agreed to stop copying the association's materials and questions, according to the lawsuit.

Thinking the matter was resolved at that time, the association stopped monitoring Warren, according to the lawsuit.

But on July 17, Walter Steven Pray, a Southwestern Oklahoma State University professor, e-mailed the pharmacy association and told him Warren was again giving out exam questions to students in his review courses, the lawsuit said.

Pray said he heard from a former student that Samford University in Alabama had hired Warren to visit and help prepare students there for the exam, the lawsuit said. Someone also forwarded Pray an e-mail that Warren had supposedly sent to a Samford student June 20 with the heading, "New NAPLEX Questions for the 2007 Exam."

The e-mail included an attachment that listed hundreds of exam questions, "apparently sent to Warren by recent attendees," according to the lawsuit.

Less than two weeks after receiving Pray's tip, Kerri Hochgesang, one of the association's attorneys, traveled to Athens and paid \$100 to UGA for Warren's course materials.

The association compared a portion of Warren's course materials with its exam questions and found "at least 150 questions are verbatim, nearly verbatim or substantially similar," the lawsuit alleged.

There are 185 questions on the exam and 150 are used to calculate the test score.

In addition to the national test, students in Georgia also take the Georgia Multistate Pharmacy Jurisprudence Examination.

That test, too, has been suspended.

Professor's defenders

In the meantime, some UGA pharmacy students are defending their program and Warren on the student newspaper's Web site.

"Why is it that Professor Warren is being treated this way?" wrote Alex Ward, who said he is a third-year pharmacy student. "Is it because he is an individual offering this course service, and not an organization such as KAPLAN or ASHP?"

UGA graduates about 125 pharmacy majors a year and has a 99 percent pass rate on the exam — higher than the national average, according to UGA spokesman Tom Jackson.

Jackson said the university did not track the number of graduates who had taken Warren's review class, offered through the Continuing Education & Outreach. Students from other pharmacy schools could also sign up for the class.

According to a UGA Web site, Warren's August class was canceled.

Jackson said he could not comment on the lawsuit but said, "There is no basis to question the high quality of education of the College of Pharmacy, and the lawsuit provides no basis to question the competency of any licensed pharmacist who graduated from the UGA program."

Amit Gajira, a recent graduate of the Massachusetts College of Pharmacy, said he just wants the issue resolved — and quickly.

Gajira says he faces losing a \$15,000 signing bonus if he can't take his exam soon.

"This has thrown a curve ball at a lot of people," he said.

Staff writer Rebecca McCarthy contributed to this report.

Find this article at:

http://www.ajc.com/metro/content/metro/stories/2007/08/30/pharmacy_0830.html?cxntlid=homepage_tab_newstab

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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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Memorandum

To: Licensing Committee

Date: August 30, 2007

From: Board of Pharmacy

Subject: Regulation Proposal

Following is draft regulation language for the committee to consider 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 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 \$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.

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.



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UGA professor caught in exam scandal

Test suspended nationwide; teacher accused of giving students answers

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Scandal prevents pharmacy students from taking current exam

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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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