California State Board of Pharmacy
1625 North Market Blvd., N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

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

NOTICE OF MEETING and AGENDA
Licensing Committee

Contact: Virginia Herold
(916) 574-7911

Date: September 29, 2008
Time: 9:30 a.m. – 12:30 p.m.

Place Department of Consumer Affairs
Del Paso Office Building - Sequoia Room, Number 109 A/B
2420 Del Paso Road
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 Michelle Leech (916) 574-7912, 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.**

All Agenda Items Are Items for Discussion:

1. Emergency and Disaster Response Planning
   - California Department of Public Health: Request from San Diego County for Exemption to Distribute Prophylaxis Drugs to Emergency Response Staff Prior to a Declared Emergency
   - New Name for ESAR-VHPS
2. Patient Privacy Issues Arising from Abandonment of Records – The Abandoned Records Project of the California Office of Privacy Protection
3. Update on the 2007 Compromise of the NAPLEX Examination
4. Fact Sheets on Application Procedures for Pharmacist Applicants
5. Licensing Unit Workload Adjustments Made to Accommodate Budget Restrictions
6. The Coalition on Shortages of Allied Health Professionals - formation of a pharmacy services workgroup to deal with shortages of pharmacists and pharmacy technicians
7. Update: Task Force to Evaluate Pharmacy Technician Qualifications
8. Veterinary Food Animal Drug Retailers – Qualification Processes for Designated Representatives
9. Continuing Education for Competency Committee Members
10. Competency Committee Report
    1. Update of the CPJE
    2. Report to the Legislature on the Impact of Requiring Foreign Graduates to Take Remedial Education After Failing the Pharmacist Licensure Examinations Four Times

Adjournment **12:30 p.m.**

Meeting materials will be available from the board's Web site by September 25, 2008

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

Date: **September 24, 2008**

To: **Licensing Committee**

Subject: **Emergency and Disaster Response Planning**

Request from San Diego County

In 2007, 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. This request was later withdrawn.

In September 2008, the board received a new request from San Diego County. This plan calls for Doxycycline 100mg #20 to be prescribed to approximately 100,000 First Responders and Critical Access Employees and their family members. Each prescription will be written by the Public Health Officer (a licensed California prescriber) and transmitted to a pharmacy for dispensing.

San Diego County is seeking confirmation that this model satisfies the requirements in pharmacy law. Following this memo is a copy of the First Responder and Critical Access Employee Home Emergency Prophylaxis Kit Plan.

New Name for ESAR-VHPS

In August board staff received notification that the ESAR-VHPS was renamed to Disaster Healthcare Volunteers of California.

This system, coordinated by the Emergency Medical Services (EMS) Authority, is to allow for health care professional to sing up to serve as a volunteer in response to a disaster. The EMS will continue to work diligently to increase the number of volunteers in this program.

Following is a copy of the memo provided by EMS Authority.

FIRST RESPONDER AND CRITICAL ACCESS EMPLOYEE HOME EMERGENCY PROPHYLAXIS KIT PLAN

County of San Diego
Health and Human Services Agency
Disaster Medical and Health Emergency Preparedness

September 2008

DRAFT

Note: Attach this official document to the County Local Pharmaceutical Cache Plan as a reference

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<<<<DRAFT>>>>

Dear Virginia Herold, you may recall some emails and discussion from June of last year where we discussed the County of San Diego and the Home Med Kit Project. You helped us look into the feasibility of a waiver on the labeling requirements and it was subsequently concluded that it would involve a change to the law. You can understand, the County of San Diego has decided not to pursue this avenue. Since then the County has been pursuing a more "traditional" model. Dana Grau, Pharm.D., Senior Consulting Pharmacist, Emergency Preparedness Office, California Department of Health Services suggested that we run it by you so that we keep you in the loop and you can be aware of the project. You may wish to share it with some of your colleagues on the board. You'll notice, at the bottom of this email is an executive summary of the plan which will refresh your memory on the overall goal.

The plan calls for approximately 100,000 First Responders and Critical Access Employees (FRCAE) plus their family members. The medication being prescribed is Doxycycline 100mg capsules #20. Each employee will complete a screening form questionnaire that will be reviewed by a clinician for allergies & contraindications. This form will be sent to the Public Health Officer (a licensed California prescriber) who will make the final decision and write individual prescriptions for each employee and their family members. Each prescription will then be transmitted to a licensed California pharmacy, that will utilize licensed California pharmacists to dispense (all labeling requirements will be met) the medication.

It is our interpretation that the above model meets the furnishing and dispensing requirements set by California law. If you have or need any points of clarification or wish to discuss this further, please do not hesitate to ask. Moreover, it is anticipated that following the completion of this project, many jurisdictions within the State of California may decide to follow our lead on preparing the FRCAE's in a similar manner.

Sincerely,
<____>

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EXECUTIVE SUMMARY

In the aftermath of a widespread weaponized anthrax bioterrorism attack, traditional and non-traditional first responders will focus on initial response activities designed to mitigate public morbidity and mortality. Weaponized anthrax can cause catastrophic loss of life within 72 hours. The response time to administer prophylaxis to the public is 48 hours in order to save as many lives as possible. When a suspected or confirmed act of bioterrorism or other public health emergency occurs, mass prophylaxis operations countywide may be initiated. However, for this to occur effectively, first responders and other critical access employees must be available and initially protected themselves to respond to and initiate this massive countywide public health response operation. In order to protect the public in a compressed timeframe, these traditional and non-traditional first responders will receive priority prophylaxis.

The County of San Diego, Health and Human Services Agency (HHSA) is preparing its First Responders and Critical Access Employees (FRCAE) and members of their immediate household with a ten day supply of doxycycline to be stored in the home. This medication is intended to be used only for post exposure prophylaxis in the event of a public health emergency involving the release of a biological organism such as *bacillus anthracis*, the bacteria that causes anthrax. Doxycycline would be started and continued as directed under order by the County
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Public Health Officer (PHO). The ten (10) day supply provided is intended to protect during the initial phase of the exposure. If additional medication is required beyond the ten days, it will be made available by HHSA.

The County of San Diego PHO is responsible for the overall management of emergency public health services within the Operational Area (OA) during such an event. The forward placement of the Home Emergency Prophylaxis Kit (ProphyKit) in an anticipated 100,000 FRCAE households will provide immediate emergency access to antibiotics for the intended recipients (anticipated 500,000 people) within 2 to 3 hours after notification by the PHO. This alternative mass prophylaxis dispensing method increases the probability that the FRCAE will report for duty because they and their household members are protected. By forward placing the ProphyKit in the home, the time needed for the FRCAE to begin response activities will decrease by 50%. This will allow these employees more time to set up public dispensing sites and rapidly deploy other public alternative dispensing modalities to meet the compressed time frame for the response.

STATE OF CALIFORNIA – HEALTH AND HUMAN SERVICES AGENCY

ARNOLD SCHWARZENEGGER, *Governor*

EMERGENCY MEDICAL SERVICES AUTHORITY
1930 9th STREET
SACRAMENTO, CA 95811-7043
(916) 322-4336 FAX (916) 324-2875

DATE: August 27, 2008

TO: California Medical Volunteers System Administrators
County Health Executive Association of California
California Department of Public Health
Department of Consumer Affairs Boards and Bureaus
Governors Office of Emergency Services
Local EMS Agencies
Local Public Health Departments
Medical Health Operational Area Coordinators
Members of the ESAR-VHP Committee of the Whole
Regional Disaster Medical Health Specialists
Regional Disaster Medical Health Coordinators

FROM: R. Steven Tharratt, MD, MPVM
Director

SUBJECT: California Medical Volunteers/Emergency System for the Advanced Registration of Volunteer Health Professionals Program Name Change

The Emergency Medical Services Authority (EMS Authority) is very pleased to announce that after an extensive process, we have established a new name for the *California Medical Volunteers* program. We will now be implementing the name ***Disaster Healthcare Volunteers of California.***

Based on feedback that we have received over the last several months, the EMS Authority has determined that the current name for California's Emergency System for the Advanced Registration of Volunteer Health Professionals (ESAR-VHP), *California Medical Volunteers,* does not accurately depict either the program or each of the medical and health professions who are part of this program.

Over the next several months, the EMS Authority will be working diligently to market the State's volunteer health professional program and increase the numbers of volunteers in the Disaster Healthcare Volunteers of California System.

We look forward to continuing to work with each of you to further implement this program - the home for all medical and health volunteers in California. We encourage counties and Medical Reserve Corps Coordinators to utilize this vital system to meet the medical and health needs of Californians during future disasters.

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

Date: **September 24, 2008**

To: **Licensing Committee**

Subject: **Patient Privacy Issues Arising from Abandonment of Records**

The California Office of Information Security and Privacy Protection recently convened a meeting to discuss abandoned records. This can involve health information, financial information or other personal information. Such records contain personal information for which no responsible owner or custodian can be located, but does not include improperly disposed of records, such as being placed in a dumpster.

The problem arises when records containing personal information are left behind by a professional or business. Sometimes these records are stored in self-service storage areas. The responsible party may have died, gone out of business or otherwise abandoned the premises, practice or records. The abandoned records pose a risk to the individuals whose personal information is compromises could make them victims of identity theft, physical harm etc. One possible solution is to notify the regulatory agency that licenses the professional who abandoned the records to take care of such records.

At this meeting, which is envisioned to become a series of meetings, the board shared our current records retention requirements for both current businesses as well as those that discontinue business. It appears that pharmacy law appropriately addresses several aspects of this issue, however it was clear from the meeting that not all professions have similar requirements to protect consumer information. However, pharmacy law does not address certain types of abandoned records such as those stored on unwanted computer equipment or offsite storage that becomes abandoned. We will develop a proposal to address this in the future.

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

Date: **September 24, 2008**

To: **Licensing Committee**

Subject: **Update on the 2007 Compromise of the NAPLEX Examination**

Recently the board was provided an update on the litigation against the Board of Regents of the University System of Georgia and two University of Georgia (UGA) College of Pharmacy professors. This litigation allege that the University offered and the professors conducted a pharmacy examination review class in with the participants were provided with actual test questions from the North American Pharmacist Licensure Examination (NAPLEX) and the Multistate Pharmacy Jurisprudence Examination (MPJE).

The NABP states that it continues to gather information related to this matter, which calls into question whether participants of the review course, met the qualifications for licensure to practice pharmacy competently and safely. The NABP also indicated that they believe that this course was also offered at other schools and colleges of pharmacy. The NABP is taking steps to identify relevant students and will communicate any and all score invalidation and cancellations to the board of pharmacy, as well as the affected candidates.

Should any California licensed pharmacist be identified, the board will be required to pursue disciplinary action against the pharmacist to remove them from practice.

In addition, the board received a copy a formal complaint filed by the NABP with the Accreditation Council for Pharmacy Education (ACPE) in regards to the accreditation status of the University of Georgia College of Pharmacy. This notification states that the ACPE Report of Proceedings for June 18-22, 2008, Meeting of the ACPE Board of Directors that the University of Georgia College of Pharmacy was placed on probation (Spring 2009). NABP is requesting the immediate revocation of the University of Georgia's accreditation.

Following is copy of NABP's update on the compromise as well as a copy of the formal complaint filed with the ACPE.

nabp
National Association of Boards of Pharmacy
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Web Site: www.nabp.net

TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: Carmen A. Catizone, Executive Director/Secretary

DATE: August 15, 2008

RE: Update on Georgia Litigation and Score Invalidation

NABP continues to move forward in its litigation against the Board of Regents of the University System of Georgia and two University of Georgia (UGA) College of Pharmacy professors, in which it has alleged, among other things, that the University offered and the professors conducted a pharmacy examination review class in which participants were provided with actual test questions from the North American Pharmacist Licensure Examination (NAPLEX) and Multistate Pharmacy Jurisprudence Examination (MPJE). NABP also alleges that Warren and UGA had previously been involved in similar activities in the mid 1990s, their activities were discovered by NABP and, to preclude litigation, in 1995 NABP, UGA, and Warren entered into a settlement agreement in which Warren, UGA, and the Board of Regents agreed to cease and desist from all copying, transcribing, or other infringing use of NABP materials and examination questions. NABP recently filed a breach of contract suit in state court against UGA and Warren, and also filed an appeal in the 11th Circuit Court of Appeals to challenge the district court's decision dismissing the Board of Regents and UGA from the federal copyright infringement lawsuit.

In addition, NABP continues to gather information related to this matter, which calls into question whether participants of this review course, which NABP understands was offered at other schools and colleges of pharmacy, meet the qualifications for licensure in order to practice pharmacy competently and safely. In the interest of honoring the Association's mission to assist our members in protecting the public health, NABP is taking steps to identify students who participated in these review courses, and is evaluating all information regarding the use of material provided in these courses using the following criteria:

- Those students who used, disclosed, or offered to disclose NAPLEX or MPJE examination information, in violation of the exam confidentiality agreement, may have their examination score(s) for NAPLEX and/or MPJE reevaluated and invalidated, and may be subject to further action, including, but not limited to lawsuits.

- Any students who participated in these review courses may have their NAPLEX and/or MPJE scores canceled due to the forced removal of breached items and a resulting invalid examination.

- Any students who received academic credit for such activities as collecting, compiling, formatting, and/or disseminating NAPLEX or MPJE examination information may have their examination score(s) for NAPLEX and/or MPJE reevaluated and invalidated, and may be subject to further action, including, but not limited to lawsuits.

NABP will communicate any and all score invalidations and cancelations to the boards of pharmacy, as well as the affected candidates.

In the future, should NABP discover similar student activities related to the NAPLEX, MJPE, or another NABP examination, the Association may initiate the steps outlined above, among others.

If you have any questions or information you would like to share with NABP, please do not hesitate to contact me or Moira Gibbons, legal affairs senior manager, at 847/391-4400, extension 4460, or via e-mail at mgibbons@nabp.net.

NABP is grateful for the tremendous support we have received from our member boards of pharmacy.

cc: J. Rodgers Lunsford III, NABP Counsel
NABP Executive Committee

nabp

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227

September 4, 2008

Peter H. Vlasses, PharmD, BCPS, FCCP
Executive Director
Accreditation Council for Pharmacy Education
20 North Clark Street
Suite 2500
Chicago, Illinois 60602-5109

Via Overnight Mail

Re: Complaint: University of Georgia College of Pharmacy Accreditation Status

Dear Dr Vlasses:

The National Association of Boards of Pharmacy® (NABP®) is filing a formal complaint in regard to the accreditation status of the University of Georgia College of Pharmacy (UGA) professional program pursuant to the Accreditation Council for Pharmacy Education's (ACPE) complaint policy, which is set forth below:

> *ACPE has an obligation to assure itself that any institution which seeks or holds a preaccreditation or accreditation status for its professional program(s) conducts its affairs with honesty and frankness. Complaints from other institutions, students, faculty, or the public against a college or school of pharmacy, including tuition and fee policies, and as related to ACPE standards, policies or procedures, shall be placed in writing in detail by the complainant and submitted to the ACPE office.*

NABP understands that, as specifically stated in ACPE's complaint policy:

> *The procedure shall provide for treatment of complaints in a timely manner that is fair and equitable to all parties. The complainant shall be advised of the decision or action as soon as possible. When ACPE has cause to believe that any institution with which it is concerned is acting in an unethical manner or is deliberately misrepresenting itself to students or the public, it will investigate the matter and provide the institution an opportunity to respond to the allegations. If, on the basis of such investigation, after notice to the institution and opportunity for institutional response, ACPE finds an institution has engaged in unethical conduct or that its integrity has been seriously undermined, ACPE will either:*

> *a. request that the institution show cause, within a stated time period, why adverse action should not be taken, or*
> *b. in extreme cases, immediately discontinue its relationship with the institution by denying or withdrawing preaccreditation or accreditation status.*

Based on the facts set forth in the Facts Common To All Counts section of the enclosed federal Amended Complaint (pages 8-13), the additional factual paragraphs of the federal Motion for Leave to Further Amend and Restate Complaint (pages 1-5), and the Factual Background and Count I sections of the state court Complaint (pages 2-5), NABP asserts that the Board of Regents System of the University of Georgia (Board), UGA and its faculty egregiously violated ACPE's Accreditation Standards and Guidelines for the Professional Program in Pharmacy leading to the Doctor of Pharmacy Degree (Standards). NABP will also forward documents which, the Association asserts, demonstrate that pharmacy students unethically and illegally disclosed secured and copyrighted NAPLEX questions by transmitting them to UGA after sitting for the NAPLEX. NABP asserts that such NAPLEX questions were incorporated into the course content that was distributed and taught by the UGA instructors. NABP maintains that such actions and activities represent an extreme case as described in the ACPE complaint policy and warrant that ACPE "*immediately discontinue its relationship with the institution by withdrawing accreditation status.*"

Specifically, NABP alleges that copyrighted and secured content of the NAPLEX and MPJE examinations was compromised by UGA and its faculty and administration involved in and responsible for UGA's doctor of pharmacy professional program. The Association further contends that a member of the UGA faculty, who was also the Assistant Dean for Student Affairs, conducted a pharmacy examination review course through UGA, collected NAPLEX and MPJE questions from students who had taken such examinations, and presented and distributed those NAPLEX and MPJE test questions to students preparing for such examinations. NABP alleges that the course offering was approved by UGA and that the Associate Dean for the College of Pharmacy attended at least a portion of one such review course.

NABP maintains that by providing students with licensure exam questions and answers, UGA and its faculty may have allowed otherwise unqualified students to pass the licensure examinations, which has serious patient health care implications, and UGA and its faculty compromised the integrity of the licensure process and academic integrity of UGA. Moreover, NABP contends that the Board, UGA, and the Assistant Dean for Student Affairs engaged in such misconduct after acknowledging that such activities were prohibited and detrimental and legally agreeing to halt such activities, and to prevent future occurrences when they executed a settlement agreement with NABP in 1995, as a result of identical allegations of misconduct related to NABP's national pharmacist licensure examination.

Even further, NABP provides its **analysis** of the 1997-2007 ACPE Standards and Guidelines, which are specifically referenced below, describing how UGA violated such Standards based upon the above allegations in the federal and state court pleadings. The Association contends that this

analysis supports NABP's strong recommendation that the accreditation of the UGA Doctor of Pharmacy program be immediately revoked.

I.

PHARMACY SCHOOL MISSION AND GOALS

ACPE Standard No. 1. College or School of Pharmacy Mission and Goals

The College or School of Pharmacy should have a published statement, formulated within an *ethical context [emphasis added]*, of its mission, goals, and objectives in the areas of education, research, service, and pharmacy practice. This statement should be congruent with the mission of the University; the term "University" includes independent Colleges and Schools of Pharmacy. This statement should include a fundamental commitment to the preparation of its students for the general practice of pharmacy with provision of the professional competencies necessary to the delivery of pharmaceutical care. This statement should also demonstrate sensitivity to the importance of diversity in its commitment to the educational preparedness of its students for a health professional career. Goals should be compatible with the general and specific objectives of pharmaceutical education in keeping with the scope of pharmacy practice and as reflected in the accreditation standards and guidelines.

ACPE Guideline 1.4

The mission statement of a College or School should acknowledge pharmaceutical care as an evolving mode of pharmacy practice in which the pharmacist, in concert with other health professionals, takes an active role on behalf of patients in making appropriate drug choices, by effecting distribution of medications to patients, and by assuming direct responsibilities to empower patients to achieve the desired outcomes of drug and related therapy. The professional program in pharmacy should provide educational preparedness so as to enable the pharmacist to collaborate with other health professionals and to share in responsibility for the outcomes of drug and related therapy. The professional program in pharmacy should promote the knowledge, skills, abilities, attitudes, and values necessary to the provision of pharmaceutical care for the general practice of pharmacy in any setting. The College or School should assure an understanding of pharmaceutical care by its students early in the professional program in pharmacy. *The philosophy of practice as well as the necessary professional attitudes, ethics, and behaviors should evolve during the course of study [emphasis added]*. Moreover, the College or School should insure the professionalization of students, including the provision of a positive outlook for all aspects of pharmacy practice.

UGA Mission Statement [not included in pleadings]

1. Maximize the health and well being of society by furthering the frontiers of Pharmacy practice and biomedical and clinical research through selection of the finest faculty scholars and the most promising students;
2. *Deliver the highest quality education [emphasis added]* through a state-of-the art Pharmacy care environment and research laboratories; and
3. Provide innovative leadership in advancing and refining the role of Pharmacy as it relates to practitioners and graduate biomedical scientists.

The Guideline clearly states that "the philosophy of practice *as well as the necessary professional attitudes, ethics, and behaviors* should evolve during the course of study" [emphasis added]. Although the UGA Mission Statement avows to "maximize the health and well being of society...deliver the highest quality education...and provide innovative leadership in advancing and refining the role of [p]harmacy," UGA's actions, as asserted in the pleadings, in disclosing confidential and secure copyrighted NAPLEX and MPJE questions, contravene this standard and its own mission by violating copyright laws, established state pharmacist licensure examination processes, and NABP's 1995 legal agreement executed by the Board, UGA, and faculty member and Assistant Dean for Student Affairs Flynn Warren in which the Board, UGA, and Warren acknowledged wrong doing and agreed not to engage in such unethical and illegal activities in the future, and by engaging in activities that are devoid of scholarship and educational quality.

II.

ACPE Standard No. 6. College or School of Pharmacy Organization and Administration

The College or School of Pharmacy should be organized in a manner which facilitates the accomplishment of its overall mission, promotes the goals and objectives of the professional program in pharmacy, supports pharmacy disciplines, and effectively deploys resources. The College's or School's organizational and administrative structure should clearly identify lines of authority and responsibility. There should be evidence of a spirit of collegiality as well as evidence of mutual understanding and agreement among the faculty, the Dean, and other administrative leaders of the College or School on its mission, goals, and objectives as well as evidence of acceptance of the responsibilities necessary to their achievement.

UGA and faculty, in engaging in the alleged activities outlined in this letter, completely disregarded their responsibilities related to upholding the mission of the school.

Additionally, given NABP's contentions that both UGA and the Assistant Dean for Student Affairs continued to collect and distribute actual NAPLEX and MPJE questions, after agreeing to stop in 1995, and that the ultimate responsibility is vested in UGA to monitor and halt such misconduct, which did not appear to occur, it is apparent that adherence to ACPE Standards was entirely disregarded.

III.

ACPE Standard No. 7. Responsibilities of the Dean of the College or School of Pharmacy

The Dean should demonstrate progressive, constructive academic and professional leadership and effectively unite and inspire faculty and students toward achievement. The Dean is responsible for assuring: development, articulation, and implementation of the mission statement; recruitment, retention, and development of a competent faculty and staff..." development, implementation, and evaluation of the educational, research, service, and pharmacy practice programs and their enhancement; initiation, implementation, and management of programs for the recruitment and admission of qualified students; establishment and implementation of standards for academic performance and progression; resource acquisition and allocation; and continuous enhancement of the visibility of the College or School both on campus and to external constituencies.

The UGA Dean and faculty, in performing the actions alleged in this letter, engaged in activities in complete opposition to the requirements of the Standard. Their actions were non-progressive, non-constructive, unprofessional, and uninspiring, and in fact led students down a path that violated the law and compromised the licensure process and academic integrity of UGA. This will especially ring true for students whose NAPLEX and/or MJPE scores are invalidated as a result of their participation in these activities.

IV.

ACPE Standard No. 12. Teaching and Learning Processes

The College or School of Pharmacy should address the ways by which curricular content is taught and learned in the student's achievement of the professional competencies. Attention should be given to teaching efficiencies and effectiveness as well as innovative ways and means of curricular delivery. Educational techniques and technologies should be appropriately integrated to support the achievement of the professional competencies, to foster the development and maturation of critical thinking and problem solving skills, and to meet the needs of diverse learners. Evidence that the educational process involves students as active, self-directed

learners and *shows transition from dependent to independent learning as students progress through the curriculum [emphasis added]* should be provided.

Guideline 12.1

The educational process should ensure that students are afforded a broad conceptual mastery of pharmacy practice through the integration of subject matter, literature, theory, and methods. The educational techniques and technologies should sequentially develop and demonstrate the capacity of students to interpret, organize, and communicate knowledge, to engage in critical thinking, *and to develop those analytical, ethical, and professional skills needed to practice and advance the profession of* pharmacy *[emphasis added]*.

Guideline 12.3

The educational process should promote life-long learning through emphasis on active, self-directed learning and *the fostering of ethical responsibility for maintaining and enhancing professional competence [emphasis added]*.

Again, the facts alleged in the federal and state court pleadings demonstrate that this UGA-approved academic course led students to become dependent on memorized examination questions rather than on the knowledge and skills obtained through a valid pharmacy curriculum, effectively stunting the ability of students to develop analytical, ethical, and professional skills necessary to practice competently now and in the future, and resulting in the invalidation of their examination performance.

IV.

ACPE Standard No. 14. Curriculum Evaluation

Evaluation measures focusing on the efficacy of the curricular structure, content, process, and outcomes should be systematically and sequentially applied throughout the curriculum in pharmacy. Evidence should exist that evaluation outcomes, including student achievement data, are applied to modify or revise the professional program in pharmacy.

Guideline 14.1

A system of outcome assessment should be developed which fosters data-driven continuous improvement of curricular structure, content, process, and outcomes. Evaluation of the curriculum should occur systematically in order to monitor overall

effectiveness, to enable the achievement of the professional competencies in accord with outcome expectations, and to provide a studied basis for improvement. The ongoing evaluation process should include input from faculty, students, administrators, practitioners, and state board of pharmacy members and other publics. The curriculum as a whole, as well as individual courses, should be evaluated with respect to the goals and objectives for the professional program in pharmacy. Experimentation and innovation within the curriculum in pharmacy should occur continuously. Experimental or innovative approaches should be adequately planned and coupled with an appropriate evaluation system. Evaluation should assure that the curriculum is responsive to changes in pharmacy practice as well as to changes in educational technologies, and insure that an educational setting and methods of instruction exist that maximize the development of effective and efficient learning experiences.

Guideline 14.2

A curriculum committee or other appropriate body with defined authorities and responsibilities, should be in place to manage an orderly and systematic review of the curriculum structure, content, process, and outcomes. Duties of this committee should include assurances for coordination of course material, minimization of unwarranted repetition, deletion of outdated or unessential content, and provision of a reasonable course load for students. A curricular editing process should assure that additions are counterpoised with deletions. The appropriateness of emphasis, presentation mode, and proper sequencing should be considered so as to provide the optimal environment for learning. The committee should assess the extent to which innovative teaching methods are effectively deployed, and outcome measures are systematically applied for purposes of improvement.

As asserted in this letter by NABP, the solicitation and distribution of pharmacist licensure examination questions, from and to students within the Doctor of Pharmacy program, and UGA administration's approval of this examination review course fails to meet and contravenes all of the responsibilities of the curriculum committee and governance of the UGA College of Pharmacy, as outlined in ACPE Standards.

It is NABP's understanding from the ACPE Report of Proceedings for June 18-22, 2008 Meeting of the ACPE Board of Directors that the following action was taken in regard to the accreditation of the University of Georgia College of Pharmacy Continuing Pharmacy Education Program: "*Following a site visit to evaluate issues related to compliance with criteria, the University of Georgia College of Pharmacy was placed on probation (Spring 2009).*" In filing this complaint, NABP cannot confirm that an investigation of UGA occurred and NABP is disappointed that it was never contacted in regard to the action taken by ACPE against UGA's Continuing Education

Provider status. Therefore, we respectfully request information regarding whether the action against UGA College of Pharmacy Continuing Education Program was the result of misconduct either as NABP alleges in this letter or through some other source. Notwithstanding such request, NABP maintains that UGA's Office of Continuing Education and Outreach Program is directly and formally affiliated with, and the responsibility of, UGA and its Dean, as documented in the enclosed organizational chart outlining the administrative structure of the college of pharmacy. Moreover, the facts alleged in the court pleadings and the very nature of the NAPLEX as the entry-level pharmacist licensure examination for students, demand that ACPE investigate UGA's Doctor of Pharmacy professional program.

NABP respectfully submits the information contained in this complaint for immediate action against the present accreditation status of UGA's Doctor of Pharmacy Program and requests immediate revocation of said accreditation. We are available to discuss the information presented in the complaint and to further substantiate our complaint and request. Please do not hesitate to call upon us to answer any questions or provide additional information in this serious matter. NABP sincerely appreciates your time and assistance.

Cordially,

NATIONAL ASSOCIATION OF
BOARDS OF PHARMACY

Carmen A. Catizone, MS, RPh, DPh
Executive Director/Secretary

CAC/mg

Enclosures

cc: NABP Executive Committee

California State Board of Pharmacy
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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: **September 24, 2008**

To: **Licensing Committee**

Subject: **Fact Sheets on Application Procedures for Pharmacist Applicants**

Approximately 50% of the pharmacist examination applications the board receives are deficient. In an effort to improve applicant understanding of the requirements for licensure, board staff has developed fact sheets that will be placed on the board's Web site. These fact sheets are specific to each of the three groups of applicants who qualify for the pharmacist examination: recent graduate, foreign graduate and licensed pharmacists from out of state. We hope the end result of these fact sheets will be a reduced number of deficient applications and fewer inquiries to board staff.

For the last several years, board staff has made site visits to California Schools of Pharmacy to provide presentations on the application process. These presentations reduce the number of deficient applications received from California graduates. Unfortunately, we cannot complete this type of outreach to out of state schools; however, we are hopeful that these fact sheets will have a similar affect.

Draft copies of the fact sheets will be provided at the meeting for review and discussion.

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ARNOLD SCHWARZENEGGER, GOVERNOR

Date: **September 24, 2008**

To: **Licensing Committee**

Subject: **Licensing Unit Workload Adjustments Made to Accommodate Budget Restrictions**

Effective August 1, 2008, the Governor signed Executive Order 09-08, which required the board to dismiss several non-permanent employees and to furlough one additional staff member. As a result, the board lost six key staff responsible for, among other duties, assisting with the processing of applications and other licensee maintenance processes such as change of pharmacist-in-charge applications, change of designated representative-in-charge forms, discontinuance of business forms, etc.

To further aggravate this, the board lost its licensing manager to another state agency the first week in August. Unfortunately, also pursuant to the Executive Order, the board has been unable to fill this vacancy.

When faced with the challenge and the limited resources, board executive staff directed staff to suspend responding to status inquiries. This allowed board staff to focus on the most mission critical functions for licensing - - processing applications.

We are pleased to report the following workload statistics for August 2008.

APPLICATION TYPES

Clinic Permit	5
Drug Room/Exempt Pharmacy	0
Wholesaler Designated Representative	10
Veterinary Food-Animal Drug Retailer Designated Representative	0
Hospital Pharmacy	6
Hypodermic Permits	0
Intern Pharmacist	282
Licensed Correctional Facility	0
Resident Licensed Sterile Compounding	2

Non-Resident Pharmacy	8
Non-Resident Licensed Sterile Compounding	0
Non-Resident Wholesaler	3
Retail Pharmacy	23
Registered Pharmacist	291
Pharmacy Technician	926
Veterinary Food-Animal Drug Retailer	0
Wholesalers	5

Currently, board staff is again responding to status inquiries, but the result is that several staff lose at least one day per week responding to such inquiries, rather than processing applications, deficiencies, etc.

While we continue to evaluate our processes, should board staff have to continue to operate with these limited resources, we may need to permanently suspend status inquiries. We recognize that this creates frustration with applicants as well as board staff who pride themselves on providing excellent customer service. However, until staffing levels return to appropriate levels, we cannot continue to complete all tasks and respond to such inquiries without resulting in significant workload backlogs.

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Date: **September 24, 2008**

To: **Licensing Committee**

Subject: **The Coalition on Shortages of Allied Health Professionals**

The California Hospital Association recently established a coalition to examine the shortages of allied health professionals. The mission of this coalition is to create and lead a statewide coordinated effort to develop and implement strategic solutions to the shortage of non-nursing allied health professionals. This coalition is comprised of workforce committees, an advisory council and four workgroups. Board executive staff was invited to participate on the pharmacy services workgroup. The focus is on pharmacists and pharmacy technicians in the hospital setting.

The first workgroup meeting was held on September 16, 2008. Participants included staff and members of the California Hospital Association, the California Society of Health-Systems Pharmacists, a representative from academia, representatives from various hospitals and health systems as well as board staff. During this first meeting, barriers to the profession for both pharmacists and pharmacy technicians were identified. Further discussion resulted in the group concluding that there is not a shortage of pharmacy technicians; rather it is a shortage of qualified pharmacy technicians.

Some of the barriers identified for pharmacists included a limited number of student slots for individuals looking to enter the profession, the pharmacist examination and reciprocity, losing potential candidates to other healthcare professions, e.g., medical school, and untested new schools of pharmacy.

Workgroup meetings will continue quarterly over the next year. Based on the results of this workgroup as well as two others, it is the hope the coalition will develop and implement solutions to eliminate barriers, foster collaboration among CHA member hospitals and health systems, promote a long-term vision for the allied health workforce in California and develop links with workforce partners and stakeholders.

Following is the some of the information provided at the meeting as well as the meeting minutes.

Coalition on Shortages of Allied Health Professionals

Mission

To create and lead a statewide, coordinated effort to develop and implement strategic solutions to the shortage of non-nursing allied health professionals.

Organizational Structure

The Coalition on Shortages of Allied Health Professionals is comprised of the CHA Workforce Committee, Allied Healthcare Workforce Advisory Council and four workgroups.

CHA Workforce Committee Goals

- Through the establishment of service area workgroups, identify barriers, such as legislative and regulatory obstacles, that are linked to the causes of shortages of professionals in the areas of imaging, laboratory and pharmacy services.
- In conjunction with the Allied Healthcare Workforce Advisory Council, develop and implement solutions to eliminate these barriers.
- Foster collaboration among CHA member hospitals and health systems, other advocacy organizations, education, research, business and state government, among others.
- Promote a long-term vision for the allied health workforce in California.
- Further develop links with workforce partners and stakeholders.
- Pursue joint public/private partnerships for workforce training and education.

Workgroup Goals

- Identify and analyze barriers and challenges in developing, recruiting and retaining imaging, laboratory and pharmacy service professionals statewide.
- Draft an issue statement to the CHA Workforce Committee by December 1, 2008 that outlines and explains the barriers.
- Work with the CHA Workforce Committee to develop recommendations that will address the identified barriers with consideration given to emerging technologies and their future impact on the allied health workforce.

Guiding Principles for Committee, Council and Workgroups

- Coalition participants will have a fiduciary responsibility to the committee, council or workgroup of which they are a member.
- Recommendations will increase access to and improve quality of health care for Californians.
- Recommendations should take into consideration the need to build a diverse and culturally competent allied health workforce.
- Involving multiple partners and stakeholders is a valuable and necessary component for the success of the coalition.
- Proposed solutions must be statewide in nature.
- Recommendations must take into account the emergence of new technologies and their impact on the allied health workforce in the future.

Source: U.S. Department of Labor, Bureau of Labor Statistics.

Employment by occupation, 2006 and projected 2016 [Numbers in thousands]						
2006 National Employment Matrix		Employment		Change		Total job openings due to growth and net replacements, 2006-16 (1)
		Number				
Title	Code	2006	2016	Number	Percent	
Pharmacists	29-1051	243	296	53	21.72	95
Pharmacy technicians	29-2052	285	376	91	32.04	178

(1) Total job openings represent the sum of employment increases and net replacements.
If employment change is negative, job openings due to growth are zero and total job openings equal net replacements.

Projected growth in employment between 2006 and 2016 is indicated by a descriptor such as "Average", "Faster than average", "Much faster than average", etc. These descriptors were developed by the Bureau of Labor Statistics and correspond to a percentage (%) range. The table below serves as a legend.*

If employment will:	The growth is considered:
Increase 27 % or more	**Much faster than average**
Increase 18 % - 26 %	**Faster than average**
Increase 9 % - 17 %	Average
Increase 0 % - 8 %	More slowly than average
	Decline

*Table created by UCSF, Center for the Health Professions

California Occupational Projections of Employment 2006-2016
Pharmacists and Pharmacy Techs

Annual Openings Due to Growth

Area	Code	Occupation	Est Yr-Proj Yr	Annual Openings Due to Growth
California	291051	Pharmacists	2006 - 2016	620
California	292052	Pharmacy Technicians	2006 - 2016	840

Annual Openings Due to Separation

Area	Code	Occupation	Est Yr-Proj Yr	Annual Openings Due to Separations
California	291051	Pharmacists	2006 - 2016	410
California	292052	Pharmacy Technicians	2006 - 2016	710

Total Estimated Annual Openings due to Growth and Separation

Area	Code	Occupation	Est Yr-Proj Yr	Total Annual Openings
California	291051	Pharmacists	2006 - 2016	1030
California	292052	Pharmacy Technicians	2006 - 2016	1550

Occupational Projections of Employment

Area		Occupation	Est Yr-Proj Yr	Estimated Employment
California	291051	Pharmacists	2006 - 2016	23,800
California	292052	Pharmacy Technicians	2006 - 2016	23,300

Source: State of California, EDD, Labor Market Info
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COALITION ON SHORTAGES OF ALLIED HEALTH PROFESSIONALS

PHARMACY WORKGROUP
MEETING NOTES

Tuesday, September 16, 2008
10:00 a.m. – 2:00 p.m.

California Hospital Association Board Room
1215 K Street, Suite 800
Sacramento, CA 95814
(916) 443-7401

Workgroup Members Present:
Dawn Benton
Allan Cohen
James Colbert (via conference line)
Virginia Herold
Mariann Novarina
Lorie Rice
Gloria Robertson
Kenny Scott
Anne Soderegren.

Staff Present:
Cathy Martin
Gail Blanchard-Saiger
Judith Yates (via conference line)

Educational Requirements/Pathways for Pharmacy Technicians and Pharmacists:

Pharmacy Technicians	Pharmacists
• HS Diploma, GED or CDCR Certification • OR foreign grad • OR graduated from School of Pharm and couldn't pass Pharmacist exam • OR 240 hours of OJT at a tech training program in a hospital • OR pass the PTC exam • OR Associate dg from Community College • OR certification from other vocational school	• 4 Year degree • In addition to +/- 4 MORE years of Pharmacy School • Results in PharmD degree • In order to practice must pass national and state exam • After exam, 50% of PhramD grads do a residency • Other 50% go to work as pharmacists

Pharmacy Technician Supply:

Issues identified by the workgroup:

- Currently, there is lack of ***qualified*** pharmacy technicians, *but not a lack* of pharmacy techs in general.
- There is also a lack of ***quality*** pharmacy technician training programs.
- Regardless of education, substantial OJT is required to develop a skilled pharmacy technician.
- Creating long term job satisfaction for a pharmacy technician position is challenging due to the following factors:
    - Emerging technologies have lead to a "care and feeding" of the technology, instead of the employee.
    - The job is typically low in pay.
    - There is no long term career path from Pharm Tech.

How do pharmacy technicians fit into our workgroup discussions and the overall goals of the Coalition?

Workgroup members recognized that pharmacy technicians can become ***part*** of the solution to the pharmacist shortage only if the above outlined issues are addressed. Merely increasing the number of techs will not be beneficial.

Workgroup members came to a consensus that time would be better spent focusing on the pharmacist shortage specifically and reserving consideration of pharmacy technician issues for discussion only as they relate to increasing ***qualified and skilled*** technicians. It was recognized that qualified technicians can support pharmacists, allowing them to fulfill their most important role of utilization of drugs and clinical pharmacy.

Pharmacist Supply:

General notes and comments captured during workgroup session:

Currently, the pharmacists supply is a zero-sum game. There are only a certain number of them and if one facility beefs up recruiting and is able to fill a spot, it just leaves another facility with a vacancy. Addressing the cause of the shortages, as opposed to putting additional efforts into recruitment at the workforce level, will be a more effective way to deal with the shortages on the whole.

Workgroup consensus is to bridge with community and retail pharmacists further on in the process.

Issues and barriers identified by the workgroup:

Education Related

- Lack of Pharmacy School "slots". Applicants significantly outnumber the number of slots available.
- Faculty shortages.
- Faculty salaries not commensurate with the education required to teach at a Pharm School.
- Pharmacy Schools loose diverse candidates to medical schools and other professional schools.
- Getting in to Pharmacy School is extremely challenging – stringent requirements.
- Pharmacy is the "invisible" profession. Not widely promoted as an option to students.
- Cost of going to Pharmacy School could be linked to a lack of diversity.
- Disconnect between the academic preparation of pharmacists and the realities of the job.
- A lack of management of expectations – what to expect as a pharmacists.
- Because of a lack of capacity at schools like UCSD/SF, the demand is being filled by proprietary schools. There is a concern over the quality of these schools– are the graduates qualified?

Workforce Related

- Lack of qualified pharmacy technicians increases the pharmacists workload.
- Lack of qualified candidates to choose from when recruiting and hiring.
- Recent trends indicating that pharmacists desire flexible and/or part time schedules, and/or no weekends or nights. (difficult for hospitals that operate 24/7)
- Strong competition between pharmacies of all sorts as they try to fill vacancies.
- Cost of living in CA very high.
- Loosing pharmacists to other states.
- Willingness of pharmacists to relocate can be an issue because California is so diverse from region to region. (i.e. someone from the bay area or LA may not be likely to fill a vacancy in the Central Valley where shortages are high or visa versa.)
- Flat salaries throughout career. Years of experience does not pay off.
- Gender trends – with majority of women in the field, flexible working schedules are increasing demand for coverage.
- Job dissatisfaction.
- Pharmacists moving to other related professions (home therapy, research, manufacturing, etc…)
- Lack of commitment – 2-3 pharmacists needed to fill 1 FTE.

Technology Related

- Although emerging technologies may fill a gap and help with pharmacists workload, technology can be:
  - Very expensive
  - Inconsistent with regulations.

- Workgroup reaction to ROBOT-Rx:
  - Rules are not clear on how to use the technology.

Other Related Issues/Barriers:

- Lack of State reciprocity for licensing.
- State licensing of Pharmacists in general may be an issue. National licensing sufficient?
- Increased regulations leading to an increased demand for pharmacists.
- Increased need for specialty pharmacists – siphoning of pharmacists from general supply.
- Lack of specialty pharmacists training programs.
- NPLEX: If you took the exam before 2004, you need to take it again to be licensed in CA

Information and/or data needed:

- Studies that show vacancies. – Cathy to see Virginia
- How does data differ from hospital to retail pharmacies?
- Demographics of graduates

Next Steps and Action Items:

- 90 minute call-in (in person available) meeting in October and November. Agenda items will include ranking issues/barriers in terms of their impact on the shortages.
- Connect Kathryn Knapp of Touro University to the group – Cathy to work with Lori Rice.
- Cathy Martin to send out meeting notes by September 25 and include proposed dates for October call.

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ARNOLD SCHWARZENEGGER, GOVERNOR

Date: **September 24, 2008**

To: **Licensing Committee**

Subject: **Task Force to Evaluate Pharmacy Technician Qualifications**

This year the California Society of Health-System Pharmacists (CSHP) sponsored legislation to increase the requirements for an individual to become licensed in California as a pharmacy technician. This bill was pulled due to concerns expressed by key pharmacy stakeholders, with the intent of pursuing legislation again in 2009.

CSHP is sponsoring stakeholder meetings to elicit recommendations and comments to refine the proposal for next year. The first stakeholder meeting was held on June 25, 2008. Board Member Stan Weisser was designated by President Schell to represent the board at these meetings.

Discussion at both the June 2008 Licensing Committee meeting and the stakeholder meeting revealed that there is disagreement within industry about what and if there is a problem with the current existing pharmacy technician qualifications requirements as well as whether the draft legislative proposal correctly addresses the minimum qualifications. In addition, there appears to be disagreement about whether continuing education is necessary for pharmacy technicians.

CSHP is currently working jointly with the California Pharmacists Association (CPhA) to determine common outcomes and CSHP anticipates resumption of sponsoring stakeholder meetings in the future to elicit stakeholder recommendations and comments to refine the proposal for next year.

On the national level, during the NABP Annual meeting, a resolution was passed to establish a task force on standardized pharmacy technician education and training. This task force will assess and recommend revisions, if necessary, to language in *the Model State Pharmacy Act and Model Rules of National Association of Boards of Pharmacy.*

A representative from CSHP will be attending the meeting.

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ARNOLD SCHWARZENEGGER, GOVERNOR

Date: **September 23, 2008**

To: **Licensing Committee**

Subject: **Veterinary Food Animal Drug Retailers – Qualification Process for Designated Representatives**

Veterinary food-animal drug retailers (vet retailers) may distribute and label legend drugs or drugs for extra-label use prescribed by a veterinarian for use on food-animals. A vet retailer's premises must be supervised by a registered pharmacist or a specially qualified individual approved by the board who holds a current vet retailer designated representative license. A vet retailer may not operate unless the pharmacist or vet retailer designated representative is physically present on the licensed premises.

There are currently 23 vet retailers and 62 vet retailer designated representative licensed in California.

Only a vet retailer designated representative or pharmacist may label the drugs that: (1) have been prescribed by a veterinarian, and (2) will be shipped to the veterinarian's client for use on food-animals. If the sole qualifying vet retailer designated representative or pharmacist leaves the employ of the vet retailer, the vet retailer must cease operations (and cannot perform labeling or shipping duties) until another pharmacist or vet retailer designated representative is employed and present.

Individuals employed by a manufacturer, vet retailer, or wholesaler may qualify to become vet retailer designated representatives on the basis of specific education, training, and experience in areas covering the essential knowledge necessary to oversee operations of a vet retailer and to read, label and dispense vet food-animal drugs.

In addition to the training required for designated representatives, designated representatives for vet retailers to also must have **either** a course of training that includes as least 240 hours of theoretical and practical instruction, provided that at least 40 hours are theoretical instruction stressing:

- Knowledge and understanding of the importance and obligations relative to drug use on food-animals and residue hazards to consumers.
- Knowledge and understanding of state and federal law regarding dispensing of drugs, including those prescribed by a veterinarian.
- Knowledge and understanding of prescription terminology, abbreviations, dosages and

format, particularly for drugs prescribed by a veterinarian.
- Understanding of cautionary statements and withdrawal times.
- Knowledge and understanding of information contained in package inserts.

OR

- Possess a registration as a registered veterinary technician with the California Veterinary Medical Board **or**

- Be eligible to take the State Board of Pharmacy's pharmacist licensure exam or the Veterinary Medical Board's veterinarian licensure examination **or**

- Have worked at least 1,500 hours within the last three years at a veterinary food-animal drug retailer's premises working under the direct supervision of a vet retailer designated representative. Part of the 1,500 hours of work experience shall include knowledge and understanding of information contained in package inserts. A vet retailer designated representative who vouches for the qualifying experience earned by an applicant for registration must do so under penalty of perjury.

The ability to read prescriptions and prepare and label containers for food animals without the oversight of a pharmacist requires specific training.

The University of California Davis in the past had a 40 hour training course that satisfied the requirements for licensure as a vet retailer designated representative; however, the board received information that this program is no longer offered. Board staff is unaware of any other program in California that complies with the requirements in law.

Board staff is requesting that the committee consider changes in the vet retailer program, specifically to either ask the Veterinarian Association or the Veterinarian Board to offer the 40 hour course, or to consider eliminating the program. Further, board staff is requesting, that given the nature of the work being performed by such individuals that the committee discuss if the requirements as framed in law are appropriate.

A veterinarian will be available at the meeting to discuss this with the committee and answer any questions.

Provided with this memo is a copy of a letter from Greg Evans, PharmD, an Los Angeles Times article entitled, "Antibiotics in Our Livestock" , and a copy of Title 16, California Code of Regulations Section 1780.1.

To: Virginia Herold, Executive Officer
California State Board of Pharmacy
From: Greg Evans, Pharm.D.
Access Pharmacy Resources
Date: March 30, 2007
Re: Existing laws for Vet Retailer Exemptees

Ginny:

As you know, a major part of our business is offering a training seminar for Designated Representatives for California licensed medical wholesalers and for non-resident wholesalers outside the state. Because of this, we come across others who are in need of training in other areas. Some we are able to assist and others fall beyond the scope of what we provide.

One recent example of "falling beyond the scope", is in the practice area of Veterinary Food-Animal Drug Retailers (VFADR). We recently received a call from a company who is seeking to have an individual trained to become licensed as a Vet Retailer Exemptee, in order to remain compliant with California regulations.

The current regulation, as listed in CCR 1780.1(m), outlines the training requirements to qualify for licensure as a Vet Retailer Exemptee. It reads as follows:

m. Training of Vet Retailer Exemptee
- (1) A course of training that meets the requirements of section 4053(b)(4) shall include at least 240 hours of theoretical and practical instruction, provided that at least 40 hours are theoretical instruction stressing:
  - (A) Knowledge and understanding of the importance and obligations relative to drug use on food-animals and residue hazards to consumers.
  - (B) Knowledge and understanding of state and federal law regarding dispensing of drugs, including those prescribed by a veterinarian.
  - (C) Knowledge and understanding of prescription terminology, abbreviations, dosages and format, particularly for drugs prescribed by a veterinarian.
  - (D) Understanding of cautionary statements and withdrawal times.
  - (E) Knowledge and understanding of information contained in package inserts.

A course that met these criteria was offered at one time by the UC Davis School of Veterinary Medicine. When CCR 1781.1 was implemented, there was a surge of those seeking licensure. Currently, there are only 22 VFADR's licensed in California. The demand from the initial surge has greatly diminished; therefore, UC Davis no longer offers the training program. I confirmed this with them on March 29, 2007. Because there are no providers of this training, it effectively renders CCR 1781.1(m)(1) irrelevant, by mandating something that is not available.

However, CCR 1781.1 goes on to offer alternative means of satisfying the training requirements. It states:

(2) As an alternative to the training program specified in paragraph (1), other training programs that satisfy the training requirements of section 4053 include fulfillment of one of the following:

(A) Possess a registration as a registered veterinary technician with the California Veterinary Medical Board.

(B) Being eligible to take the State Board of Pharmacy's pharmacist licensure exam or the Veterinary Medical Board's veterinarian licensure examination.

(C) Having worked at least 1,500 hours within the last three years at a veterinary food-animal drug retailer's premises working under the direct supervision of a vet retailer exemptee. The specific knowledge, skills and abilities listed in sections 1780.1(m)(1)(A-E) shall be learned as part of the 1500 hours of work experience. A vet retailer exemptee who vouches for the qualifying experience earned by an applicant for registration must do so under penalty of perjury.

Because the first option of the 240 hour training program is apparently no longer available anywhere in California, the result is that the section (2) "alternative" options have now become the only options. This creates a deficit in an individual's ability to become licensed as a Vet Retailer Exemptee. If a VFADR company has turnover at the vet retailer exemptee position, it leaves very few and difficult alternatives for them to replace that person with a newly licensed individual.

The other types of licensed persons who can fulfill the vet exemptee role are hard to come by. Veterinary techs are few in number and mostly employed by veterinarians. Pharmacists and veterinarians are legally able to fill this role, but they are cost prohibitive and almost impossible to find for this type of work.

To resolve this issue, a few options come to mind. **First** - Is UC Davis willing to make their program available in some type of on-line or self-study format? No one is more knowledgeable about this topic, and it would require no changes to the law, as long as the 240 hour requirement was met. **Second** - If that is not viable, is it possible to make the training requirements similar to what is required to become a Designated Representative for a medical wholesaler? See BP 4053(b)(3)(A-E). This would require removing the mandated 240 hours of training. **Third** - I am not aware of any that offer it, but it may be possible for a trade or tech school to provide a 240 hour training program. But due to lack of high demand, I do not foresee anyone offering such an extensive program.

Ginny, I am not attempting to dilute the requirements for licensure, nor am I trying to be self-serving in bringing this issue to your attention. I am only responding to a call and subsequent discussion with a VFADR and their challenges to get licensed to stay compliant. I currently do not provide any vet exemptee training and honestly, there isn't a huge market for it. If the regulations were changed by taking away the 240 hour requirement and only mandating knowledge and understanding of certain topics, it would allow the material to be presented in a much shorter format, with review questions or an examination at the end to prove knowledge and understanding.

This would make it similar to what we do to train Designated Reps for medical wholesalers. If these changes occurred it is theoretically possible for us to develop such a program. The returns would be minimal, but if it provided a needed mechanism and filled a void to help companies and individuals get licensed and stay compliant, we could take a look at developing such a program. Whether we provide any training or not, CCR 1781.1 does not reflect current availability.

Thank you for your time and consideration of this proposal. I look forward to seeing you at future Pedigree Workgroup Meetings.

Karen Abbe/Pharmacy/DCANotes
05/06/2008 09:54 AM

To Virginia Herold/Pharmacy/DCANotes@DCANotes
cc Anne Sodergren/Pharmacy/DCANotes@DCANotes
bcc
Subject LA Times: Antibiotics in our livestock

Los Angeles Times

ANTIBIOTICS IN OUR LIVESTOCK
Their overuse in the meat and poultry industries may help spawn superbugs.

http://www.latimes.com/features/health/medicine/la-ed-antibiotics1-2008may01,0,756746.story

Los Angeles Times
May 1, 2008

Just when everyone is fretting over the price of food, the Pew Commission on Industrial Farm Animal Production released a report that outlines the ways in which factory farming exacts an additional toll on both the Earth and the consumer. The pollution of streams and groundwater and the greenhouse gases produced by animal waste entail actual dollar costs borne largely by taxpayers, as well as more intrinsic concerns about human health, environmental damage and animal well-being.

The good news is that, among the trends laid out in the report, the most troubling is also among the most fixable: overuse of antibiotics in livestock, a major contributor to the creation of drug-resistant bacteria and thus a direct assault on human health. The danger isn't in what consumers eat -- the U.S. Department of Agriculture strictly limits antibiotic residue in meat -- but in the superbugs that become part of the environment.

Not just a cure for infection anymore, antibiotics are routinely given to livestock to prevent disease in crowded pens and stockyards and to promote growth. The report says farms can buy these drugs without a prescription or veterinary permission, so it's no surprise that half of all the antibiotics worldwide are used in food production. The ubiquitous use of animal antibiotics saves consumers $5 to $10 a year on their meat and poultry bill, the National Academy of Sciences estimated in 1999. Even that relative pittance is a pseudo-saving, though, because the United States spends more than $4 billion a year to combat resistant infections, which kill 90,000 people a year in this country.

Experience elsewhere shows that meat producers can use far less medication. In 1998, Denmark banned antibiotic use in livestock except to treat illness. Four years later, a World Health Organization study found that the ban was already helping to reduce the potential for resistant bacteria, at minimal cost to meat producers and without significantly affecting the health of the livestock. Two years ago, the European Union banned the use of all growth-enhancing antibiotics.

Federal legislation that would phase out the use of livestock antibiotics (except to treat sick animals) is stalled, despite the endorsement of the American Medical Assn. and the American Academy of Pediatrics. No matter how frightening the grocery tab is getting, we cannot afford to lose the effectiveness of existing antibiotics. Public health comes before cheap meat.

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§1780.1. Minimum Standards for Veterinary Food-Animal Drug Retailers.

In addition to the minimum standards required of wholesalers by section 1780, the following standards shall apply to veterinary food-animal drug retailers.
(a) Drugs dispensed by a veterinary food-animal drug retailer pursuant to a veterinarian's prescription to a veterinarian's client are for use on food-producing animals.
(b) Repackaged within the meaning of Business and Professions Code section 4041 means that a veterinary food-animal drug retailer may break down case lots of dangerous drugs as described in 4022(a), legend drugs or extra label use drugs, so long as the seals on the individual containers are not broken. Veterinary food-animal drug retailers shall not open a container and count out or measure out any quantity of a dangerous, legend or extra label use drug.
(c) Dangerous drugs, legend drugs or extra label use drugs returned to a veterinary food-animal drug retailer from a client shall be treated as damaged or outdated prescription drugs and stored in the quarantine area specified in section 1780(e)(1). Returned drugs may not be returned to stock, or dispensed, distributed or resold.
(d) A pharmacist or person issued a permit under Business and Professions Code section 4053 (hereafter called a vet retailer designated representative) may dispense drugs for use on food-producing animals on the basis of a written, electronically transmitted or oral order received from a licensed veterinarian. Only a pharmacist or the vet retailer designated representative may receive an oral order for a veterinary food-animal drug from the veterinarian. A written copy of the oral prescription shall be sent or electronically transmitted to the prescribing veterinarian within 72 hours.
(e) When a vet retailer designated representative dispenses a prescription for controlled substances, the labels of the containers shall be countersigned by the prescribing veterinarian before being provided to the client.
(f) Whenever a vet retailer designated representative dispenses to the same client for use on the same production class of food-animals, dangerous drugs, legend drugs or extra label use drugs prescribed by multiple veterinarians, the vet retailer designated representative shall contact the prescribing veterinarians for authorization before dispensing any drugs.
(g) Refilling a veterinarian's prescription
(1) A veterinary food-animal drug retailer may refill a prescription only if the initial prescription is issued indicating that a specific number of refills are authorized. If no refills are indicated on the initial prescription, no refills may be dispensed. Instead, a new prescription is needed from the veterinarian.
(2) A veterinary food-animal drug retailer may not refill a veterinarian's prescription order six months after the issuance date of the initial order. Records of any refills shall be retained by the veterinary food-animal drug retailer for three years.
(h) Labels affixed to a veterinary food-animal drug dispensed pursuant to Business and Professions Code section 4041 shall contain the:
(1) Active ingredients or the generic names(s) of the drug

(2) Manufacturer of the drug
(3) Strength of the drug dispensed
(4) Quantity of the drug dispensed
(5) Name of the client
(6) Species of food-producing animals for which the drug is prescribed
(7) Condition for which the drug is prescribed
(8) Directions for use
(9) Withdrawal time
(10) Cautionary statements, if any
(11) Name of the veterinarian prescriber
(12) Date dispensed
(13) Name and address of the veterinary food-animal drug retailer
(14) Prescription number or another means of identifying the prescription, and if an order is filled in multiple containers, a sequential numbering system to provide a means to identify multiple units if shipped to the same client from the same prescription (container 1 of 6, container 2 of 6, etc.)
(15) Manufacturer's expiration date
(i) A record of shipment or an expanded invoice shall be included in the client's shipment, and shall include the names of the drugs, quantity shipped, manufacturer's name and lot number, date of shipment and the name of the pharmacist or vet retailer designated representative who is responsible for the distribution. Copies of the records shall be distributed to the prescribing veterinarian and retained by the veterinary food-animal drug retailer for three years.
(j) If a retailer is unable at any one time to fill the full quantity of drugs prescribed, the retailer may partially ship a portion so long as the full quantity is shipped within 30 days. When partially filling a veterinarian's prescription, a pharmacist or vet retailer designated representative must note on the written prescription for each date the drugs are shipped: the quantity shipped, the date shipped, and number of containers shipped, and if multiple containers are dispensed at one time, each container must be sequentially numbered (e.g., 1 of 6 containers),. If a retailer is unable to dispense the full quantity prescribed within 30 days, a new veterinarian's prescription is required to dispense the remainder of the drugs originally prescribed.
(k) Upon delivery of the drugs, the supplier or his or her agent shall obtain the signature of the client or the client's agent on the invoice with notations of any discrepancies, corrections or damage.
(l) If a person, on the basis of whose qualifications a certificate of exemption has been granted under Business and Professions Code Section 4053 (the vet retailer designated representative), leaves the employ of a veterinary food-animal drug retailer, the retailer shall immediately return the certificate of exemption to the board.
(m) Training of Vet Retailer Designated representative:
(1) A course of training that meets the requirements of section 4053(b)(4) shall include at least 240 hours of theoretical and practical instruction, provided that at least 40 hours are theoretical instruction stressing:

(A) Knowledge and understanding of the importance and obligations relative to drug use on food-animals and residue hazards to consumers.
(B) Knowledge and understanding of state and federal law regarding dispensing of drugs, including those prescribed by a veterinarian.
(C) Knowledge and understanding of prescription terminology, abbreviations, dosages and format, particularly for drugs prescribed by a veterinarian.
(D) Understanding of cautionary statements and withdrawal times.
(E) Knowledge and understanding of information contained in package inserts.
(2) As an alternative to the training program specified in paragraph (1), other training programs that satisfy the training requirements of 4053 include fulfillment of one of the following:
(A) Possessing a registration as a registered veterinary technician with the California Veterinary Medical Board.
(B) Being eligible to take the State Board of Pharmacy's pharmacist licensure exam or the Veterinary Medical Board's veterinarian licensure examination.
(C) Having worked at least 1,500 hours within the last three years at a veterinary food-animal drug retailer's premises working under the direct supervision of a vet retailer designated representative. The specific knowledge, skills and abilities listed in sections 1780.1(m)(1)(A-E) shall be learned as part of the 1500 hours of work experience. A vet retailer designated representative who vouches for the qualifying experience earned by an applicant for registration must do so under penalty of perjury.

NOTE: Authority cited: Sections 4005 and 4197, Business and Professions Code. Reference: Sections 4040, 4041, 4053, 4059, 4063, 4070, 4081, 4196, 4197, 4198 and 4199, Business and Professions Code.

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

Date: **September 24, 2008**

To: **Licensing Committee**

Subject: **Continuing Education for Competency Committee Members**

The Competency Committee is a subcommittee of the board's Licensing Committee. Competency Committee members serve as the board's subject matter experts for the development of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE). A committee member term is generally about eight years.

Annually, committee members attend approximately 3-4 two-day meetings to assist in examination development. Each two-day committee consists of approximately 2-4 hours of preparation time in addition to 16 hours of meeting time. Committee members also participate in 2-4 writing assignments based on the examination development need. Committee members spend approximately 50-80 hours preparing for and attending committee meetings on an annual basis in addition to multiple writing assignments and are compensated for time and travel.

Current pharmacy law requires pharmacists to earn 30 hours of approved continuing education (CE) every two years as a condition of license renewal. Currently, pharmacists can earn CE:

- Offered by approved providers (ACPE and the Pharmacy Foundation of California – 16 CCR 1732.05),
- Approved by Medical Board, Board of Podiatric Medicine, Board of Registered Nursing or Dental Board, if relevant to pharmacy practice (16 CCR 1732.2), or
- By petition of an individual pharmacist for a course that meets board standards for CE for pharmacists (16 CCR 1732.2).

Additionally, the board will award CE for:

- Attending one board meeting annually (6 hours of CE),
- Attending two committee meetings annually (2 hours of CE for each meeting, must be different committee meetings), and
- Completing the PSAM, which is administered by the National Association of Boards of Pharmacy (6 hours).

In June 2008, the Licensing Committee considered a request from the competency committee to earn 6 hours of CE annually for participation in this committee. The committee decided to request additional information on this topic and did not take action.

Based on further discussion with the committee during its annual retreat, the committee is revising and resubmitting its request. Specifically, one of the core functions of this committee is to complete on-line review of all test questions prior to administration. As the test questions cover all aspects of pharmacy practice and law, this on-line review requires a significant amount of committee time to research items and confirm that a question and answer are valid. Given this, the committee requests that the board award

up to six hours of CE annually for members that complete this on-line review. (Typically committee members are not compensated for their time to complete this function. If a committee member is seeking reimbursement for this time however, continuing education will not be awarded.)

Should the committee and board vote to approve this request, a regulation change will be necessary to implement this change.

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Date: **September 24, 2008**

To: **Licensing Committee**

Subject: **Competency Committee Report**

Update on the CPJE

Since the June 2008 Licensing Committee Meeting, the Competency Committee as a whole held its annual meeting to discuss examination development as well as other emerging issues.

While each Competency Committee workgroup was scheduled to meet this fall, the meeting scheduled in September was cancelled because of the Governor's Executive Order. A meeting is also scheduled in October and board staff is hopeful that this meeting will continue on as planned. The workgroup meetings focus primarily on examination development.

The most recent quality assurance assessment ended June 2, 2008.

4 Time Failure Report

Business and Professions Code section 4200.1 establishes a requirement in law that an applicant who fails either the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE) or the North American Pharmacist Licensure Examination (NAPLEX) four times, must complete 16 units of pharmacy education prior to being eligible to take either examination again.

In addition, this section also requires the board to collect specified data and submit a report to the legislature detailing the findings. The reporting elements include:

- The number of applicants taking the examination and number who fail the examination for the fourth time,
- The number of applicants, who after failing the examination for the fourth time, complete pharmacy studies program in California or in another state to satisfy this requirement,
- To the extent possible, the school from which the applicant graduated, the school's location and the pass/fail rates on the examination for each school.

The report includes data from January 1, 2004 through July 1, 2008.

Following is the draft report. This report is due to the legislature on September 30, 2008.

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Report on the Requirement that Candidates Failing the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE) Four Times Must Obtain Additional Education in Pharmacy

DRAFT

Pursuant to California Business and Professions Code section 4200.1, the California State Board of Pharmacy is pleased to provide the following report detailing the impact of requiring candidates for pharmacist licensure who fail the licensure examination four times to take remedial education before they can retake the licensure examination.

The board is required to submit this report for examinations taken between January 1, 2004, and July 1, 2008, inclusive.

Summary

Between January 1, 2004, and July 1, 2008, 7,578 candidates took California's pharmacist licensure examination. The pass rate during this period was 79.3 percent. There were 41 candidates who failed the exam four times. There were 21 candidates who requalified to retake the California pharmacist licensure examination who retook 16 units of pharmacy coursework. Of these 21, 11 passed the exam (52 percent).

Background

Since 1999, candidates for the California pharmacist licensure examination who fail the examination four or more times have been required to take 16 units of education in pharmacy from a school of pharmacy approved by the Accreditation Council for Pharmacy Education. This provision was set to be repealed January 1, 2005. However, subsequent legislation enacted in 2004 (Senate Bill 1913, Senate Business and Professions Committee, Chapter 695) extended the sunset date for this provision until January 1, 2008. Additional legislation enacted in 2006 (Senate Bill 1476, Senate Business, Professions and Economic Development Committee, Chapter 658) extended the sunset date for this provision until January 1, 2010.

The board sponsored the initial requirement for candidates to take remedial education after four attempts at passing the pharmacist licensure examination for various reasons. One reason was to remove a number of applicants from the licensure examination who had repeatedly failed the examination. For example, there were several applicants who had taken the examination more than 25 times (the examination was given twice a year until January 2004). A major concern was that these individuals were taking the examination only to memorize questions that could be provided to preparation course providers.

The requirement to take remedial education took effect July 1, 1998. To implement the statutory provisions, the board adopted a regulation that took effect November 4, 1998 (California Code of Regulations, Title 16, section 1725). This regulation specifies that the remedial education of 16 units must be taken in a school of pharmacy approved by the American Council on Pharmaceutical Education (which in 2003 became known as the Accreditation Council for Pharmacy Education - ACPE) or a school recognized by the board. The ACPE accredits schools of pharmacy in the United States. The Board of Pharmacy never separately recognized any school.

From July 1, 1998, until January 1, 2004, the board gave 10 examinations (January and June, 1999-2003). Each of these examinations was written and graded exclusively for California by the California State Board of Pharmacy. The examination was developed by a team of 22 subject matter experts, under the guidance of a psychometric consulting firm selected to assure that the examination met all required components for job relevancy and validity.

In January 2004, there was a substantial change in the California pharmacist licensure examination made by SB 361 (Figueroa, Chapter 539, Statutes 2003). The new provisions require the use of the National Association of Boards of Pharmacy examination called NAPLEX and a second, California-specific and jurisprudence examination initially called the California Pharmacist Jurisprudence Exam and later renamed California Practice Standards and Jurisprudence Examination for Pharmacists (or CPJE). Both are multiple-choice examinations and are given via computer, six days per week at testing centers nationwide. Testing began under the new format in late March 2004.

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Data:

The board is required to report on three components. Each of these components is individually discussed below. For each of presentation the required component appears in bold.

1. **The number of applicants taking the examination and the number who fail the examination for the fourth time.** [Business and Professions Code, Section 4200.1 (f) (1)]

Year	Candidates	Failed 4th Time	Percent
2004	1733	11	0.63
2005	1804	10	0.55
2006	1613	9	0.56
2007	1665	3	0.18
2008	763	8	1.05
Total	7578	41	0.54

2. **The number of applicants who, after failing the examination for the fourth time, complete a pharmacy studies program in California or another state to satisfy the requirements of this section and who apply to take the licensure examination required by Section 4200.** [Business and Professions Code, Section 4200.1 (f) (2)]

Year	Candidates	Requalified	Percent
2004	1733	3	0.17
2005	1804	1	0.06
2006	1613	1	0.06
2007	1665	13	0.78
2008	763	3	0.39
Total	7578	21	0.28

Of the 21 candidates that requalified to take the CPJE, 11 of the 21 passed (a pass rate of 52 percent).

3. **To the extent possible, the school from which the applicant graduated and the school's location and the pass/fail rates on the examination for each school.** [Business and Professions Code, Section 4200.1 (f) (3)]

Schools with Candidates Failing 4 Times[1] 1/1/04-7/1/08				
Pharmacy Schools and Locations	Number of Candidates Failing their 4th Time	All Candidates		
		Total	Pass (Percent)	Fail (Percent)
University of Arizona Tucson, AZ	1	39	82.05	17.95
University of the Pacific Stockton, CA	1	896	93.19	6.81
University of Southern California Los Angeles, CA	1	810	93.09	6.91
Howard University Washington, DC	1	32	53.13	46.88
Mercer University Atlanta, GA	1	23	56.52	43.48
University of Georgia Athens, GA	3	49	69.39	30.61
Xavier University of Louisiana New Orleans, LA	1	36	75.00	25.00
Massachusetts College of Pharmacy-Boston Boston, MA	4	535	71.59	28.41
Wayne State University Detroit, MI	1	22	54.55	45.45
St. Louis College of Pharmacy St. Louis, MO	1	60	48.33	51.67
Creighton University Omaha, NE	1	180	73.33	26.67

[1] As candidates may take the examination multiple times, statistics are based on each examination attempt by each candidate.

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Western University Pomona, CA	1	491	93.89	6.11
Long Island University Brooklyn, NY	1	124	66.13	33.87
Ohio Northern University Ada, OH	1	19	68.42	31.58
University of the Sciences in Philadelphia Philadelphia, PA	2	85	70.59	29.41
Wilkes University Wilkes-Barre, PA	1	15	73.33	26.67
Midwestern University-Glendale Glendale, AZ	1	74	70.27	29.73
University of Southern Nevada Henderson, NV	2	234	76.92	23.08
Foreign Graduates Various countries	16	1315	63.35	36.65
CPJE	41	7578	79.29	20.71

Schools with Candidates Requalifying After Completed Remedial Education[1]
1/1/04-7/1/08

Pharmacy Schools and Locations	Number of Candidates Failing their 4th Time	All Candidates		
		Total	Pass (Percent)	Fail (Percent)
University of Arizona Tucson, AZ	1	39	82.05	17.95
University of the Pacific Stockton, CA	2	896	93.19	6.81
University of Southern California Los Angeles, CA	1	810	93.09	6.91
Xavier University of Louisiana New Orleans, LA	1	36	75.00	25.00
Massachusetts College of Pharmacy-Boston Boston, MA	1	535	71.59	28.41
Long Island University Brooklyn, NY	3	124	66.13	33.87
University of Puerto Rico San Juan, PR	1	5	20.00	80.00
Midwestern University-Glendale Glendale, AZ	1	74	70.27	29.73
University of Southern Nevada Henderson, NV	1	234	76.92	23.08
Foreign Graduates Various countries	9	1315	63.35	36.65
CPJE	21	7578	79.29	20.71

[1] As candidates may take the examination multiple times, statistics are based on each examination attempt by each candidate. .