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STATE AND CONSUMERS AFFAIRS
DEPARTMENT OF CONSUMER
ARNOLD SCHWARZENEGGER, GO

Licensing Committee Report

Ruth Conroy, PharmD, Chair
Clarence Hiura, PharmD, Member
Susan Ravnar, PharmD, Member

Report of the September 20, 2006 Meeting

Minutes of the Licensing Committee Meeting are provided in this tab section as **Attachment A**.

1. California Schools of Pharmacy Project to Identify and Test on the Professional Competencies that Should be Achieved by the End of Basic Intern Experience

RECOMMENDATION for Board Action: That the Board of Pharmacy Support and Participate in This Project

The board was recently advised about a review of the intern experience component of pharmacy education that is being initiated by California's schools of pharmacy. This group will examine both the required and elective components of ACPE approved intern experience at both the basic (IPPE) and advanced (APPE) levels. The project will be called the California Pharmacy IPPE/OSCE Initiative (*note: OSCE is the acronym for objective structured clinical examination*). The goal is to develop an assessment exam to assess intern experience at the basic level. There is currently no assessment method used in California for any intern experience; California law requires only the completion of 1,500 hours of intern experience that complies with ACPE requirements (basic and advanced).

The California pharmacy schools are collaborating in this initiative to determine the competencies that students should achieve by the end of their introductory pharmacy practice experiences (IPPEs) and before starting their advanced pharmacy practice experiences (APPEs). This initiative is in response to new ACPE accreditation standards that spell out how much time students must spend in IPPEs and APPEs rather than what they should learn (outcomes).

At this board meeting, Barbara Sauer, PharmD, Clinical Professor, Department of Clinical Pharmacy, UC Davis Med Center, will provide a presentation about what this group will evaluate and hopes to accomplish. Details about the initiative are provided in this **Attachment 1**.

During the first phase of the project, the group will determine the competencies that students should achieve as interns. One item they will reference is the formerly required Board of Pharmacy Intern Affidavits. The second phase involves developing a reliable and valid performance-based exam (i.e., objective structured clinical exam, OSCE) to assess student achievement of these competencies.

One motivating concern of the group is that laws requiring a specific duration of experience (i.e., 1,500 intern experience hours) -- but without specifying the components to be gained from the experience -- are not beneficial.

The goals of the initiative are to:

1. Reach consensus on the basic foundational competencies that all pharmacy students in California should master during basic intern experiences.
2. Train faculty members from each pharmacy school in California how to develop and administer an OSCE-based assessment.
3. Develop a validated and standardized OSCE-based examination to assess achievement of the basic competencies
4. Develop a mechanism to assure replenishment of the OSCEs and exam security in the future
5. Petition ACPE to accept an OSCE-based assessment for basic experience as evidence of compliance with specific ACPE standards.

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

Because the first meeting of this group will occur before this board meeting, President Powers has appointed Board Member Susan Ravnan as the board's representative to this group.

2. Request from California Pharmacy School Intern Pharmacists to Increase the Number of Intern Hours That Can Be Earned Outside a Pharmacy from 600 to 1,000 Hours

RECOMMENDATION for Board Action: None at this time

Under current law, an intern must earn 1,500 hours of intern experience. California law requires that a minimum of 900 hours of experience be earned in a pharmacy, under the supervision of a pharmacist. The remaining 600 hours of intern experience can be obtained outside a pharmacy, but this experience must still be done under the supervision of a pharmacist and be substantially related to the practice of pharmacy. California pharmacy students typically earn these 600 hours for school-required experience training during the fourth year (clinical clerkship).

At the March 2006 Licensing Committee Meeting, students from various California pharmacy schools requested that the board amend its regulations to allow up to 400 hours more (for a total of 1,000 hours) of intern experience that can be earned under the supervision of a pharmacist, but outside a pharmacy. At the March meeting,

students were asked to compile information and return to the committee. The December 2006 Licensing Committee Meeting was the next opportunity for the students to return. Background materials on this topic are provided in **Attachment 2**.

The students have been invited to this Board Meeting for additional discussion.

If modified as proposed by the students, an intern would only need to earn a minimum of 500 hours of experience in a pharmacy.

According to the pharmacy students, opportunities for pharmacists have expanded beyond the traditional areas of community and hospital practice settings. Many students would like the opportunity to gain experience in the pharmaceutical industry, managed care, regulatory affairs and association management, but are unable to do so because they cannot earn intern hours for this experience. As part of the pharmacy school curriculum, students complete various rotations in their first and fourth years in both community and hospital pharmacy. In the fourth year, pharmacy experience is more clinical.

The students believe that even if the board were to change the ratio of intern hours as they propose, a large percentage of students would still earn the majority of their intern hours in a pharmacy. However, this new ratio would allow those students who show proficiency in pharmacy settings to be able to expand their experience in other areas.

The students provided a PowerPoint presentation that is provided in the background materials for this topic in **Attachment 2**. This presentation at the December Licensing Committee Meeting highlighted the additional areas that interns could pursue if the intern hours experience requirement was more flexible. They cited statistics indicating the benefit that redirected students could provide to health care, and noted that the proposal fits the board's mission.

The committee allowed considerable discussion during the meeting. Various options were discussed including a possible addition of 400 hours to the intern experience requirement (to total 1,900 hours) to permit such additional experience.

However, discussion also included the need for students to thoroughly understand the workings of a pharmacy, and why such experience is so important to a pharmacist's future as a supervisor of pharmacy functions and personnel.

The committee concluded that without a solid understanding of and actual experience in pharmacies, pharmacists will lack critical knowledge about pharmacy operations and practices because sufficient core experience in a pharmacy is lacking.

The committee concluded that it is premature to move forward with the students' proposal at this time. Instead the committee decided to wait for the results of the IPPE/OSCE Project being launched this month by California's pharmacy schools (listed

above as topic 1) that will establish a competency exam to assess basic pharmacy intern skills before recommending any changes in the ratio of intern hours.

3. Proposed Regulations for Pharmacies that Compound Medication – Amendments to 16 California Code of Regulations Sections 1716.1 and 1716.2, and the Adoption of Sections 1735-1735.8

RECOMMENDATION for Board Action: that the board move to public notice this regulation package following consideration of amendments from stakeholders at a future meeting

The committee reviewed proposed regulation language that would establish parameters for pharmacies that compound medication for patients. This language was developed in 2004 as a work product following completion of the board's Workgroup on Compounding. Legislative proposals were also developed as another work product of this workgroup, but the legislation containing these provisions was dropped during the final stages of the 2006 legislative session due to opposition that could not be resolved.

Background: The Workgroup on Compounding was formed to evaluate whether a distinction could be made between compounding by a pharmacy and manufacturing operations that are performed by a drug manufacturer.

This workgroup was comprised of staff from the board, the Department of Health Services, compounding pharmacies, pharmacy associations and others. Over the course of 2004, the group met quarterly. However, the group was unable to develop standards to distinguish when a pharmacy has crossed from compounding into manufacturing, and thus would be subject to licensure as a manufacturer. Instead, a legislative proposal and draft regulations were developed to establish standards for pharmacies that compound medication, leaving to the Department of Health Services or the DA the determination of when a pharmacy is manufacturing.

The legislative proposals were introduced in 2005 as AB 595. At the end of the 2005 Legislative Year, DHS registered its formal opposition to the bill, believing that the provisions allowing pharmacies to contract with other pharmacies for compounding was manufacturing. Over 2006, the board worked with pharmacy stakeholders to remove DHS' opposition. As the 2006 Legislative Year wound to an end, board amendments appeared in print that were aimed at reducing DHS' opposition. However, Kaiser, CPhA and Grandpa's Pharmacy came out in opposition to these amendments. The board then asked the author to drop the bill.

At this meeting: The Licensing Committee now recommends that the board move forward with the regulation language that was developed in 2004 for pharmacies that compound. These requirements can be adopted without the statutory provisions being enacted, and will establish standards for pharmacies that do compound, providing patient protection when they receive medication that has been compounded by a pharmacy. The proposed regulation changes are provided in **Attachment 3**.

What is missing from the regulations and the regulatory scheme that was initially envisioned by the board in 2004 is the authority for one pharmacy to compound medication for another pharmacy. This practice is currently allowed by Business and Professions Code section 4123 only for parenteral products.

During the Licensing Committee Meeting, various stakeholders made recommendations for slight modifications to the regulations. The individuals were asked to submit the comments in writing so that the language can be finalized. These comments have not yet been submitted to the board.

The comments included that adding flavoring to a medication should not be included in the regulation's requirements, and reconstitution of ocular products should be excluded from definition of compounding. Other comments included that obtaining components from suppliers for some items, such as sugar, should not be required by the record keeping requirements of section 1735.2(c), and a better definition of container needs to be developed, including a definition of a unit-dose container. Concern was also expressed about the meaning of section 1735.7(b) regarding the required quality assurance plan.

Modifications to the regulation can be made at the March 2007 Licensing Committee Meeting and final language shared with the board at the April Board Meeting for final review and approval before being released for public comment.

4. Emergency Preparedness for California Pharmacy

INFORMATION ONLY:

One of the Governor's key initiatives is emergency preparedness. The board has an important role in this because the provision of pharmaceuticals, and who will provide them, will certainly be an important component in any emergency response.

At the October 2006 Board Meeting, the board amended and then approved a general policy statement that outlines its expectations for how disaster response in California may proceed. A copy of the final policy statement containing the amendments is in **Attachment 4**. This policy statement was published in the recent January 2007 issue of *The Script*, and is on the board's Web site.

Over the coming months, the board will work with the Department of Health Services to establish procedures for emergency response. The goal is to assure that licensees and the public have better knowledge of what the board will require, and licensees will be comfortable volunteering to participate in emergency response and obtain training before a disaster occurs.

5. Request to Add the Exam for the Certification of Pharmacy Technicians as a Qualifying Method for Pharmacy Technician Registration

INFORMATION ONLY:

Currently, pharmacy technicians may become qualified for registration in California by one of four methods:

1. Possessing an associate degree in pharmacy technology
2. Completing a course of training specified by the board in regulations (accredited by ASHP, provided by the armed forces, or at least 240 hours of instruction covering specific topics)
3. Graduating from a school of pharmacy recognized by the board
4. Being certified by the Pharmacy Technician Certification Board (PTCB).

In September, the Licensing Committee initiated discussion about a new pharmacy technician examination, the Exam for the Certification of Pharmacy Technicians (ExCPT). This exam has been developed by the Institute for the Certification of Pharmacy Technicians.

This examination is accepted by Connecticut, New Jersey, Minnesota, Oregon and Virginia as a qualifying route for registration for pharmacy technicians. According to material provided by the institute, the exam is a computer-based exam, which is administered in 700 locations nationwide. The National Community Pharmacists Association and the National Association of Chain Drug stores support use of the exam.

At the October 2006 Board Meeting, the board directed staff to initiate a review of the ExCPT, and whether the examination is job related and has been validated as required by California Business and Professions Code section 139.

To use the ExCPT exam as a qualifying method for pharmacy technician licensure, either a statutory or regulation amendment needs to be adopted. The board should not act to implement this exam until this review is completed.

Within the Department of Consumer Affairs, is the Office of Examination Resources. This office provides examination and psychometric services to professional and vocational licensing boards in the department. At the current time, this office is undergoing recruitment for a chief. Until such time as a new chief is hired, the board probably should not initiate a review of the ExCPT examination using this office.

However, there are other options to perform this review that the committee discussed – including suggesting that the NABP form an independent task force to determine if the exam is psychometrically valid as the ICPT insists. This is a bit sensitive as the NABP is one of the owners of the currently used competing exam – the Pharmacy Technician Certification Board Examination.

Alternatively, the board could direct what organization the ICPT could submit its exam to for independent evaluation. This is a process suggested by the American Society of Health System Pharmacists (which is also an owner of the Pharmacy Technician

Certification Board Examination). The committee reviewed a letter from this association expressing concern whether the ExCPT exam has been appropriately validated, and recommending an independent organization to evaluate the exam (see **Attachment 5**).

The committee took no action on this agenda item, pending the hiring of a psychometric expert by the Department of Consumer Affairs.

6. National Provider Identifier

INFORMATION ONLY:

One component of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) required that the Health and Human Services Agency adopt a unique health identifier for health care providers. On January 23, 2004, the government published the final rule creating the National Provider Identifier (NPI) as the identifier.

All HIPAA-covered providers, whether they are individuals or companies, must obtain an NPI for use in HIPAA covered, HIPAA standard transactions (e.g., NCPDP for retail prescription drugs). This means that pharmacists and pharmacies will need to obtain an NPI. Once issued, a provider's NPI will not change, even if a pharmacist's job or pharmacy location changes.

HIPAA-covered entities must use only the NPI to identify covered health care providers in standard transactions by May 23, 2007.

Pharmacists and pharmacies can obtain this number from CMS.

Materials regarding the NPI are contained in **Attachment 6**.

7. Competency Committee Report:

- *Test Administration Contract*

The Office of Examination Resources (OER) within the Department of Consumer Affairs is seeking a new contract with a vendor to provide computer based testing through a Request for Proposal (RFP) process. The board uses this contract to administer the CPJE. The current contract expires December 1, 2006.

The second Request for Proposal (RFP) was cancelled effective November 8, 2006. OER has received approval to extend the current contract with Thomson Prometric to extend services from December 1, 2006, to May 31, 2007. A third contracting process is now underway to provide exam administration services beginning June 1, 2007. The preliminary award of this contract is set to occur January 23, 2006.

- *CPJE Pass Rate Summary*

A total of 1,633 applicants took the CPJE in fiscal year 2005/06. Of the 1,633 applicants, 325 failed the CPJE while 1308 passed the CPJE. The pass rate for the CPJE in fiscal year 2005/06 is 80 percent.

8. Meeting Summary:

A summary of the Licensing Committee Meeting of September 20, 2006, is provided in **Attachment A.**

Attachment 1

*Materials on the California Pharmacy
IPPE/OSCE Initiative*

California Pharmacy IPPE/OSCE Initiative

The experiential component of the pharmacy curriculum provides a continuum of required and elective practice experiences that progress from basic (IPPEs) to more advanced (APPEs) activities under the supervision of qualified preceptors. Together, IPPEs and APPEs are designed to provide students with multiple opportunities to perform patient-centered care in a variety of real practice settings.

Background Situation

Recently, ACPE adopted new accreditation standards and guidelines (Standards 2007).

- Requirements for practice experiences are based upon amount of time spent:
 - IPPEs must be 5% of length of the curriculum; and
 - APPEs must be 25% of the length of the curriculum.
- Appendix C provides guidance on types of experiences appropriate for IPPEs and APPEs.
- The desired curricular outcomes (professional competencies) as a whole (i.e., for graduates) are described, but there is no delineation between IPPEs and APPEs in terms of the competencies that should be mastered in IPPEs prior to progressing to APPEs.

The California State Board of Pharmacy requires candidates for licensure to submit proof of 1500 hours of internship.

- Minimum of 900 hours must be completed in community or hospital practice settings.
- Up to 600 hours may be granted for other experiences substantially related to practice of pharmacy, which are generally provided by the schools for practice-related educational experiences.
- Students may apply for Intern licenses once registered in a school of pharmacy.

In the past, the State Board required candidates to submit two intern experience affidavits, one for community practice and one for institutional practice experiences. These affidavits listed specific practice objectives (competencies) that had to be signed off by licensed pharmacists. Currently, candidates for licensure only submit a 2-sentence affidavit, which they sign, stating that they have met the required internship requirements and have experience in both community and institutional pharmacy settings.

Relative to many other states, California schools of pharmacy admit a high percentage of educationally mature students. It is not uncommon for 90-95% or more of the entering classes at California schools to have earned a bachelors degree or higher. Many students have worked or volunteered in pharmacies prior to entering pharmacy school, with some having extensive experience as pharmacy technicians. While in school, the majority of California pharmacy students work as pharmacy interns and participate in professional organizations and co-curricular activities (e.g., health fairs, disease screenings, immunizations, smoking cessation programs, Medicare Part D outreach, indigent care clinics).

The Problems

The emphasis on the duration of experiences rather than the curricular outcomes resulting from them is problematic for many reasons. First, established schools are faced with adding course work to their (already packed) existing curricular, with no assurance that doing so would improve the quality of education for their graduates. If more time is to be spent in one aspect of the

curriculum, something will need to be removed elsewhere to avoid prolonging the time to graduation. This is especially problematic in California, where a high percentage of students already spend eight or more years in college prior to entering the profession.

Secondly, although individual schools have goals and learning objectives for IPPEs, there is no consistency or standard across schools regarding the types of practice activities offered or what students should learn or master. There is even less direction regarding appropriate activities for the State Board internship, which often results in pharmacy interns remaining in positions where they perform repetitive tasks at the expense of gaining experience with a broader array of more advanced professional responsibilities.

A third problem is that the new IPPE requirement does not provide sufficient flexibility in how schools will meet the standard. Students with extensive pharmacy technician experience should not be forced to repeat experiences that are of little educational value to them. Students working as interns in retail and hospital pharmacies may be able to achieve some of the foundational competencies through employment. Schools may wish to capture student participation in co-curricular activities such as disease screenings, Medicare outreach, and providing services to patients of indigent care clinics, which contribute to the development of professionalism and leadership skills among students. These types of activities promote a positive image of the profession and increase the public's awareness of the contributions that pharmacists make to improving health care outcomes.

Goals

The goals of this initiative are to:

- 1) Reach consensus on the basic foundational competencies that all pharmacy students in California should master during IPPEs (June 2007).
- 2) Train faculty members from each pharmacy school in California how to develop and administer an OSCE-based assessment (September 2007).
- 3) Develop a validated and standardized OSCE-based examination to assess achievement of the IPPE competencies (academic year 2007-08).
- 4) Develop a mechanism to assure replenishment of the OSCEs and exam security in the future (academic year 2007-08).
- 5) Petition ACPE to accept an OSCE-based assessment for IPPEs as evidence of compliance with Standards 10 and 14 in California (academic year 2007-08).

Proposal

- 1) The IPPE/OSCE Committee will identify and agree on the competencies that should be achieved by the end of IPPEs.
 - a) Composition: 2-3 representatives from each school
 - b) Invited participants: representatives from the state Board of Pharmacy, CPhA, CSHP, and other appropriate entities
 - c) Meetings:
 - a. January 23, 2007, 10:00 am – 3:00 pm, San Francisco (UCSF)
 - b. February 27, 2007, 10:00 am – 3:00 pm, Los Angeles (USC)
 - c. March 27, 2007, 10:00 am – 3:00 pm, San Francisco (UCSF)
 - d) Decisions: Each participating school would have one vote when making decisions.

- e) Background materials: The State Board of Pharmacy's community and institutional internship experience affidavits, NAPLEX Blueprint 2005
- 2) The committee will sponsor two 1.5 day statewide OSCE conferences to train faculty teams from each school on how to develop and administer OSCEs. The goal is to produce a bank of 40+ OSCE stations for the IPPE assessment. Zubin Austin (University of Toronto) has agreed to lead the conferences.
 - a) First conference (San Francisco, June 5-6, 2007). Topics will include an overview of OSCEs (primer), developing the exam blueprint, defining stations, and developing the initial cases.
 - b) Interlude: faculty teams will develop additional cases/stations (5-7 per school).
 - c) Second conference (San Diego, week of August 20, 2007). Topics will include review and validation of the additional cases/stations, setting standards, determining station set up and training requirements, determining data analysis (cut scores), determining security procedures and establishing a mechanism to replenish cases in the future.
 - 3) The committee will pursue external funding to offset the expenses associated with committee meetings and the OSCE conference(s). If not successful, schools will share the costs equally.
 - 4) Schools will select 7-9 OSCE cases/stations from the database for each assessment, based upon individual needs and preferences. Exams may be offered at different times, but all schools agree to follow the established procedures and security measures.
 - 5) Appoint representative(s) from each school to meet on an annual basis to share experiences with the exams and generate new cases/stations to replenish the database.

Attachment 2

*Proposed Change in the Hours
Pharmacist Interns Must Earn in a
Pharmacy, Under the Supervision of
a Pharmacist*

DRAFT

**RESOLUTION FOR CONSIDERATION BY THE
CALIFORNIA STATE BOARD OF PHARMACY**

WHEREAS the scope of practice opportunities in the profession of pharmacy has expanded beyond the traditional areas of community and-institutional pharmacy, and

WHEREAS the increased scope of pharmacy based opportunities exist for pharmacy school graduates in such areas as the pharmaceutical industry, managed care; regulatory affairs, and other pharmacy-related areas to yet be defined, and

WHEREAS the present existing laws place requirements on both the experience expectations and the quantity of time required of students enrolled in California Schools of Pharmacy in order for them to satisfy both the board exam and licensure standards as stated in the following California statutes and regulations:

CA Bus. & Prof. Code, Sec. 4200(a)(5): "The board may license as a pharmacist any applicant who meets the following requirements... Has completed 1,500 hours of pharmacy practice experience or the equivalent in accordance with Sec. 4209."

CA Bus. & Prof. Code, Sec. 4209(a)(1)(2): An intern pharmacist shall complete 1,500 hours of pharmacy practice before applying for the pharmacist licensure examination. This pharmacy practice shall comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy Education or with regulations adopted by the board.

Title 16, CA Code of Regulations, Sec. 1728(a): ...Applicants shall submit to the board the following: Proof of 1,500 hours of pharmacy practice experience that meets the following requirements:

(A) A minimum of 900 hours of pharmacy practice experience obtained in a pharmacy.

(B) A maximum of 600 hours of pharmacy practice experience may be granted at the discretion of the board for other experience substantially related to the practice of pharmacy.

(C) Experience in both community pharmacy and institutional pharmacy practice settings.

(D) Pharmacy practice experience that satisfies the requirements for both introductory and advanced pharmacy practice experiences established by the Accreditation Council for Pharmacy Education. And

WHEREAS while the American Council on Pharmaceutical Education (ACPE) does support that the Schools of Pharmacy engage students during the experiential portions of its academic program in various patient care settings, it also encourages other extended boundaries of learning during the experiential portion of the academic program. Under Standard No. 14 (Curricular Core: Pharmacy Practice Experiences), Guideline 14.1 it states the following:

“The scope, intensity, and duration of all of the pharmacy practice experiences should afford students the opportunity to develop skills consistent with expected professional competencies and outcomes. The pharmacy practice experiences should ensure that every student has multiple opportunities to perform pharmaceutical/patient-centered care activities in a variety of settings (including acute care, long-term care, home care, community, ambulatory, administrative)...” And

WHEREAS all students who undergo the pharmacy curriculum at the University of Southern California School of Pharmacy have multiple pharmacy-related experiences that might include managed care and industrial pharmacy settings that count toward their 600 required hours of experiential training, those areas of experiences that are more directly patient based are assessed by the use of competency criteria once established by the California State Board of Pharmacy for both community and institutional practices. Students, based upon those competency standards, must achieve a passing mark on each competency stated in order to pass that practice-based course. In passing the practice-based courses, the School is essentially stating that that student is competent to sit for the board examination and practice as a competent pharmacist once the student has passed the board exam, and

WHEREAS, at this point in time, only a small contingent of those graduating seek positions in the pharmaceutical and managed care industries (perhaps less than 10% of the graduating students), their role in being versed in good patient care principles and standards of care is not diminished based upon the demands of these entities both directly and indirectly being responsible for the assurance that the highest of standards be undertaken that all services and/or products rendered or produced shall be of the highest quality to the recipients of those services and/or products, and

WHEREAS it has not been established, as to at least the knowledge of those who have created this resolution and recommendation, that 1500 hours of patient-related contact is either over or under abundant in assuring that a pharmacist will be minimally competent to practice patient-care pharmacy upon being licensed,

THEREFORE LET IT BE RESOLVED/RECOMMENDED that the California State Board of Pharmacy (Board) recognize that intern experiences in the areas of pharmaceutical industry and managed care can have both a direct and indirect impact on patient care. In so recognizing, be it resolved and recommended that the Board allocate up to 400 hours from the 900 hour remainder that does not include the 600 hours allocated to pharmacy school experiential programming for the purposes of gaining experience in new pharmacy practice related areas such as and not limited to industrial pharmacy and managed care.

THEREFORE LET IT FURTHER BE RESOLVED/RECOMMENDED as a modification of Title 16, Calif. Code of Regulations, Section 1718[a][1][A-D] that presently reads as follows:

- (a) Prior to receiving authorization from the board to take the pharmacist licensure examinations required by section 4200 of the Business and Professions Code, applicants shall submit to the board the following:
 - (1) Proof of 1500 hours of pharmacy practice experience that meets the following requirements:
 - (A) A minimum of 900 hours of pharmacy practice experience obtained in a pharmacy.
 - (B) A maximum of 600 hours of pharmacy practice experience may be granted at the discretion of the board for other experience substantially related to the practice of pharmacy.
 - (C) Experience in both community pharmacy and institutional pharmacy practice settings.
 - (D) Pharmacy practice experience that satisfies the requirements for both introductory and advanced pharmacy practice experiences established by the Accreditation Council for Pharmacy Education.

THAT THE MODIFICATION OF Title 16, Calif. Code of Regulations, Section 1718[a][1][A-D] BE AS FOLLOWS:

- (a) Prior to receiving authorization from the board to take the pharmacist licensure examinations required by section 4200 of the Business and Professions Code, applicants shall submit to the board the following:
 - (1) Proof of 1500 hours of pharmacy practice experience that meets the following requirements:
 - (A) A minimum of 500 hours of pharmacy practice experience must be obtained in community and institutional pharmacy practice settings.
 - (B) A maximum of 1000 hours of pharmacy-related practice experience must be obtained under the supervision of a pharmacist. This 1000 hours may involve, but is not limited to the attainment of pharmacy-related practice experience in a community pharmacy, an institutional pharmacy setting, a managed care organization, and a pharmaceutical industrial setting. The 1000 hours shall include the current 600 hours that is granted for pharmacy school experiential programming, and the additional 400 hours for other pharmacist supervised pharmacy-related experiences.
 - (C) Pharmacy practice experience that satisfies the requirements for both introductory and advanced pharmacy practice experiences established by the Accreditation Council for Pharmacy Education.

Serving Patient Needs Through Alternative Pharmacy Practice

David Truong
Jonathan Watanabe
Richard Young
Tom Wang

Increasing Need for Pharmacists in Crucial, Non-Traditional Sectors

- Health Plans are actively procuring new pharmacy graduates to develop Care Management Plans, Drug Utilization Review, Patient Care Initiatives, and Medication Management serving millions of patients
- Drug Information Services is burgeoning into a critical resource for physicians and other pharmacists to provide care and for patients to inquire about their own therapy
- Drug Firms are demanding more pharmacist services for safe, effective management and design of clinical trials affecting thousands of enrolled patients
- Health Systems are actively seeking pharmacists to provide clinically efficacious, outcomes based formulary management to provide the highest quality care to most patients
- Many of the skills demanded for these pharmacist roles are not taught in traditional sectors (outcomes research, mail-order pharmacy, clinical operations)

Sample of Patient Lives Impacted

Organization	Patient Lives
United Health Group	70,000,000
Kaiser Foundation Medicare group	353,455
LA County Department of Health Services	165,000
Torcetrapib Trial	15,000
Vioxx Patients	20,000,000

Total
90.5 Million Patient Lives

Vioxx Threat First Noticed by Managed Care Pharmacist

- Jennifer Hrachovec, PharmD of non-profit Group Health Cooperative (Seattle) was the first to publicly questioned the safety of Vioxx in August 2001
- Dr. Hrachovec had been reviewing data on an FDA website indicating that patients in a Vioxx clinical trial had suffered more heart attacks than the the New England Journal of Medicine article had reported
- On the air, the pharmacist, Jennifer Hrachovec, begged Dr. Drazen, editor of the New England Journal of Medicine, to update an article in the journal that touted the benefits of the painkiller Vioxx while playing down its heart risks.
- "My concern is that doctors are still using this and exposing their patients to higher risks of heart problems and they just don't even know that that's the case."
- Vioxx was removed from the market in September 30, 2004 with an estimated 20 million patients taking it at the time.

Pharmaceutical Industry

Current Environment

- Rise in health care costs
- Baby boom spur for innovation
- Consumer demand for more information
- Safety and drug interactions have taken a back seat in today's competitive market

The Pharmaceutical Industry Experience

- There is a need for knowledgeable pharmacists in the profession
 - Safety is paramount concern
- Training in pharma internships provide practical clinical skills and information for the intern

Who would benefit?

Consumers

- Internships focus on specific disease states
 - Better safety knowledge
 - Better efficacy knowledge

Where do pharmacists fit in?

- Research development
 - Develop of new drugs and novel dosage forms
 - Conduct and administrate clinical drug trials
- Production
 - Conduct in both early production development and quality control
- Regulatory affairs
 - Liaise with the U.S. Food and Drug Administration (FDA) on regulation of drug development, safety and consumer protection
- Medical information
 - Provide vital drug information to health care providers (HCP) and consumers
- Medical Education
 - Develop and provide programs that enhance HCP knowledge of specific drugs and disease state management

How can everyone benefit?

- Patients get a better trained pharmacist
- HCP get a much more informed pharmacist

Managed Care

Managed Care Pharmacy FACTS & Figures

- Prescription drug costs increase (on average, 15.66%: \$224 billion in 2005 to \$521 billion in 2014).
- Employer-offered health benefits declined @ 9% (2000-2005) & premiums increased by 73%.
- In 2004, the utilization rate for generic drugs was 46% a 3% rise from 2003.
- In 2003, 37% of Americans who do not have health insurance reported that they did not fill a prescription because of cost.
- # of prescriptions filled by retail pharmacies in the US will exceed 4 billion by 2005.
- # of licensed pharmacists in US ~196,000 & expected to climb by 28,500 in the next 10 years.

Managed Care Pharmacy Summary

- Increasing drug cost, demand, & utilization.
- Cost shifting from employer to employee.
- Privatization of Medicare prescription benefit.
- Rising volume is due to increasing:
 - Aging population
 - Prescription
 - Treatment guidelines
 - Lifestyle medication
 - DTC advertising
- Increasing demand for Pharmacist in Managed Care.

Managed Care Pharmacy Pharmacist Roles

- Clinical Program Development
- Pharmaceutical Care
- Disease State management
- Patient Safety, education & communication
- Drug Benefit & formulary Design
- Drug distribution & Dispensing
- Cost & Business management
- Pharmacoeconomics & outcomes research

Other Boards of Pharmacy

Non-traditional experiences in 16 states are applicable towards licensure requirements

State Boards of Pharmacy that accept non-traditional intern hours	Maximum number of hours permitted	any approved experience	Industrial Pharmacy	Manufacturing	FDAB/analytical pharmacy	consultant pharmacy	demoproscription pharmacy	drug utilization project	pharmacy center review	drug information	military pharmacy	infusion pharmacy	IMC pharmacy	home health care	nuclear pharmacy	compliance pharmacy	contracted pharmacy services	community service projects
Alaska	N/S	X	X															
Arizona	500	X	X	X														
Delaware	500	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
D.C.	500	X	X	X	X													
Iowa	N/S	X	X	X	X													
Kentucky	400	X	X	X	X													
Massachusetts	500	X	X	X	X	X												
Michigan	400	X	X	X	X													
Minnesota	N/S	X	X	X	X				X									
Montana	N/S	X	X	X	X													
North Carolina	500	X	X	X	X													
Ohio	500	X	X	X	X	X	X	X										
Oregon	N/S	X	X	X	X													
Tennessee	400	X	X	X	X													
Vermont	N/S	X	X	X	X													
Washington	N/S	X	X	X	X													

Providing for Non-Traditional Training Enhances Ability to Achieve BOP Mission

“The Board of Pharmacy protects and promotes the health and safety of Californians by pursuing the highest quality of pharmacist’s care and the appropriate use of pharmaceuticals through education, communication, licensing, legislation, regulation, and enforcement.”

Providing for Non-Traditional Training Enhances Ability to Achieve BOP Mission

Current

- 1500 hours
 - 600 hours from Schools of Pharmacy
 - 900 hours from individual's inpatient or outpatient pharmacy experience

Proposal

- 1500 hours
 - 600 hours from Schools of Pharmacy
 - 900 hours from individual's inpatient or outpatient pharmacy experience
 - Out of 900 hours, a student have the option of using 400 hours for non-traditional pharmacy experience

§1728. Requirements for Examination.

(a) Prior to receiving authorization from the board to take the pharmacist licensure examinations required by section 4200 of the Business and Professions Code, applicants shall submit to the board the following:

(1) Proof of 1500 hours of pharmacy practice experience that meets the following requirements:

(A) A minimum of 900 hours of pharmacy practice experience obtained in a pharmacy.

(B) A maximum of 600 hours of pharmacy practice experience may be granted at the discretion of the board for other experience substantially related to the practice of pharmacy.

(C) Experience in both community pharmacy and institutional pharmacy practice settings.

(D) Pharmacy practice experience that satisfies the requirements for both introductory and advanced pharmacy practice experiences established by the Accreditation Council for Pharmacy Education.

(2) Satisfactory proof that the applicant graduated from a recognized school of pharmacy.

(3) Fingerprints to obtain criminal history information from both the Department of Justice and the United States Federal Bureau of Investigation pursuant to Business and Professions Code section 144.

(4) A signed copy of the examination security acknowledgment.

(b) Applicants who hold or held a pharmacist license in another state shall provide a current license verification from each state in which the applicant holds or held a pharmacist license prior to being authorized by the board to take the examinations.

(c) Applicants who graduated from a foreign school of pharmacy shall provide the board with satisfactory proof of certification by the Foreign Pharmacy Graduate Examination Committee prior to being authorized by the board to take the examinations.

Authority cited: Sections 851, and 4005, Business and Professions Code.

Reference: Sections 144, 851, and 4200, Business and Professions Code.

University of California
San Francisco



School of Pharmacy
Office of the Dean

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April 18, 2006

Ms. Patricia Harris, Executive Officer
State Board of Pharmacy
1625 North Market Blvd., N219
Sacramento, CA 95834

Dear Patty,

I am writing regarding the agenda item titled, "Request to Modify Intern Hours Earned for Pharmacy-Related Experience," a proposal to amend 16 CCR 1728. The UCSF School of Pharmacy opposes this proposal and appreciates the opportunity to convey our rationale.

I am familiar with the genesis of this proposal, since it is not the first time intern hours have been open to debate. In fact, I strongly supported a change in the regulation, which allowed students to receive credit for up to 600 hours of clinical clerkship experiences that were "substantially related to the practice of pharmacy," several decades ago. While I strongly encourage and promote student leadership initiatives and applaud the activism of our student groups, I differ with the views of students on this issue.

Currently, the Board of Pharmacy requires a total of 1500 Intern hours. Of these, 600 can be in a setting that is "substantially related to the practice of pharmacy"; the remaining 900 hours must be in a pharmacy under the supervision of a pharmacist. One of the stated reasons for the proposal (to allow up to 1000 hours of experience that is substantially related to the practice of pharmacy) is that it would provide students the opportunity to earn intern hours for new and innovative experiences that are not in a pharmacy. It has also been suggested that students do not pursue experiences in contemporary practices outside of licensed pharmacies because these do not qualify for intern hours required for licensure. We believe that the current regulation provides ample opportunity for students to pursue innovative experiences without jeopardizing their ability to complete the Board's requirement before graduation. We also believe that practice experience in a licensed pharmacy is absolutely essential to the development of a future pharmacist.

The UCSF School of Pharmacy curriculum currently includes *more than 1000 hours* of advanced pharmacy practice experience (clerkship) that would meet the Board's criteria for hours that are "substantially related to the practice of pharmacy." We assume the other California Schools of Pharmacy also meet or exceed this 1000 hour threshold. Therefore, the proposed change to 1000 intern hours "substantially related to the practice of pharmacy" would be entirely covered by the School's advanced pharmacy practice experiences. Consequently, the majority of students would simply be required to spend 400 fewer intern hours in a licensed pharmacy if this change is approved.

For more than 40 years the UCSF School of Pharmacy has designed and refined the educational experience it requires of students in the context of the Board of Pharmacy's requirement of 900 hours of practice experience in a pharmacy. This relationship has allowed the School to be creative in the types of practice experiences that are offered to our students since we know that an essential foundation for practice is provided through internship experiences in a pharmacy. A substantial change in the number of intern hours that are required in a licensed pharmacy (both institutional and community) will significantly disrupt the balance between the School's curricular experiences and the core skills and competencies students develop through their work as interns in licensed pharmacies. Our curriculum is predicated on this balance of experience and we believe the proposed change would not insure that our graduates have the core pharmacy skills and experiences we believe the public expects.

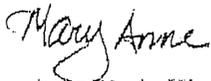
The UCSF School of Pharmacy has long embraced innovation in the profession and our new curricular pathways in *Pharmaceutical Health Policy & Management* and *Pharmaceutical Sciences* support our commitment to engaging students in new and expanding areas of practice. We also have mechanisms that allow individual students to substitute innovative practice experiences for some of their elective advanced pharmacy practice experiences. This process is evaluated by a faculty committee and allows for additional practice activities that are individualized, creative and innovative - though not yet mainstream.

Finally, the current requirement for 900 intern hours in a pharmacy under the supervision of a pharmacist can be met by one summer's full-time internship coupled with part time internship work during the student's academic year(s). We believe this allows most students at least one summer to explore outside professional activities that are professionally rewarding but do not meet the Schools' or Board's criteria for earning credit towards their academic degree and licensure.

The students' desire to expand the areas of practice experience and their focus on innovation -- which are at the heart of this proposal -- is to be commended. At the same time, we believe that the Board's requirement of 900 hours (less than one-half year) experience in a licensed pharmacy remains an essential component of the training and licensure of pharmacists who can best serve the public's needs. I also encourage the Board to once again adopt a statement of competencies to be gained from internship experiences in licensed pharmacies. Such a statement can be used to guide both students and preceptors in creating experiences that develop core competencies and skills the public deserves.

I am happy to discuss this in more detail with you and the Board.

Sincerely,



Mary Anne Koda-Kimble, PharmD
Professor and Dean
TJ Long Chair in Chain Practice Pharmacy

Memorandum

To: Licensing Committee

Date: March 9, 2006

From: Patricia Harris 
Executive Officer

Subject: Request to increase the number of intern hours that
can be earned outside of a pharmacy

At the February meeting, the board was provided with a proposal from a group of pharmacy students representing various schools of pharmacy requesting an increase in the number of intern hours that could be earned outside a pharmacy. Since the proposal was not on the agenda, the board could not take action.

The proposal is now being provided to this committee for consideration. The proposal requests that the board allocate up to 400 hours that an intern can earn for pharmacy-related experience (under the supervision of a pharmacist) outside a pharmacy. The proposal is attached.

Under current law, an intern must earn a minimum of 900 hours of pharmacy experience under the supervision of a pharmacist in a pharmacy. The board has the discretion to grant a maximum of 600 hours for other experience substantially related to the practice of pharmacy. California pharmacy students earn the 600 hours for school required experiential training (clinical clerkship).

Therefore as proposed, an intern would only need to earn a minimum of 500 hours in a pharmacy and could earn a maximum of 1,000 hours of experience substantially related to the practice of pharmacy under the supervision of a pharmacist.

16 CCR § 1728 states in part:

(a) Prior to receiving authorization from the board to take the pharmacist licensure examinations required by section 4200 of the Business and Professions Code, applicants shall submit to the board the following:

(1) Proof of 1500 hours of pharmacy practice experience that meets the following requirements:

(A) A minimum of 900 hours of pharmacy practice experience obtained in a pharmacy.

(B) A maximum of 600 hours of pharmacy practice experience may be granted at the discretion of the board for other experience substantially related to the practice of pharmacy.

(C) Experience in both community pharmacy and institutional pharmacy practice settings.

(D) Pharmacy practice experience that satisfies the requirements for both introductory and advanced pharmacy practice experiences established by the Accreditation Council for Pharmacy Education.

Attachment 3

*Proposed Regulations for Pharmacies
that Compound Medication*

§1716.1. Compounding Unapproved Drugs for Prescriber Office Use.

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

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

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

§1716.2. Record Requirements—Compounding for Future Furnishing.

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

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

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

Article 4.5 General Compounding

§1735. Definitions

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

Compounding does not include the reconstitution of a drug pursuant to the manufacturer's direction for oral, rectal or topical administration.

(b) "Integrity" means the drug will retain its effectiveness until the beyond use date noted on the label.

(c) "Quality" means the drug is free of any contaminants and only contains those active ingredients indicated on the label.

(d) "Strength" means the amount of active ingredient in each unit of the drug.

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

(1) "Reasonable quantity" means that quantity of an unapproved drug which:

(A) is sufficient for that prescriber's office use; and

(B) is reasonable considering the intended use of the compounded medication and nature of the prescriber's practice; and

(C) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for strength, quality and integrity of the compounded medication.

(2) "Prescriber office use" means application or administration in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients as estimated by the prescriber.¹

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

§1735.1. Requirements

(a) Prior to compounding a drug, the dispensing pharmacist shall establish a professional relationship with the prescriber and patient.

(b) A drug may not be compounded without a written master formula record that includes at least the following elements:

(1) Active ingredients to be used.

(2) Inactive ingredients to be used.

(3) Process and/or procedure used to prepare the drug.

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

(5) Post compounding process or procedures required, if any.

(6) Beyond use dating requirements.

(c) The pharmacist shall be responsible for assuring that the compounded drug retains its strength, quality, and integrity until dispensed.

(d) All chemicals, drug products, and components must be used and stored according to compendial and other applicable requirements to maintain their strength, quality and integrity.

¹ Moved from 1716.1

(e) The beyond use date of the finished product must not exceed 180 days or the shortest expiration date of any component in the finished product unless a longer date is supported by stability studies of drugs using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

(f) A pharmacy may contract with another pharmacy to compound drug products, pursuant to a prescription, for delivery to another pharmacy. The compounded product must be labeled with the name of the pharmacy that compounded the drug and the information required by Business and Professions Code Section 4076.

(g) Pharmacists who compound drugs, or supervise the compounding of drugs, shall be responsible for ensuring that the compounded drug has been prepared, labeled, stored, and delivered properly.

(h) Prior to allowing any drug to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment form for compounding pharmacies developed by the board (form XXXXX). The self assessment shall subsequently be performed before July 1 of each year, within 30 days of the designation of a new pharmacist-in-charge, or within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4051, 4052, and 4076, Business and Professions Code.

§1735.2. Records

(a) For each compounded drug a record shall be made that includes at least the following elements:

- (1) The information required of a master formula record.
- (2) The date the drug was compounded.
- (3) The identity of the pharmacy personnel who compounded the drug.
- (4) The identity of the pharmacist reviewing the final product.
- (5) The quantity of each component used compounding a drug.
- (6) The supplier and lot number of each component.
- (7) The equipment used compounding a drug.
- (8) The internal reference (lot) number.
- (9) The expiration date of the final drug.
- (10) The quantity or amount of drug product compounded.

(b) Pharmacies must maintain records of the acquisition, storage, and proper destruction of chemicals, drug products, and components used in compounding.

(c) The chemicals, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The pharmacy shall maintain certificates of purity or analysis for components, chemicals, or drug products used in compounding. Certificates of purity or analysis are not required for drugs used in compounding that are approved by the Food and Drug Administration.

(d) Pharmacies must prepare, maintain, and retain all records required by this article in the pharmacy in a readily retrievable form for a period of three years from the date the record was created.

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

§1735.3. Labeling

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

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

(c) Drugs compounded into unit-dose containers shall be labeled with the name of the active component, concentration or strength, volume or weight, and an expiration date.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005 and 4076, Business and Professions Code.

§1735.4. Policies and Procedures

(a) Pharmacies must maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures for the pharmacy.

(b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge.

(c) Provisions to notify the staff assigned compounding duties of any changes in the policy and procedure manual must also be included.

(d) The policy and procedure manual shall include written documentation of a plan for the recall of dispensed compounded products where subsequent verification demonstrates the potential for adverse effects with continued use of the compounded drug.

(e) Written processes used to maintain, store, calibrate, clean/disinfect equipment used in compounding drug shall be contained in the policy and procedure manual and shall be incorporated as part of the staff training and competency evaluation process.

(f) The pharmacist-in-charge shall establish policies and procedures to ensure that compounded drugs have the strength indicated by the label.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005 and 4113, Business and Professions Code.

§1735.5. Facilities and Equipment

(a) Pharmacies shall provide written documentation of facilities and equipment necessary for the safe and accurate compounding of a drug, to also include, where applicable, certification of the facility/equipment.

(b) Equipment shall be stored, used, and maintained in accordance with manufacturers' specifications.

(c) Equipment used in compounding drug products shall be calibrated prior to use to ensure accuracy. Documentation of calibration shall be recorded in writing.

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

§1735.6. Training of Staff, Patient and Caregiver

- (a) Pharmacies shall maintain written documentation that pharmacy personnel have the skills and training required to correctly perform their assigned responsibilities relating to compounding.
- (b) The training of pharmacy personnel shall be documented and retained as part of an on-going competency evaluation process for pharmacy personnel involved in compounding.
- (c) Pharmacy personnel assigned compounding duties shall demonstrate knowledge about the processes and procedures used to compound drug drugs prior to compounding any drug.

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

§1735.7. Quality Assurance

- (a) Pharmacies shall provide written documentation of the development of and adherence to a quality assurance plan.
- (b) The quality assurance plan shall include verification, monitoring, and review of the adequacy of the compounding process and shall include documentation of that review by the assigned personnel to demonstrate the compounded drug meets the specified criteria of strength and quality.
- (c) As part of the quality assurance plan, all qualitative/quantitative analysis reports for compounded drug drugs shall be retained and collated with the compounding record and master formula.
- (d) The quality assurance plan shall also include a written process that describes and documents the action taken when a compounded drug fails to meet the minimum standards for quality, strength and integrity.

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

Attachment 4

Policy Statement for Pharmacy Disaster Response

Disaster Response Policy Statement

The California State Board of Pharmacy wishes to ensure complete preparation for, and effective response to, any local, state, or national disaster, state of emergency, or other circumstance requiring expedited health system and/or public response. Skills, training, and capacities of board licensees, including wholesalers, pharmacies, pharmacists, intern pharmacists, and pharmacy technicians, will be an invaluable resource to those affected and responding. The board also wishes to encourage an adequate response to any such circumstance affecting residents of California, by welcoming wholesalers, pharmacies, pharmacists, intern pharmacists, and pharmacy technicians licensed in good standing in other states to assist with health system and/or public response to residents of California.

The board encourages its licensees to volunteer and become involved in local, state, and national emergency and disaster preparedness efforts. City or county health departments, fire departments, or other first responders can provide information on local opportunities. The Emergency Preparedness Office of the California Department of Health Services is a lead agency overseeing emergency preparedness and response in California, particularly regarding health system response, drug distribution and dispensing, and/or immunization and prophylaxis in the event of an emergency. At the federal level, lead contact agencies include the Department of Health and Human Services, the Centers for Disease Control, and/or the Department of Homeland Security and its Federal Emergency Management Agency (FEMA). Potential volunteers are encouraged to register and get information at www.medicalvolunteer.ca.gov (California) and www.medicalreservecorps.gov (federal). The board also continues to be actively involved in such planning efforts, at every level.

The board further encourages its licensees to assist in any way they can in any emergency circumstance or disaster. Under such conditions, the priority must be protection of public health and provision of essential patient care by the most expeditious and efficient means. Where declared emergency conditions exist, the board recognizes that it may be difficult or impossible for licensees in affected areas to fully comply with regulatory requirements governing pharmacy practice or the distribution or dispensing of lifesaving medications.

In the event of a declared disaster or emergency, the board expects to utilize its authority under the California Business and Professions Code, including section 4062, subdivision (b) thereof, to encourage and permit emergency provision of care to affected patients and areas, including by waiver of requirements that it may be implausible to meet under these circumstances, such as prescription requirements, record-keeping requirements, labeling requirements, employee ratio requirements, consultation requirements, or other standard pharmacy practices and duties that may interfere with the most efficient response to those affected.¹ The board encourages its licensees to assist, and follow directions from, local, state, and national health officials. The board expects licensees to apply their judgment and training to providing medication to patients in the best interests of the patients, with circumstances on the ground dictating the extent to which regulatory requirements can be met in affected areas. The board further expects that during such emergency, the highest standard of care possible will be provided, and that once the emergency has dissipated, its licensees will return to practices conforming to state and federal requirements.

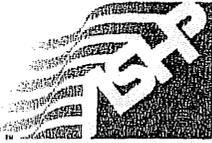
¹ Expanded powers in the event of a disaster are also granted to the Governor and/or other chief executives or governing bodies within California by the California Emergency Services Act [Cal. Gov. Code, §§ 8550-8668] and the California Disaster Assistance Act [Cal. Gov. Code, §§ 8680-8690.7], among others. Section 8571 of the Government Code, for instance, permits the Governor to suspend any regulatory statute during a state of war or emergency where strict compliance therewith would prevent, hinder, or delay mitigation.

Furthermore, during a declared disaster or emergency affecting residents of California, the board hopes that persons outside of California will assist the residents of California. To facilitate such assistance, in the event of a declared California disaster or emergency, the board expects to use its powers under the California Business and Professions Code, including section 900 and section 4062, subdivision (b) thereof, to allow any pharmacists, intern pharmacists, or pharmacy technicians, who are not licensed in California but who are licensed in good standing in another state, including those presently serving military or civilian duty, to provide emergency pharmacy services in California.² The board also expects to allow nonresident pharmacies or wholesalers that are not licensed in California but that are licensed in good standing in another state to ship medications to pharmacies, health professionals or other wholesalers in California. Finally, the board also expects to allow use of temporary facilities to facilitate drug distribution during a declared disaster or state of emergency. The board expects that its licensees will similarly respond outside of the state to disasters or emergencies affecting populations outside California, and will pursue whatever steps may be necessary to encourage that sort of licensee response.

² See also the Interstate Civil Defense and Disaster Compact [Cal. Gov. Code, §§ 177-178], the Emergency Management Assistance Compact [Cal. Gov. Code, §§ 179-179.5], and the California Disaster and Civil Defense Master Mutual Aid Agreement [executed 1950], regarding cooperation among the states.

Attachment 5

*ExCEPT Pharmacy Technician
Certification Exam*



Health-System Pharmacists®

American Society of

7272 Wisconsin Avenue
Bethesda, Maryland 20814
301-657-3000
Fax: 301-664-8892
www.ashp.org

October 24, 2006

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

**Re: Licensing Committee-Request to Add the Exam for the Certification of
Pharmacy Technicians Developed by the Institute for the Advancement of Community
Pharmacy Technicians**

Dear Ms. Herold:

On behalf of the American Society of Health-System Pharmacists, I am writing to express our interest in the Board's recent discussions regarding pharmacy technician education and training.

ASHP is the 30,000-member national professional association that represents pharmacists who practice in hospitals, health maintenance organizations, ambulatory care clinics, long-term care facilities, home care, and other components of health care systems. Over the last twenty years ASHP has been accrediting pharmacy technician training programs and currently there are over ninety programs across the United States accredited by ASHP.

ASHP wishes to express our concerns with the potential inclusion of the alternative exam by the Institute for the Certification of Pharmacy Technicians (ICPT). ASHP has opposed this exam in several states (see attached), based on policy adopted by our Board of Directors and House of Delegates. ASHP supports, "...mandatory certification by the Pharmacy Technician Certification Board (or another comparable nationally validated, psychometrically sound certification program) approved by the state board of pharmacy". ASHP strongly encourages the California Board of Pharmacy to carefully evaluate any exam it approves as an alternative to PTCB, which has been recognized as the national standard, and has been endorsed by the National Association of State Boards of Pharmacy. ASHP has made efforts to review the information provided by ICPT, and based on information that has been provided to our organization, we do not feel that it meets the standards set forth in ASHP policy.

Based on our analysis, ASHP has encouraged PTCB to submit its examination to the National Commission for Certifying Agencies (NCCA). NCCA is the accrediting body for the National Organization for Competency Assurance (NOCA), which is the national leader in setting quality standards for credentialing organizations. NCCA uses a peer review process to: establish accreditation standards; evaluate compliance with the standards; recognize organizations/programs which demonstrate compliance; and serve as a resource on quality certification. 1 NCCA's Standards exceed the requirements set forth by the American Psychological Association and the U.S. Equal Employment Opportunity Commission. Since ICPT has suggested that its alternative exam meets the standards set forth by the American Psychological

Association, we therefore urge the Board to request that ICPT submit its exam to NCCA prior to review and approval by the California. PTCB has also submitted its exam to NCCA for an independent review and accreditation. We believe that without an independent review the Board should consider any alternative exam to the already established national standard met by PTCB. That standard is based on its inclusion in the majority of states, its recognition by major employers in all settings (hospital, major chains etc) and its recognition by the National Association of State Boards of Pharmacy.

ASHP urges the Board to conduct a comprehensive review, requesting full and complete disclosure of relevant information in order to evaluate the ICPT certification process. The National Association of State Boards of Pharmacy (NABP) issued a memorandum to its member Boards earlier this year (see attached) which provided guidance evaluating proposals for examinations that test pharmacy technicians. ASHP strongly encourages the Board to carefully review the recommendations made by NABP and other stakeholders who have expressed concerns with this exam before it is approved in your state.

If you have any questions or comments please do not hesitate to contact Maria D. Spencer, Director of State Government Affairs at 301.664.8687 or m Spencer@ashp.org.

Sincerely,



Brian M. Meyer, M.B.A.
Director, Government Affairs Division

cc: Brian Hodgkins, Pharm.D, President, California Society of Health System Pharmacists
Maria Serpa, Pharm.D, Government Affairs Committee, California Society of Health System Pharmacists
Robert Batman, Pharm.D., Chair, Government Affairs Committee, California of Health System Pharmacists

Enclosures

Attachment 6

National Provider Identifier



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[CMS Home](#) > [Regulations and Guidance](#) > [National Provider Identifier Standard \(NPI\)](#) > [Overview](#)

National Provider Identifier Standard (NPI)

Overview

[What's New](#)
[How to Apply](#)
[Educational Resources](#)
[Enumeration Reports](#)
[Medicare NPI Implementation](#)
[EFI](#)
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Overview

Only 188 more days until the National Provider Identifier (NPI) compliance date!
Do you have your NPI?

Transcript for 9/26/06 NPI Roundtable Now Available

The complete transcript for the 9/26/06 NPI Roundtable is now available – click on "Educational Resources" to the left of your screen to view this document.

NPI Tip

When applying for your NPI, CMS urges you to include your legacy identifiers, not only for Medicare but for all payors. If reporting a Medicaid number, include the associated State name. This information is critical for payors in the development of crosswalks to aid in the transition to the NPI.

View a letter (located in the Downloads section below) from CMS Administrator, Dr. Mark B. McClellan, announcing the start of NPI enumeration for all health care providers.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) mandated that the Secretary of Health and Human Services adopt a standard unique health identifier for health care providers. On January 23, 2004, the Secretary published a Final Rule that adopted the National Provider Identifier (NPI) as this identifier.

All HIPAA covered healthcare providers, whether they are individuals or organizations, must obtain an NPI for use to identify themselves in HIPAA standard transactions. Once enumerated, a provider's NPI will not change. The NPI remains with the provider regardless of job or location changes.

HIPAA covered entities such as providers completing electronic transactions, healthcare clearinghouses, and large health plans, must

use only the NPI to identify covered healthcare providers in standard transactions by May 23, 2007. Small health plans must use only the NPI by May 23, 2008.

Downloads

[NPI Final Rule \[PDF, 249KB\]](#)

[Dear Provider Letter from CMS Administrator \[PDF, 125KB\]](#)

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What is an NPI? (revised 7/1/06)

The National Provider Identifier (NPI) is the provider identifier, replacing the different provider identifiers pharmacies currently use including the NCPDP Provider ID number (formerly the NABP number). This identifier, which implements a requirement of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), must be used by most HIPAA covered entities, which are health plans, health care clearinghouses, and health care providers that conduct electronic transactions for which the Secretary has adopted a standard (i.e., standard transactions). Health care providers include individuals, such as physicians, dentists, and pharmacists, and organizations, such as hospitals, nursing homes, pharmacies, and group practices. The use of the number on HIPAA transactions is **mandatory by May 23, 2007** for most health plans (2008 for small health plans). More information can be found at http://www.cms.hhs.gov/apps/npi/01_overview.asp

How do pharmacies obtain their NPI? (revised 7/1/06)

Pharmacies are able to apply for their NPI in one of three ways:

- (1) **With their permission**, NCPDP will submit their application in an electronic file and provide the pharmacy's NPI to them. NCPDP recommends this option as a service to the industry. **This authorization process is underway and the NCPDP bulk enumeration process has begun.** Go to http://www.ncdp.org/frame_news_npi-info.htm
- (2) Pharmacies may prepare a paper application and send it to the entity that will be assigning the NPI on behalf of the Secretary (the Enumerator). A copy of the application, including the Enumerator's mailing address, is available on at http://www.cms.hhs.gov/NationalProvIdentStand/03_apply.asp#TopOfPage Pharmacies may also call the Enumerator for a copy. The phone number is 1-800-465-3203 or TTY 1-800-692-2326.
- (3) Pharmacies may apply through a web-based application process. The web address is the same as #2 above.

What is the NPPES? (revised 7/1/06)

NPPES is the National Plan and Provider Enumeration System. CMS and the Enumerator, Fox Systems, Inc., use this system to enumerate and maintain information on all providers who apply for an NPI or submit changed information. The NPPES does not have the capability to link a group of pharmacies together into a chain or other affiliations. In addition, it is not currently known if, how, or when CMS will disseminate NPI numbers to industry. For this reason, it is important that the industry continue to use the NCPDP Pharmacy Database, which will include a pharmacy's new NPI(s) cross-walked to their NCPDP Provider ID to avoid industry disruption in converting from the NCPDP Provider ID to the NPI.

What is an "EFI Organization"? (revised 7/1/06)



FAQs on NPI Enumeration

An EFI Organization (EFIO) is a term used by CMS to describe an entity that has been certified by CMS to serve as an authorizing provider's agent in submitting an electronic NPI application for the provider and to distribute the NPI to the provider(s). EFIOs may also submit changes to provider data such as address and maintain provider data in the NPDES. EFIOs are certified by CMS through their Enumerator before they are able to perform these functions. There is no other way to batch enumerate a group of pharmacies. All other NPI enumeration methods (web and paper) require individual applications, one-by-one, and require one-by-one updates.

NCPDP is a certified EFIO and recommends pharmacies obtain their NPIs by authorizing NCPDP as their EFIO. This will insure data are correct on the NPDES as well as on the NCPDP Pharmacy Database available to industry.

Do all pharmacies need an NPI?

All pharmacies that submit HIPAA covered transactions must obtain and use an NPI by May 23, 2007. NCPDP recommends all pharmacies obtain an NPI, even if HIPAA covered transactions are not used by the pharmacy.

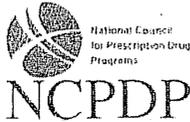
Has CMS approved NCPDP to be an EFIO? (revised 7/1/06)

Yes. NCPDP is certified to submit records for enumeration on behalf of pharmacies with their authorization. In May, NCPDP submitted smaller files and streamlined business processes in the live environment. NCPDP has steadily increased the number of files submitted weekly as well as the size of those files. NCPDP is currently accepting updated information and authorizations from pharmacies. With the exception of new pharmacies and change of ownerships, pharmacies are enumerated in the order in which their updated information is received, allowing for CMS file size and frequency restrictions. New pharmacies and Change of Ownership situations take priority.

Why should a pharmacy use NCPDP as an EFIO to obtain NPIs? (revised 7/1/06)

NCPDP has been successfully enumerating pharmacies since 1981 during which time NCPDP has provided pharmacies with NCPDP Provider ID numbers (formerly known as NABP numbers). In addition to enumeration, NCPDP maintains the NCPDP Pharmacy Database, which is purchased by industry for many uses including claims processing, product recalls, publications, network development and health plan directories. Using NCPDP to obtain NPIs will insure pharmacy information is current on the NCPDP Pharmacy Database, result in minimal industry disruption and aid in proper claims reimbursement.

If a pharmacy is owned or are affiliated with a group of pharmacies, there is no other way of applying for NPIs other than a single web-based or paper application per pharmacy. Enumerating a large group of pharmacies can result in significant administrative burden associated with gathering, formatting, editing, validating, applying over the web (which CMS states takes 20 minutes per number) and maintaining data in NPDES.



FAQs on NPI Enumeration

Will NCPDP discontinue issuing NCPDP Provider (formerly NABP) ID numbers? (revised 7/1/06)

No, NCPDP will continue to issue NCPDP ID numbers, even if they are not used on a HIPAA standard transaction. NCPDP expects Workers Compensation and other programs not covered by HIPAA will continue to use NCPDP Provider ID numbers for some time into the future. It is expected that many processors will crosswalk the NPI to the NCPDP Provider ID and will continue to use the NCPDP ID for processing in the near to intermediate term. The relationship and demographic information found on the NCPDP Database files is needed more than ever by the industry. NCPDP will continue issuing NCPDP Provider ID numbers - even if the only future use is internal to NCPDP and users of our database. There are no plans to phase out the numbers.

So, NCPDP is going to continue to assign NCPDP numbers even after NPI is fully operational? If so, for how long? (revised 7/1/06)

Yes. Industry is continuing to use NCPDP ID numbers on claims until May 23, 2007 and after that date, most claims processors if not all will simply convert the NPI to the NCPDP ID before processing. NCPDP has committed to industry that there will be a one-to-one relationship between NCPDP Provider ID numbers and NPIs so that industry can easily develop crosswalks between the NPI and the NCPDP Provider ID number for information and claims processing systems. NCPDP will perform this service indefinitely.

How can NCPDP do all the work necessary for EFI submission at *no additional cost to pharmacies*?

NCPDP can do all the work required at no additional cost to pharmacies just like they do today in maintaining the NCPDP Pharmacy Database. NCPDP sells this database to the industry to recoup its pharmacy NPI enumeration costs. NCPDP, with a pharmacy's authorization and the required information on an NCPDP-developed Application Form or Excel format, will obtain pharmacy NPI(s) and maintain NPIs (i.e. maintaining the CMS National Plan and Provider Enumeration System, NPPES) for authorizing pharmacies as required by Federal Law. NCPDP agrees that all this work will be done at no additional cost to pharmacies. The only cost involved is the current cost of \$100 for enumerating *new* pharmacies or those that *change ownership*.

What are the advantages of using NCPDP as an EFIO? (revised 7/1/06)

If a pharmacy is owned or are affiliated with a group of pharmacies, there is no other way of applying for NPIs other than becoming an EFIO or applying for each pharmacy using an individual web-based or paper application. Enumerating a large group of pharmacies can result in significant administrative burden gathering, formatting, editing, validating, and maintaining data in addition to filling applications and correcting errors.

Pharmacies benefit from the various industry uses of NCPDP's Pharmacy Database information. Specifically, entities within the pharmacy industry use this pharmacy

information for affiliating pharmacies with their respective chain headquarters or networks, claims processing, direct mailings of product recalls and publications, network development, health plan directories and rebate information. NCPDP, functioning as an EFIO provides pharmacies with a single method of maintaining pharmacy information in this important industry database as well as the NPPES, which does not contain all the information needed by industry to process claims.

NCPDP's Pharmacy Database contains pharmacy NPI(s) as well as legacy NCPDP Provider ID numbers (formerly the NABP number). This provides industry with the much-needed crosswalk between the two IDs and minimizes industry disruption or errors in claims payment.

What entities other than pharmacies will NCPDP enumerate?

There are some entities or non-pharmacy dispensing sites that dispense medication under the supervision of a physician such as certain clinics, emergency rooms or dispensing physicians. NCPDP can enumerate those non-pharmacy dispensing organizations (not the physician) in addition to pharmacies.

Will NCPDP also enumerate pharmacists?

No. NCPDP is only enumerating pharmacies, non-pharmacy dispensing sites and certain DME providers. If a pharmacist *bills* for medication therapy management or other professional pharmacy services or conducts any other HIPAA standard transactions, pharmacists must obtain an individual NPI.

Will this allow my pharmacist to be paid directly for their services?

In some cases, it will be the pharmacy that is to be paid for the pharmacist's medication therapy management or professional services. In that case, the NPI of the pharmacy is the biller, (NCPDP Service Provider ID on the Telecommunication Standard Version 5.1 Claim) and the NPI of the pharmacist is the rendering provider (Pharmacy Provider Segment on the Version 5.1 Claim).

What was the purpose of the pledge pharmacies were asked to sign last year on behalf of our affiliated pharmacies? (revised 7/1/06)

The pledge NCPDP requested from organizations representing various groups of pharmacies in late 2005 was to determine industry interest in NCPDP becoming an EFIO and to help NCPDP size the level of effort NCPDP would have enumerating pharmacies. The pledge also insured organizations received regular communication regarding the status of the enumeration. Now that NCPDP is an authorized EFIO, the pledge has no importance. It is important now that pharmacies **authorize NCPDP to be their EFIO**. This can be done by updating pharmacy data with NCPDP using the NCPDP Application/Update Form, Checking the box and signing Section 11 of the Application. The Form can be found at http://www.ncdp.org/frame_news_npi-info.htm. If the organization is a larger chain, an Excel Template is available and an Authorization



FAQs on NPI Enumeration

Letter. This information is also available at http://www.ncdp.org/frame_news_npi-info.htm.

What do pharmacies do to authorize NCPDP to be their EFIO in obtaining NPIs? (revised 7/1/06)

NCPDP has emailed all those that have submitted pledges and asked for authorization. There is also a link to the NCPDP website where individual pharmacies can download a form to fill out the necessary information and authorize NCPDP. The link is http://www.ncdp.org/frame_news_npi-info.htm. The form can be faxed or mailed to NCPDP.

If an organization owns many pharmacies, an Excel file template and Chain Authorization Letter is available at the same site.

Our chain has more than one relationship or chain code. Do we need to fill out one Excel Template for each chain code? (revised 7/1/06)

Yes. NCPDP needs one spreadsheet for each chain code. This is because NCPDP sets permission flags for authorization to enumerate based on chain codes and NCPDP submits batches or files to NPPES for chains based on chain code.

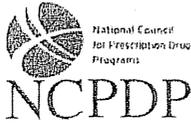
What are the pharmacy's responsibilities in order for NCPDP to enumerate? (revised 7/1/06)

Federal Law requires the information sent to NPPES to enumerate a pharmacy be correct. The pharmacy's responsibility is to verify NCPDP has the correct information on the pharmacy. The best way to do this is to go to http://www.ncdp.org/frame_news_npi-info.htm and send NCPDP the updated Application and indicate the pharmacy is updating pharmacy information and authorizing NCPDP to be an EFIO.

NCPDP is updating information on the NCPDP Pharmacy Database based upon these Applications and Excel spreadsheets to insure pharmacy information is current prior to enumeration of authorizing pharmacies. If the pharmacy has not authorized NCPDP to enumerate the pharmacy NCPDP will not enumerate the pharmacy until the pharmacy does so.

Why is NCPDP asking pharmacies to maintain more information than that needed for getting an NPI?

NCPDP can do all the work required to obtain pharmacy NPI(s) and maintain the NPPES at no additional cost to pharmacy because NCPDP sells the NCPDP Pharmacy Database to industry to recoup its pharmacy NPI enumeration and maintenance costs. The NCPDP Pharmacy Database contains more information than that required by NPPES and has been licensed to industry for over 20 years.



FAQs on NPI Enumeration

Pharmacies benefit from the various industry uses of NCPDP's Pharmacy Database information. Specifically, the entities within the pharmacy industry use this pharmacy information for different business reasons. For example, for affiliating pharmacies with their respective networks or chain headquarters, claims processing, direct mailings of product recalls and publications, network development, health plan directories and rebate information. This information will not be available to industry from NPPES.

How will NCPDP determine which pharmacies to enumerate first? (revised 7/1/06)

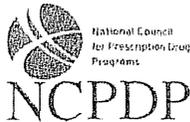
NCPDP has worked with CMS and the Enumerator, Fox Systems, Inc. to develop an enumeration plan for pharmacies. NCPDP was asked to submit small files initially and until all processes are tested. Non-chain pharmacies, new pharmacies, and resubmission of rejected records are sent on weekly files to the NPPES system for enumeration. Chain pharmacies are enumerated in batches corresponding with primary relationship codes or "chain codes". Any record issues are triaged between NCPDP, the Enumerator and the pharmacy contact person on the Application.

Effective May 1, 2006, before the NSC can process any Medicare Supplier ID enrollment documentation or make any updates to a supplier file, the supplier must ensure their NPI has been listed on the CMS-855S application. How does this impact NCPDP's ability to enumerate pharmacies? (revised 7/1/06)

NCPDP has changed our processes so that new pharmacies and pharmacies who change ownership will receive priority when NCPDP submits records to NPPES for NPI enumeration. NCPDP then provides non-chain pharmacies with an email containing the pharmacy NPI to attach to the CMS-855S application. For chain pharmacies, written notification is provided to satisfy this Medicare requirement. For more information on the NPI and CMS-855S applications, please contact Jeannine Deese at jdeese@ncpdp.org. It is expected the need for a paper copy of the NPI notification will not be necessary after NPPES dissemination is functional.

What happens if NPPES rejects some of the information submitted by NCPDP? (revised 7/1/06)

If the NPPES system rejects information submitted by NCPDP such as invalid zip code, phone number or address or a potential duplicate submission, NCPDP attempts to correct the error and resubmit the application. NCPDP contacts the individual authorized as the pharmacy "contact person" if NCPDP requires aid in resolving the rejected or pended application record. The most common reason for rejection of independent pharmacy records is "potential duplicate". This means that although the pharmacy gave NCPDP permission to be their EFIO, pharmacies may have already enumerated themselves and the rejection is sent to NCPDP. If NCPDP calls a pharmacy to verify information and clear the pended or rejected record with CMS, it is very important and required by law that the pharmacy aid NCPDP in resolving the matter on a timely basis. This also insures the NCPDP Pharmacy Database is correct and the pharmacy's NPI is on file to avoid payment disruption.



FAQs on NPI Enumeration

If NPPES *ponds* the information on a record for Enumerator review, then the Enumerator contacts NCPDP or the pharmacy to receive clarification, if necessary and either accepts or rejects the record. If rejected, the record can be corrected and resubmitted.

If NPPES rejects an *entire NCPDP submission* on behalf of a chain or other affiliate because it contains an unusual number of errors, NCPDP retains the right to request that chain or affiliate resolve the errors and resubmit a file to NCPDP. Pharmacies are responsible for the quality and validity of the information provided.

How important is it that NCPDP has current information on pharmacies? (revised 7/1/06)

Federal Law requires that pharmacies certify the information submitted to NPPES is correct and that changes are sent to NPPES within 30 days of a change. For this reason, NCPDP is requesting pharmacies fill out the form at http://www.ncpdp.org/frame_news_npi-info.htm and update NCPDP within 20 days of a change of information. The Form provides a method for individual pharmacies to certify the information is correct. NCPDP will also require those sending the Excel Template file to certify the information sent to NCPDP is correct.

Our organization has downloaded the Excel Template. Can we just cut and paste from other lists or spreadsheets to provide the information NCPDP needs? (revised 7/1/06)

Yes. As long as all periods, apostrophes, dashes, ampersands & # symbols are removed. Make sure these characters are removed from the legal business name, dba name, physical address¹, contact name, cross streets, mailing address 1 & 2, mailing city, and state license fields. Follow the instructions carefully to avoid the need for more clean-up. NCPDP suggests a sample file with a dozen records or so are sent for review prior to an entire Excel File

What is the process once files are sent to NPPES and the Enumerator? How soon will our organization receive our NPI(s) (revised 7/1/06)

NPPES sends a response file 6 days after NCPDP sends the submission file. Records on the response file can either be enumerated, rejected or pended to the Enumerator. NCPDP researches and resubmits rejected records. This sometimes requires calling the pharmacy and working with the pharmacy to resolve the problem. The Enumerator resolves pended records. The Enumerator contacts NCPDP and/or the pharmacy contact person to aid in resolution. Pended records that have been finalized are sent on another file 6 days later. It is very important as a Federal requirement that pharmacies respond to calls from NCPDP or the Enumerator to resolve these pended records.

Remember, the 6-day turnaround time is for the NPPES first and all future response files as a result of the original submission. NCPDP notifies pharmacies of their NPI on enumerated records. In the case of independents, an email is sent. From NPI_EFIO@ncpdp.org. In the case of chains, an email and file of NPIs is sent once all pharmacies are enumerated. Keep this email as some payers or processors may

require a copy including Medicare when enrolling/changing information related to the Medicare Supplier ID.

How are pharmacies notified of their NPI(s)? (revised 7/1/06)

After obtaining a file's NPIs, NCPDP notifies pharmacies (or chain headquarters of the pharmacy if it is part of a chain) of their NPI(s) via email. Please watch for an email from NPI_EFIO@ncpdp.org. NCPDP plans to have all authorizing pharmacies enumerated by late fall 2006 and will then begin outreach to pharmacies for which no NPI is on file. If a pharmacy is late in sending information to NCPDP, the pharmacy will be enumerated later. Enumeration is an ongoing process and will not cease. The NPI must be used on all HIPAA transactions by May 23, 2007. Therefore, NCPDP and its members recommend all pharmacies obtain NPIs by December 2006. Industry needs adequate time for testing prior to May 2007.

After getting NPIs from NCPDP, what are a pharmacy's responsibilities in the future?

Over time, information on pharmacies may change. It is the pharmacy's or chain headquarter's responsibility to notify NCPDP of changes as soon as possible so that NCPDP can update NPPES within 30 days as required by Federal law.

How often should a pharmacy update information with NCPDP?

NCPDP recommends pharmacies submit an update form to NCPDP or an updated file within 10 days of a change in information or annually if information has not changed.

Our pharmacy already has an NPI. What do we do?

If a pharmacy already has an NPI, pharmacies can still authorize NCPDP to maintain data in NPPES for them. Simply fill out the NCPDP Application Form on the NCPDP website at http://www.ncpdp.org/frame_news_npi-info.htm, provide the NPI in the proper space, check the authorization box in Section 11 and sign the NPI authorization line. If a pharmacy wished to maintain NPPES information itself, but wants to insure information and NPI on the NCPDP Pharmacy Database are correct, fill out the same form, provide the NPI on the application, do not check the authorization box or sign the NPI authorization line, and send or fax the application form to NCPDP.

If one of our group of pharmacies has already applied (separately) and received an NPI, will the one that NCPDP gives us when the EFIO enumeration occurs replace that NPI? What if we don't know that a pharmacy has already obtained a number? (revised 7/1/06)

If a pharmacy already has an NPI and NCPDP does not have the number on our database, NCPDP will attempt to submit for an NPI on behalf of that pharmacy. The NPPES system will pend or deny the record as a potential or exact duplicate. If a chain or group of pharmacies is aware of NPIs for some in the group, please provide them to

NCPDP to avoid this situation. If not, after some research, the actual NPI of the pharmacy will be determined and the duplicate record will be denied in NPPES.

If our organization authorizes NCPDP to be our EFIO, must we also use NCPDP for ongoing maintenance?

Pharmacies can notify NCPDP if they wish to rescind authorization. NCPDP contacts the Enumerator, Fox Systems, Inc. who provides pharmacies with a log-on ID and password for the NPI website for each pharmacy that wishes to maintain their own information after previously authorizing NCPDP. If this option is chosen, NCPDP asks that the pharmacy maintain information with NCPDP as in the past so that the Database reflects accurate information.

CMS requires that the pharmacy notify NPPES within 30 days of a change of address or other information. The easiest way to do this is to notify NCPDP using the proper form on the NCPDP website. NCPDP will update the NCPDP Pharmacy Database and update NPPES (CMS).

What is a taxonomy code and where will we find them? (revised 7/1/06)

Taxonomy codes describe the type and specialty of providers. A minimum of one taxonomy code is required for obtaining an NPI. The NCPDP Pharmacy Database has been modified to carry up to 15 taxonomy codes per pharmacy. This is an example of additional information NCPDP needs from pharmacies prior to enumerating a pharmacy.

Taxonomy codes are codes maintained by the National Uniform Claim Committee (NUCC) to describe provider types and specialties. There are currently twelve (12) taxonomy codes for pharmacies as well as other specialties such as DME. They are listed at www.wpc-edi.com/taxonomy. If a pharmacy applies for their own NPI, pharmacies will need to include these code(s) on the NPI application. If NCPDP is applying for a pharmacy's NPI on their behalf, check the appropriate pharmacy taxonomy codes on the NCPDP application form.

Can a pharmacy have multiple NCPDP numbers? For example, if pharmacies are performing multiple services (LTC vs. Retail vs. Home Infusion), could a pharmacy have an NCPDP number and NPI for each? Moreover, would it depend on what types/numbers of state licenses or taxonomies that the pharmacy has? (revised 7/1/06)

Although NCPDP has always had a policy of one NCPDP Provider ID for each pharmacy and that has generally worked in the past, the NPI Final Rule does allow organizational providers to have more than one NPI. This does not apply to individuals or sole proprietorships. The most frequent example of this will be an NPI for the pharmacy and a separate NPI for DME. With the exception of DME, NCPDP discourages the use of multiple NPIs for a pharmacy as it goes against administrative simplification and often there are other attributes of a standard claim that can indicate whether the pharmacy is performing services as community/retail, long term care or a home infusion pharmacy. If



FAQs on NPI Enumeration

a pharmacy is unsure of what to do, contact jdeese@ncdpd.org and NCPDP will work with the pharmacy to determine the best course of action.

Our pharmacy also sells DME supplies. Do we need a second NPI? (revised 7/1/06)

No. Medicare requires providers have a separate DME NPI for each location. However, the DME NPI can be the same as that location's pharmacy NPI. This is the provider's choice. Please include the appropriate taxonomy code(s) on the application. Taxonomies are maintained in the NCPDP Pharmacy Database and submitted to NPDES. If, a pharmacy currently has two NCPDP Provider ID numbers for business reasons (one for pharmacy and one for DME), NCPDP recommends pharmacies obtain a second NPI corresponding with the second NCPDP Provider ID number and include the appropriate taxonomy under each number.

Our pharmacy currently has two NCPDP ID numbers for different operations. Do we need two NPIs? (updated 3/2/06)

No. However, if a pharmacy currently has two NCPDP ID numbers, NCPDP recommends the pharmacy apply for two NPIs. Pharmacies are organizations and organizations can have more than one NPI for their respective "subparts".

There is a chance NPDES will reject or pend the second application as a possible duplicate. NCPDP will work with the Enumerator, Fox Systems, that the pharmacy or pharmacy headquarters to allow the second NPI. Make sure the Taxonomy Code/Business Type section on the application is **different** for each application to describe the respective business subpart operation.

Industry has developed taxonomy codes (including LTC) so pharmacies can more clearly describe the services pharmacies perform. They are on the NCPDP application. Additional codes are available at <http://www.wpc-edi.com/taxonomy>.

Does the NCPDP Database design allow for more than one NCPDP number to be linked to the same NPI; or will it allow different NCPDP numbers to be linked to the same NPI at different times? (revised 7/1/06)

No. Only one NPI can be assigned to each NCPDP Provider ID and only one NCPDP Provider ID is assigned to any given NPI. If an NPI or NCPDP Provider ID is deactivated due to a store closing or change in ownership, the corresponding number is deactivated as well. In the case of a change in ownership, it is the decision of the sellers and buyers whether the buyer will retain the seller's NCPDP ID and NPI. If the buyer is to retain the seller's identifiers, the seller must provide NCPDP with written and notarized permission that the buyer can retain the identifiers. The transaction is reflected on the next monthly file sent to subscribers. A given NCPDP Provider ID and NPI are always linked; although EINs, relationship codes and other information related to those numbers may change.

Does a change in ownership require a change in NCPDP numbers? (revised 7/1/06)

Current rules will continue to be effective. A change in ownership does not require a change in identifiers. Whether or not there is a change of identifiers is a condition of the sale. The seller must notify NCPDP if the buyer is to retain the identifiers and the notification must be notarized. If an NPI is to be deactivated, only the pharmacy or chain headquarters is authorized by CMS to do so.

What if a pharmacy deactivates their NCPDP ID and NPI and later needs to reinstate the numbers? (revised 7/1/06)

In the past, NCPDP was able to re-instate a pharmacy with its original number relatively easily. This may not be the case with an NPI. It is not known at this time whether there is the ability to reinstate a deactivated NPI. Please contact NCPDP if the pharmacy encounters this situation and we will contact CMS to determine how best to solve the problem.

When should pharmacies begin using NPIs instead of NCPDP Provider ID Numbers? (updated 3/2/06)

The Workgroup on Electronic Data Interchange (WEDI) and NCPDP members have drafted a white paper that includes guidance for the industry and a timeline for the pharmacy industry for transition from the current NCPDP Provider Pharmacy ID to the NPI. Testing between pharmacies, processors and other trading partners will begin in late 2006. Certification testing and production use of the NPI is scheduled to begin in January 2007 with full transition to the NPI by May 23, 2007. After that date, the NPI must be used on all HIPAA covered transactions. The finalized white paper is available at www.wedi.org and on the NCPDP website at http://www.ncdp.org/pdf/NPI_NCPDP_impact_on_phcy_services_sector_NCPDP_white_papers_2005-12-19.pdf. It also contains more detail on NPI implementation issues.

Does the NPI replace NCPDP Provider ID numbers on a HIPAA standard transaction such as a v5.1 claim?

Yes. Using the industry timeline, once a pharmacy's trading partners are "live", the NPI will replace the NCPDP ID on the HIPAA transaction. During the transition period in early 2007, it is possible that a pharmacy will need to submit the NCPDP ID on some claims to certain claims processors and the NPI to others. Please verify that your pharmacy system software is able to perform in this manner. Note that in addition to claims, the NPI will be used on standard HIPAA transactions including eligibility and prior authorization transactions. Note that this affects the real-time Telecommunication transactions, as well as the Batch Standard submissions.

When should pharmacies update data with NCPDP? (revised 7/1/06)

The time is now. Updating pharmacy information now will place the pharmacy in the enumeration queue maintained by NCPDP. After bulk enumeration, Federal Law requires that the NPPES be updated within 30 days of a change in information. NCPDP

encourages pharmacies to update NCPDP as soon as possible to insure the change meets the 30-day window. For pharmacy chains, NCPDP recommends chains provide NCPDP with one file that includes all updated information each month and another file with new stores to obtain NPIs

What should pharmacies be doing now to prepare for NCPDP's submission? (revised 7/1/06)

If the organization represents many pharmacies, NCPDP recommends obtaining the new standard NCPDP Excel™ Template at http://www.ncdp.org/frame_news_npi-info.htm. Begin collecting the data needed from the appropriate sources and submit the file as soon as possible. An individual's pharmacy or small chain can download the new NCPDP Provider ID and NPI Application Form now at http://www.ncdp.org/frame_news_npi-info.htm and submit data to NCPDP so that data is current.

When gathering information for the application, double check to insure that all information, such as demographic information, phone, fax, Taxonomy/Business Types, DEA, Medicaid, Medicare, Federal Employer Identification Numbers, are correct. This will reduce rejected applications and aid in resolving any potential duplicate issues.

Now that NCPDP is live and enumerating pharmacies, when will NCPDP add the NPI to the NCPDP Pharmacy Database and when that information will start to be provided to the subscribers of that file? (revised 7/1/06)

NCPDP has enhanced the database to provide the NPI among other data elements on pharmacies as in the past. Subscribers must modify their systems and obtain the NCPDP v2.0 Processor Set to receive the NPI. Please contact Jeannine Deese at jdeese@ncdp.org to begin receiving the v2.0 output file. The Pharmacy Database v2.0 Implementation Guide is available at http://www.ncdp.org/frame_news_npi-info.htm.

Where can pharmacies learn more about NCPDP's progress with NPI enumeration? (revised 7/1/06)

The best place to learn the current status of NCPDP's progress with NPI enumeration is the NCPDP website. Go to www.ncdp.org for information related to NCPDP's EFIO activities, updates to this FAQ document and applications. This site will be updated at least monthly. In addition, pharmacies will receive information periodically through *NCPDP Now*, e-mails, industry publications and other associations. If a pharmacy wishes to receive broadcast emails specific to NPI enumeration progress, please notify kdeininger@ncdp.org and NCPDP will add the organization's email name to the broadcast email list.

Who should pharmacies contact if they have more questions?

Please e-mail Jeannine Deese, NCPDP Manager of Pharmacy Services at jdeese@ncdp.org. Please e-mail the question and it will be answered via return e-mail.

Attachment 7

Competency Committee Report



California State Board of Pharmacy

1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
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www.pharmacy.ca.gov

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

To: Licensing Committee

Date: January 22, 2007

From: Board of Pharmacy

Subject: Competency Committee Report

Test Administration Contract

The Office of Examination Resources (OER) within the Department of Consumer Affairs is seeking a new contract with a vendor to provide computer based testing through a Request for Proposal (RFP) process. The board uses this contract to administer the CPJE. The current contract expires December 1, 2006. The second Request for Proposal (RFP) was cancelled effective November 8, 2006. OER secured a Noncompetitive Bid (NCB) to continue services with the current contractor through May 31, 2007.

The OER Invitation for Bid (IFB) IFB-OER-07-1 for computer-based testing (CBT) was released on December 4, 2006. The procurement method is no longer an RFP as the decision to change the format was made by both the Department of General Services and Department of Consumer Affairs. Proposals were received, evaluations conducted and the cost opening is scheduled for January 23, 2007.

CPJE Pass Rate Summary

The next CPJE statistical report will cover performance data for 10/1/06-3/31/07. This report should be available at the April board meeting.

Attachment A

*Meeting Summary of the
Licensing Committee Meeting
of December 6, 2006*



California State Board of Pharmacy

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

**Licensing Committee
Summary of the Meeting of December 6, 2006**

Hilton Airport Hotel and convention Center
2500 Hollywood Way
Burbank, CA 91505

Present: Ruth Conroy, PharmD, Chair and Board Member
Clarence Hiura, PharmD, Board Member
Susan Ravnar, PharmD, Board Member

Virginia Herold, Interim Executive Officer
Anne Sodergren, Legislation Coordinator
Robert Ratcliff, PharmD, Supervising Inspector

Chairperson Conroy called the meeting to order at 9:35 a.m.

Proposal from the California Schools of Pharmacy to Identify Professional Competencies that Should be Obtained by the End of the Basic Internship Experience

Barbara Sauer, PharmD, provided information about a project recently initiated by California's pharmacy schools to review the basic intern experience earned by California pharmacy students. The group will examine both the required and elective components of ACPE approved intern experience at the basic (IPPE) and advanced (APPE) levels. The project will be called the California Pharmacy IPPE/OSCE Initiative. The goal is to develop an alternative component to assessing intern experience besides simply the accrual of hours.

One concern of the educators is that requiring a specific duration of experience (i.e., 1,500 intern experience hours) but without specifying the components to be gained from the experience is not beneficial.

The California schools are collaborating on this new initiative to determine and assess the competencies that should be achieved by the end of introductory pharmacy practice experiences (IPPEs) before students start their advanced experiences.

President Powers has appointed Board Member Ravnan as the board's representative to this group.

Dr. Sauer stated that the schools of pharmacy believe it would be educationally sound for interns to pass an objective exam to assess performance at the end of the basic phase of internship. The benefits of such an assessment are:

- Students know what they need to learn at the basic level
- Schools know what should be learned and instructed

The assessment will include identification of some of the skills listed on the prior intern experience skills affidavit developed by the board in the early 1990s.

The 1,500-hour intern requirement would not be eliminated, but added would be an assessment when the basic skills have been mastered.

The goals of the initiative are to:

1. Reach consensus on the basic foundational competencies that all pharmacy students in California should master during intern experiences.
2. Train faculty members from each pharmacy school in California how to develop and administer an OSCE-based assessment.
3. Develop a validated and standardized OSCE-based examination to assess achievement of the basic competencies.
4. Develop a mechanism to assure replenishment of the OSCEs and exam security in the future.
5. Petition ACPE to accept an OSCE-based assessment for basic experience as evidence of compliance with specific ACPE standards.

Motion: Recommend that the board support and participate in this initiative

The project will be completed by mid-2007.

Request to Increase the Number of Intern Hours That Can Be Earned Outside a Pharmacy

Students from California pharmacy schools returned to the committee to advance a proposal seeking changes in board regulation section 1728 regarding the maximum number of intern hours that an intern pharmacist may earn outside a pharmacy from 600 to 1,000 of the total of 1,500 intern experience hours.

The students indicated that pharmacy practice is no longer confined to pharmacy environments and students would benefit by gaining experience performing services in the pharmaceutical industry, managed health care, regulatory affairs and association management. However the students cannot earn intern hours for this experience, which impedes their experience as students and future development as pharmacists. As part of the pharmacy school curriculum, students complete various rotations in their first and fourth years in both community and hospital pharmacy. In the fourth year,

pharmacy experience is more clinical. If the intern hour requirements were changed, a large percentage of pharmacy students would still earn the majority of the intern hours in a pharmacy. However, those students that show proficiencies in the pharmacy settings and would like to expand their experience in other areas.

The students, Jonathan Watanabe, Tom Wang, David Truong and Jennifer provided a Power Point presentation highlighting the additional areas that interns could pursue if the intern hours experience requirement was more flexible. They cited statistics indicating the benefit that redirected students could provide to health care and that the proposal fits the board's mission.

Discussion during this meeting included a possible increase of 400 hours to the intern experience requirement, to total 1900 hours, to permit such additional experience. Discussion also included the need for students to thoroughly understand the workings of a pharmacy, and why such experience is so important to a pharmacist's future as a supervisor of pharmacy functions and personnel. Without a solid understanding and actual experience in such environments, pharmacists will have a difficult time because core experience in a pharmacy is lacking.

The committee concluded that it is premature to move forward with the students' proposal at this time. Instead the committee wants to wait for the results of the pharmacy schools' project discussed earlier at this meeting that will establish a competency assessment of basic pharmacy intern skills before considering any changes in the ratio of intern hours.

Proposed Regulation Requirements for Compounding by Pharmacies

The committee reviewed proposed regulation language that would establish parameters for pharmacies that compound medication for patients. This language was developed two years ago as a work product following completion of the board's Workgroup on Compounding. Legislative proposals were also developed as another work product of this workgroup, but the legislation containing these provisions was dropped during the final stages of the 2006 legislative session due to opposition that could not be resolved. The regulation proposals are being submitted to the committee for refinement and presentation to the board to ensure basic standards for public safety when pharmacies compound medicine.

Dan Wills, Grandpa's Pharmacy, made several comments on segments of the regulation. He stated that it is impossible to ensure a compound is free from any contaminants. He also had questions regarding unit dose containers.

Comments were also made by those present at the meeting on various provisions. Comments included that adding flavoring to a medication should not be included in the regulation's requirements, and reconstitution of ocular products also should be excluded from definition of compounding. Other comments included that obtaining components from suppliers for some items, such as sugar, should not be required by the record

keeping requirements of section 1735.2(c), and a better definition of container needs to be developed, including a definition of a unit-dose container. Concern was also expressed about the meaning of section 1735.7(b) regarding the required quality assurance plan.

Ms. Herold ask those who had comments on the language to please submit them in writing to the board.

Motion: Bring the regulation to the board for future adoption as a regulation.

Request to Add the ExCPT Exam as an Additional Qualifying Method to Become a Pharmacy Technician

Ms. Herold updated the committee on the status of the review of the ExCPT exam, which has been developed by the Institute for the Advancement of Community Pharmacy Technicians (ICPT) as a means to assess the knowledge of applicants for a pharmacy technician registration. The National Community Pharmacists Association and the National Association of Chain Drug Stores support use of the exam. Five states currently authorize the use of this exam as a qualifying route to technician registration.

Currently California uses the Pharmacy Technician Certification Board examination as one route that individuals can use to qualify for pharmacy technician registration. Until recently, this was the only pharmacy technician certification examination available.

At the last committee meeting, the board directed staff to develop a plan to review the ExCPT exam to determine if it meets the requirements of the California Business and Professions Code section 139 regarding a valid examination.

Ms. Herold explained that within the Department of Consumer Affairs is the Office of Examination Resources. This office provides examination and psychometric services to professional and vocational licensing boards within the department. Any review of any licensing examination considered by the board should likely include staff from this office as part of the review process. However, at the current time this office is undergoing recruitment for a new chief. Ms. Herold suggested that until such time as a new chief is hired, the board should delay the review of the ExCPT exam because professional expertise and objectivity are needed. Moreover, legislation will be needed to authorize use of the examination, and should the board sponsor such a proposal, the board will need to submit evidence of psychometric validation.

However, there are other options to perform this review that the committee discussed – including suggesting that the NABP form an independent task force to determine if the exam is psychometrically valid as the ICPT insists. This is a bit sensitive as the NABP is one of the owners of the currently used competing exam – the Pharmacy Technician Certification Board Examination.

Alternatively, the board could direct what organization the ICPT could submit its exam to for independent evaluation. This is a process suggested by the American Society of Health System Pharmacists (which is also an owner of the Pharmacy Technician Certification Board Examination). The committee reviewed a letter from this association expressing concern whether the ExCPT exam has been appropriately validated, and recommending an independent organization to evaluate the exam.

The committee took no action on this agenda item.

Request to Accept the Certification Examination of the Commission for Certification in Geriatric Pharmacy for Continuing Education Credit for Pharmacists

The committee reviewed a request from the Commission for Certification in Geriatric Pharmacy to award continuing education credits to those pharmacists who pass the certification examination to become a Certified Geriatric Pharmacist. According to the association, there are 1,300 certified geriatric pharmacists in the US, Canada, Australia and other countries. To become certified, the individual must pass a 3-hour, 150-question examination covering three areas: patient specific, disease specific, and population specific activities. Two states, Ohio and Washington, do award CE units for passing this examination.

The committee wanted to know more about the examination and qualifying process. However, there was no one from the commission present at the committee meeting, so the committee voted not to approve the item until someone from the commission could appear.

Motion: Table the item until someone from the Commission for the Certification in Geriatric Pharmacy can meet with the committee.

Ms. Herold will contact the commission to assure someone will attend before this item is rescheduled for a future Licensing Committee Meeting.

Emergency Preparedness for California Pharmacy – Review of the Board's Proposed Disaster Response Policy

At the October Board Meeting, the board amended and approved a general policy statement that outlines its expectations for how disaster response in California could proceed. The policy encourages pharmacists, interns and technicians to seek out disaster response training in advance of an emergency so qualified individuals are available to assist in disaster response.

Staff made several additions to the text requested by the board following the adoption of the policy.

The committee reviewed the modifications and agreed they met the minor additions sought by the board.

Motion: Publish the modified policy in the next *The Script* newsletter.

Ms. Herold added that in the coming months, staff will continue to work with the Emergency Preparedness Office of the Department of Health Services on matters relating to the distribution of medicine when a state of emergency has been declared.

National Provider Identifier (NPI)

The committee reviewed materials regarding the National Provider Identifier (NPI) number, which is a unique identifier for health care providers, including pharmacies and pharmacists. The NPI was developed by the federal Health and Human Services Agency as part of HIPAA. All HIPAA-covered providers, whether they are individuals or companies, must obtain an NPI for use in HIPAA-covered, HIPAA standard transactions. Once issued, a provider's NPI will not change, even if a pharmacist's job or pharmacy location changes.

Pharmacists and pharmacies can obtain this number from CMS. All covered entities must have the NPI in place by May 23, 2007.

Competency Committee Report

Ms. Herold advised the board about current matters involving the California Pharmacist Jurisprudence Examination (CPJE).

The test administration contract for the Department of Consumer Affairs, which the board uses to administer the CPJE, will again need to be reissued for bids for examinations that will be administered starting June 2007. This is the second time the request for proposals has been cancelled in the last few years.

The pass rate on the CPJE for 2005/06 was 80 percent: during the fiscal year 1,633 attempts to pass the exam were made, and 1,308 individuals passed the exam.

The board's Competency Committee was split into two divisions in August to decrease the heavy meeting schedule associated with examination development and administration. The committee also developed its meeting schedule for 2006-07.

Adjournment

There being no additional business, Chairperson Conroy adjourned the meeting at 1 p.m.

Board of Pharmacy Licensing Statistics - Fiscal Year 2006/07

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
APPLICATIONS													
Received													
Pharmacist (exam applications)	111	156	79	113	81								540
Pharmacist (initial licensing applications)	5	405	122	241	71								844
Intern pharmacist	31	471	57	468	56								1083
Pharmacy technician	450	574	626	492	552								2694
Pharmacy	18	46	33	28	32	29							186
Sterile Compounding	1	7	1	4	1	0							14
Clinics	2	8	6	8	3	3							30
Hospitals	2	2	2	0	0	3							9
Nonresident Pharmacy	3	4	3	6	5	8							29
Licensed Correctional Facility	0	0	0	0	0	0							0
Hypodermic Needle and Syringes	2	2	0	2	2	0							8
Nonresident Wholesalers	6	17	10	13	9	7							62
Wholesalers	5	4	6	7	13	0							35
Veterinary Food-Animal Drug Retailer	0	0	0	0	0	0							0
Designated Representatives	20	50	18	35	32	35							190
Issued													
Pharmacist	115	276	141	236	98	41							907
Intern pharmacist	36	245	243	456	85	46							1111
Pharmacy technician	646	883	660	580	502	434							3705
Pharmacy	35	24	36	31	57	27							210
Sterile Compounding	5	4	9	6	5	2							31
Clinics	13	10	4	5	3	5							40
Hospitals	0	0	0	0	12	1							13
Nonresident Pharmacy	0	3	2	3	6	2							16
Licensed Correctional Facility	0	0	0	0	0	0							0
Hypodermic Needle and Syringes	0	0	0	0	8	2							10
Nonresident Wholesalers	5	3	1	10	7	2							28
Wholesalers	1	1	1	7	4	0							14
Veterinary Food-Animal Drug Retailer	0	0	0	0	0	1							1
Designated Representatives	17	1	24	36	31	24							133

Board of Pharmacy Licensing Statistics - Fiscal Year 2006/07

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Pending													
Pharmacist Examination	u/a	u/a	139	u/a	u/a	160							
Intern pharmacist	u/a	u/a	371	u/a	u/a	196							
Pharmacy technician	974	845	878	797	780	498							
Pharmacy	39	55	49	65	59	66							66
Sterile Compounding	33	34	33	32	28	27							27
Clinics	57	56	52	41	43	39							39
Hospitals	7	8	8	13	7	10							10
Nonresident Pharmacy	51	53	52	51	49	55							55
Licensed Correctional Facility	0	0	0	0	0	0							0
Hypodermic Needle and Syringes	1	1	1	12	9	8							8
Nonresident Wholesalers	101	108	117	115	124	139							139
Wholesalers	47	50	52	39	44	41							41
Veterinary Food-Animal Drug Retailer	0	0	0	3	3	2							2
Designated Representatives	105	154	148	147	148	159							159
Change of Pharmacist-in-Charge													
Received	72	168	83	131	151	132							737
Processed	86	86	75	140	132	110							629
Pending	62	144	182	173	192	214							214
Change of Exemptee-in-Charge													
Received	1	4	2	2	4	0							13
Processed	0	0	0	5	0	0							5
Pending	7	11	12	11	15	15							15
Change of Permits													
Received	33	59	44	39	44	22							241
Processed	33	18	25	11	90	10							187
Pending	150	191	186	214	168	180							180
Discontinuance of Business													
Received	17	24	13	9	23	27							113
Processed	41	0	0	0	0	0							41
Pending	26	50	63	72	95	122							122

LICENSING COMMITTEE

Goal 2: Ensure the qualifications of licensees.

Outcome: Qualified licensees

Objective 2.1	Issue licenses within 3 working days of a completed application by June 30, 2011.								
Measure:	Percentage of licenses issued within 3 work days.								
Tasks:	1. Review 100 percent of all applications within 7 work days of receipt.								
	Apps. Received:				Average Days to Process:				
		Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4
	Pharmacist (exam applications)	364*	194**	N	N	9.27	3	N	N
	Pharmacist (initial licensing)	532*	312**	N	N	3.5	5	N	N
	Pharmacy Intern	559*	539**	N	N	30	30	N	N
	Pharmacy Technician	1650*	1044**	N	N	16	16	N	N
	Pharmacies	120	92	N	N	10	12	N	N
	Non-Resident Pharmacy	7	19	N	N	30	16	N	N
	Wholesaler	7	20	N	N	30	30	N	N
	Veterinary Drug Retailers	0	0	N	N	0	0	N	N
	Designated Representative	93	102	N	N	4	15	N	N
	Out-of-state distributors	31	29	N	N	30	30	N	N
	Clinics	23	14	N	N	15	13	N	N
	Hypodermic Needle & Syringe Distributors	0	4	N	N	10	15	N	N
	Sterile Compounding	10	5	N	N	4	7	N	N
	**Denotes October and November 2006 information available at time of report development.								
	*Denotes updated to include September 2006 information								
	2. Process 100 percent of all deficiency documents within 5 work days of receipt.								
		Average Days to process deficiency:							
		Qtr 1	Qtr 2	Qtr 3	Qtr 4				
	Pharmacist (exam applications)	10	10	N	N				
	Pharmacist (initial licensing)	10	10	N	N				
Pharmacy Intern	10	10	N	N					
Pharmacy Technician	4	5	N	N					
Pharmacies	15	2	N	N					
Non-Resident Pharmacy	12	15	N	N					
Wholesaler	11	10	N	N					
Veterinary Drug Retailers	0	10	N	N					
Designated Representative	10	10	N	N					
Out-of-state distributors	10	10	N	N					
Clinics	10	7	N	N					
Hypodermic Needle & Syringe	0	6	N	N					

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

	Average Days to Determine to Deny/ Issue License:			
	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist (exam applications)	1	1	N	N
Pharmacist (initial licensing)	1	1	N	N
Pharmacy Intern	1	1	N	N
Pharmacy Technician	3	3	N	N
Pharmacies	5	4	N	N
Non-Resident Pharmacy	3	1	N	N
Wholesaler	3	5	N	N
Veterinary Drug Retailers	0	2	N	N
Designated Representative	1	2	N	N
Out-of-state distributors	3	5	N	N
Clinics	1	2	N	N
Hypodermic Needle & Syringe	0	1	N	N

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

	Licenses Issued:			
	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist	532	375	N	N
Pharmacy Intern	524	587	N	N
Pharmacy Technician	2189	1516	N	N
Pharmacies	95	128	N	N
Non-Resident Pharmacy	5	11	N	N
Wholesaler	3	11	N	N
Veterinary Drug Retailers	0	1	N	N
Designated Representative	42	91	N	N
Out-of-state distributors	9	19	N	N
Clinics	27	13	N	N
Hypodermic Needle & Syringe	0	10	N	N
Sterile Compounding	18	13	N	N

5. Withdrawn licenses to applicants not meeting board requirements.

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacy Technician	0	11	N	N
Pharmacies	2	4	N	N
Non-Resident Pharmacy	2	13	N	N
Clinics	0	22	N	N
Sterile Compounding	0	0	N	N
Designated Representative	0	0	N	N
Hypodermic Needle & Syringe	0	1	N	N
Out-of-state distributors	0	14	N	N
Wholesaler	2	16	N	N

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

Objective 2.2

Cashier 100 percent of all application and renewal fees within two working days of receipt by June 30, 2011.

Measure:

Percentage of cashiered application and renewal fees within 2 working days.

Tasks:

1. Cashier application fees.
1st Qtr 2006: The average processing time for processing new application fees is 2-3 working days.
2nd Qtr 2006: The average processing time for processing new application fees is 2-3 working days.
2. Cashier renewal fees.
1st Qtr 2006: The average processing time for central cashiering is 2-3 working days.
2nd Qtr 2006: The average processing time for central cashiering is 2-3 working days.
3. Secure online renewal of licenses.
1st Qtr 2006: Board meets with programmers to initiate parameters for board licensing programs.

Objective 2.3	Update 100 percent of all information changes to licensing records within 5 working days by June 30, 2011.
Measure:	Percentage of licensing records changes within 5 working days
Tasks:	<ol style="list-style-type: none"> <li data-bbox="363 341 1527 404">1. Make address and name changes. <i>1st Qtr 2006: Processed 1,832 address changes. 2nd Qtr 2006: Processed 1,322 address changes.</i> <li data-bbox="363 414 1527 476">2. Process discontinuance of businesses forms and related components. <i>1st Qtr 2006: Processed 41 discontinuance-of-business forms. Processing time is 46 days. 2nd Qtr 2006: Processed 0 discontinuance-of-business forms.</i> <li data-bbox="363 486 1527 673">3. Process changes in pharmacist-in-charge and designated representative-in-charge. <i>1st Qtr 2006: Processed 247 pharmacist-in-charge changes. Average processing time is 30 days. Processed 0 designated representative-in-charge changes. 2nd Qtr 2006: Processed 382 pharmacist-in-charge changes. Average processing time is 30 days. Processed 5 designated representative-in-charge changes. Average processing time is 10 days.</i> <li data-bbox="363 683 1527 787">4. Process off-site storage applications. <i>1st Qtr 2006: Processed and approved 42 off-site storage applications. Average processing time is 30 days.</i> <li data-bbox="363 797 1527 942">5. Transfer of intern hours to other states. <i>1st Qtr 2006: Processed 76 applications. Average processing time is 30 days. 2nd Qtr 2006: Processed 45 applications. Average processing time is 30 days.</i>

Objective 2.4	Implement at least 25 changes to improve licensing decisions by June 30, 2011.
Measure:	Number of implemented changes.
Tasks:	<ol style="list-style-type: none"> <li data-bbox="363 200 1485 375">1. Determine why 26 states do not allow the use of a CA license as the basis for transfer a pharmacist license to that state. <i>Jan. 2007: Survey of some statistics indicate misunderstanding of why California cannot accept NAPLEX scores earned before January 1, 2004. Educational efforts, on a state by state basis, initiated.</i> <li data-bbox="363 381 1474 451">2. Work with the University of California to evaluate the drug distribution system of its clinics and their appropriate licensure. <li data-bbox="363 457 1469 486">3. Work with the Department of Corrections on the licensure of pharmacies in prisons. <li data-bbox="363 493 1485 783">4. Work with local and state officials on emergency preparedness and planning for pandemic and disasters. Planning to include the storage and distribution of drugs to assure patient access and safety. <i>Sept. 2006: Committee hears presentation by DHS on emergency preparedness.</i> <i>Oct. 2006: Presentation by Orange County and LA emergency response staff at NABP District 7 & 8 meeting. Board meeting has presentation by DHS and board develops policy statement for licensees in responding to declared emergencies.</i> <li data-bbox="363 789 1433 818">5. Evaluate the need to issue a provisional license to pharmacy technician trainees. <li data-bbox="363 824 1485 1114">6. Evaluate use of a second pharmacy technician certification examination (ExCPT) as a possible qualifying route for registration of technicians. <i>Sept. 2006: Committee hears presentation on ExCPT exam approved for certification of techs by five states. Committee directs staff to evaluate exam for possible use in California.</i> <i>Dec. 2006: Department of Consumer Affairs recruiting for Chief of Examination Resources Office; review postponed. Additional methods to accomplish review considered.</i> <li data-bbox="363 1120 1485 1342">7. Implement the Department of Consumer Affairs Applicant Tracking System to facilitate implementation of I-Licensing system, allowing online renewal of licenses by 2008. <i>Dec. 2006 - Jan. 2007: Preparatory work and pilots completed; Board Staff initiates transfer to ATS system as sole platform for applicatn tracking for all licensing programs.</i>