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Licensing Committee Report

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

Report of the September 20, 2006 Meeting

For Action:

1. **Request to Recognize the School of Pharmacy at the University of Charleston for Purposes of Issuing California Pharmacist Intern Licenses**

After the September 20th Licensing Committee Meeting, the board received a request from the University of Charleston seeking board approval for purposes of issuing California intern pharmacist licenses (**Attachment 1**). Current board regulation section 1719 states that a "recognized school of pharmacy" means a school accredited or granted candidate status by the Accreditation Council for Pharmacy Education (ACPE). The University of Charleston has "pre-candidate" status with ACPE, and according to ACPE is progressing toward candidate status.

Approval will mean the University of Charleston's students can work as interns in California pharmacies.

A motion is needed for the board to take action on this request.

2. **Emergency Preparedness for California Pharmacy**

Recommendation: Develop and Approve Policy Statement for Licensees Regarding Authorized Activities During Declared Disasters (Attachment 3)

One of the Governor's key initiatives is emergency preparedness. Currently within the Department of Health Services is the Emergency Preparedness Office, which has been formed to coordinate state government's planning for emergencies.

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 disaster response.

Dana Grau, PharmD, of the Emergency Preparedness Office, Emergency Pharmaceutical Services Unit of the Department of Health Services provided

information about the state's planning and preparing for disaster response to the Licensing Committee on September 20.

Dr. Grau will attend this meeting to present his information to the full board. Materials for this discussion are provided in **Attachment 2**.

The DHS indicates that it wants to ensure that the board is aware of DHS' plans so that concerns can be addressed at the front end, and licensees and the public will have better knowledge of what the board will require and be willing and comfortable volunteering to participate in emergency response.

Current California law, Business and Professions Code section 4062 provides the board with broad waiver authority (this provision was written and sponsored by the board):

> **4062.** (a) Notwithstanding Section 4059 or any other provision of law, a pharmacist may, in good faith, furnish a dangerous drug or dangerous device in reasonable quantities without a prescription during a federal, state, or local emergency, to further the health and safety of the public. A record containing the date, name, and address of the person to whom the drug or device is furnished, and the name, strength, and quantity of the drug or device furnished shall be maintained. The pharmacist shall communicate this information to the patient's attending physician as soon as possible. Notwithstanding Section 4060 or any other provision of law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.
> (b) During a declared federal, state, or local emergency, the board may waive application of any provisions of this chapter or the regulations adopted pursuant to it if, in the board's opinion, the waiver will aid in the protection of public health or
> the provision of patient care.

Also, a section of law dealing with refills could aid pharmacists in providing medication to patients in an emergency:

> **4064.** (a) A prescription for a dangerous drug or dangerous device may be refilled without the prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the pharmacist's professional judgment, failure to refill the prescription might interrupt the patient's ongoing care and have a significant adverse effect on the patient's well-being.
> (b) The pharmacist shall inform the patient that the prescription was refilled pursuant to this section.
> (c) The pharmacist shall inform the prescriber within a reasonable period of time of any refills dispensed pursuant to this section.
> (d) Prior to refilling a prescription pursuant to this section, the pharmacist shall make every reasonable effort to contact the prescriber. The pharmacist shall make an appropriate record, including the basis for proceeding under this section.
> (e) The prescriber shall not incur any liability as the result of a refilling of a prescription pursuant to this section.
> (f) Notwithstanding Section 4060 or any other law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

The board's prior policy in response to any inquiries from licensees who are responding to declared emergencies is perhaps simply stated as: take care of patients, and make certain they get their needed medication.

Over the coming months the board will work with the DHS on developing a plan how the board will respond to disaster response efforts if a declared emergency occurs. To frame this discussion, the DHS and the board will develop answers to 11 questions that are contained within Dr Grau's statement in Attachment 2.

Following Dr. Grau's presentation, the board will take action on a recommendation of the Licensing Committee that the board develop a policy statement that will provide the board's thoughts on how licensees can respond a disaster. The intent is to publicly release this statement (place it on the board's Web site and highlight it in the next board newsletter) – hopefully before a response is required to provide some direction to licensees.

The draft statement developed by me and Attorney General Joshua Room is provided in **Attachment 3.**

For Information:

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

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.

A new pharmacy technician examination has been brought to the board's attention, the Exam for the Certification of Pharmacy Technicians (ExCPT).

The ExCPT is accepted by Connecticut, New Jersey, Minnesota, Oregon and Virginia as a qualifying route for registration. Kenneth W. Schafermeyer, PhD, RPh, Director of Education for the Institute for the Certification of Pharmacy Technicians, which develops this exam, attended the Licensing Committee Meeting on September 20 to provide information about this examination.

According to Dr. Schafermeyer, of the 26 states that require registration of pharmacy technicians, 11 have agreed to use the ExCPT examination as a qualifying route to registration (in several of these states the approval is proceeding but is still pending).

The exam is computer administered six or seven days a week in 700 locations nationwide. The National Community Pharmacists Association and the National

Association of Chain Drug Stores support use of the exam, and were involved in its development.

The ExCPT is a competing exam to the PTCB exam, which is developed by the American Pharmacists Association, American Society of Health-System Pharmacists, Illinois Council of Health-System Pharmacists, Michigan Pharmacists Association and the National Association of Boards of Pharmacy. Over 250,000 technicians have become certified via use of this exam nationally since 1995. Currently the PTCB is a paper-and-pencil examination administered periodically, although plans are to have it go computer administered in February 2007. It has higher fee.

The committee asked staff to review the ExCPT and see if it meets the requirements of Business and Professions Code section 139, which establishes requirements for examination programs for California-licensed occupations. Staff will collect and compile this information and provide a report to a future meeting of the Licensing Committee, and then to the board.

Materials for the ExCPT are provided in **Attachment 4.**

Should the board approve the use of the ExCPT, a statutory modification to Business and Professions Code section 4202 would be required.

4. Update on AB 595 on Compounding by Pharmacies and Recent Action by the US District Court, Western District of Texas

In 2004, the Licensing Committee formed a Workgroup on Compounding 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 formed in part due to a request from the Department of Health Services seeking the board's determination of when a pharmacy is compounding, and when a pharmacy has become a drug manufacturer, and thus subject to licensure by the Department of Health Services or federal Food and Drug Administration.

This workgroup was comprised of staff from the board, the Department of Health Service, 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 FDA the determination of when a pharmacy is manufacturing.

In 2005, the board sponsored the proposed statutory provisions in legislation introduced as AB 595 (Negrete-McLeod). In August 2005, AB 595 was on the floor of the Senate when opposition from the Department of Health Services was formally

announced. During 2006, the board and interested stakeholders worked to remove the Department of Health Services' opposition, but the board was never successful. The Department of Health Services remained opposed to various provisions, but primarily the provisions that would have allowed a pharmacy to contract with another pharmacy to compound medication for the first pharmacy. Amendments desired by the Department of Health Services would have required a separate pharmacy license and annual inspections for pharmacies that compound medication for other pharmacies.

At the very end of the 2006 Legislative Session, after months of effort to remove or reduce DHS' opposition, amendments to AB 595 appeared in print that were aimed at reducing this opposition (**Attachment 5**). However, Kaiser, CPhA and Grandpa's Pharmacy came out in opposition to these amendments. Whereas former Executive Officer Patricia Harris feels that these amendments had been agreed upon earlier, the bill was dropped at the end of the session (DHS never removed its opposition).

In early September, after the board dropped AB 595, the board obtained a court decision restricting the FDA's regulation of pharmacy compounding based on a lawsuit filed in Texas. A copy of this decision is also provided in **Attachment 5**.

During the Licensing Committee Meeting on September 20, Deputy Attorney General Joshua Room provided an overview of the likely minimal impact the Texas decision might have upon California. The meeting summary of the September 20th meeting in this packet (**Attachment 7)** contains this information, which Mr. Room will provide to the board during the meeting (see page 6 of the meeting summary).

The CPhA may be interested in sponsoring similar legislation next year. The board can review and take a position on the bill that the profession introduces and sponsors.

The proposed regulations for compounding pharmacies that were developed in 2004 as part of the Compounding Workgroup will be brought to the next Licensing Committee.

5. Transfers of NAPLEX Scores to Other States

According to a survey done by the NABP last year, 26 states will not accept a North American Pharmacist Licensure Examination (NAPLEX) score if the applicant initially earned that score from being qualified to take the examination by California, and after passing the exam, later applies to become licensed as pharmacist in these states (**Attachment 6**).

There is a process by which an applicant who has not yet taken the NAPLEX may ask that his or her NAPLEX score be sent to multiple states. However, not all candidates do this before taking the exam, or discover later that they wish to become licensed as a pharmacist in another state. If the latter occurs, a license

transfer is required (which essentially is a transfer of the NAPLEX score and license verification) to the new state. The applicant is still required to meet any additional licensure requirements in the new state (e.g., pass the Multistate Pharmacist Licensure Exam for that state).

At the July Board Meeting, the board directed that staff determine why 26 states will not accept NAPLEX scores earned in California if later the pharmacists wish to transfer the score to become licensed in that state.

It has not been possible to complete the review but the survey will be completed and shared with the committee in December. However, Ms. Herold contacted the NABP for its insight, and was advised that::

1. California's acceptance of NAPLEX scores only if earned after January 1, 2004, may account for much of the reason why California scores are not accepted by these states; essentially because California does not fully accept NAPLEX scores earned by their pharmacists, but instead requires retaking the NAPLEX for many of a state's pharmacists.
2. Misunderstanding about what exams California will accept from their states (e.g., requiring passing of the old California licensure exam) may be another factor.

The NABP believes that education about California's requirements may help resolve some of this problem. Ms. Herold will contact these states one at a time to conduct the survey and hopes to provide education as well as obtain information.

6. Foreign Pharmacy Graduate Equivalency Commission Certifications

California law requires foreign-educated pharmacists to be certified by the Foreign Graduate Equivalency Commission (FPGEC) to satisfy the educational equivalency requirement with that of domestic pharmacy school graduates.

Since 1991, California has required foreign-educated pharmacists to pass the Test of Spoken English (TSE) as a condition of taking the California pharmacist licensure examination. The TSE is administered by Educational Testing Service worldwide, and has been validated to assess the spoken English proficiency of those for whom English is not their original language.

In 1997, the FPGEC began requiring a TSE score of 50 as a component of FPGEC certification. Recognizing the duplication of this requirement with California's TSE requirement, California law was amended in the late 1990s to require foreign-educated candidates who became FPGEC certified before January 1, 1998 to continue to provide a passing score on the TSE. Those certified after January 1, 1998, no longer needed to provide the board with a TSE score (due to the FPGEC's TSE requirement).

In a few months, Educational Testing Service will no longer administer the TSE, but instead rolled these requirements into the TOEFL iBT exam. The FPGEC has

begun accepting the TOEFL iBT exam as part of its requirements to become FPGEC certified in place of the TSE.

In recent months, the board has heard from several foreign-educated pharmacists who became FPGEC certified before 1998, and thus are required to complete the TSE requirement; however, these applicants have been unable to pass the TSE. The applicants have expressed concern about how they will qualify to take the pharmacist licensure examination in California if the TSE is no longer administered.

The FPGEC has agreed to recertify these individuals who have not earned a passing TSE upon passage of the TOEFL iBT.

Other Items from the Licensing Committee:

ACPE Celebrates Its 75 Birthday
The committee viewed a brief video-montage DVD prepared by the Accreditation Council for Pharmacy Education, showing the history of this organization since its formation 75 years ago. The pictorial review showed changes in pharmacy over this period.

An Overview of 340B Drug Programs
Chairperson Conroy directed the committee to materials in the packet describing 340 B Drugs. The material was provided for information only, and was not an endorsement of the provider's program.

Meeting Summary:
A summary of the Licensing Committee Meeting of September 20, 2006, is provided in **Attachment 7.**

Competency Committee Report and Test Statistics For the CPJE Earned from April 1-September 30, 2006

A quality assurance review of the exam started in mid-August and was completed at the end of September.

The Department of Consumer Affairs has a contract for test administration services used by a number of regulatory entities in the department for occupational license testing. It is through this contract that the board administers the CPJE. The contract is set to expire in December 2006, but monthly extensions will be available for several months. Unless a new contract is in place, the board may be unable to use these test facilities for the CPJE after all extensions have run out (Spring 2007). A new request for proposals has been released, and a contract should be awarded on October 20; however, several prior contracts awarded for this service have been appealed and the contracting process has been invalidated. The board continues to watch this process closely.

The Competency Committee met for its annual work and planning session in August. New members have been added to the committee so that the committee could be split into two groups. This will reduce the time commitment and work required of each committee member, who have actually had to work more to produce the new CPJE exam than they did on the old exam.

Test statistics from the CPJE are provided in **Attachment 8**.

Attachment 1

Request to Recognize the University of Charleston School of Pharmacy for Purposes of Issuing Intern Licenses

UNIVERSITY OF CHARLESTON
2300 MacCorkle Ave. S.E., Charleston, WV 25304 · Phone (304) 357-4800 · FAX (304) 357-4915 · www.ucwv.edu

September 20, 2006

Patricia Harris, Executive Officer
Board of Pharmacy
400 R Street, Suite 4070
Sacramento, CA 95814

Dear Ms. Harris:

The University of Charleston School of Pharmacy in Charleston West Virginia requests that the Board of Pharmacy process the pharmacist intern applications of 8 students that are in the Class of 2010 in time for experiential activities planned for late October 2006.

The University of Charleston School of Pharmacy opened its doors to students in August 2006. The School currently has pre-candidate status with the Accreditation Council for Pharmacy Education (ACPE) and will be reviewed by ACPE for advancement to candidate status during the 2006-2007 academic year. As you are aware, accreditation is based on adherence to ACPE Standards and is a multi-phased process, no program can achieve full accreditation until the first class graduates.

The ACPE Standards specify Introductory Pharmacy Practice Experiences or IPPEs take place during the pre-rotational portion of the curriculum. Three hundred contact hours has been suggested by many as the target for these experiences. For our program, early experiences start in the first semester and students are expected to spend approximately 4 hours/week at a site for 5 semesters. Our clinical partners expect that students enrolled in IPPEs will be licensed pharmacist interns. Therefore, the licensure process is important in meeting ACPE guidelines for accreditation. This is the basis for our request that our students be licensed in time for IPPE activities in the Fall 2006 semester.

If there are any questions about our request please call myself at (304) 357-4859 or David Bowyer, Director of Experiential Education at (304) 357-4892. The completed applications of the Class of 2009 are attached. Thank you in advance for your consideration of this request.

Sincerely,

Richard Stull, Dean

they are on file and readily retrievable in the receiving pharmacy.

(d) An "interim storage device" means as electronic file into which a prescription is entered for later retrieval by an authorized individual. Any interim storage device shall, in addition to the above information, record and maintain the date of entry and/or receipt of the prescription order, date of transmission from the interim storage device and identity of the recipient of such transmission. The interim storage device shall be maintained so as to ensure against unauthorized access and use of prescription information, including dispensing information.

(e) A pharmacy receiving an electronic image transmission prescription shall either receive the prescription in hard copy form or have the capacity to retrieve a hard copy facsimile of the prescription from the pharmacy's computer memory. Any hard copy of a prescription shall be maintained on paper of permanent quality.

(f) An electronically transmitted prescription shall be transmitted only to the pharmacy of the patient's choice. This requirement shall not apply to orders for medications to be administered in an acute care hospital.

(g) Electronic equipment for transmitting prescriptions (or electronic transmittal technology) shall not be supplied or used so as to violate or circumvent Business and Professions Code section 4000 et seq., Health and Safety Code section 11150 et seq., or any regulations of the board.

(h) Any person who transmits, maintains or receives any prescription or prescription refill, orally, in writing or electronically, shall ensure the security, integrity, authenticity, and confidentiality of the prescription and any information contained therein.

(Amended 9-22-2004; Operative 10-22-2004)

1718. Current Inventory Defined

"Current Inventory" as used in Sections 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332.

The controlled substances inventories required by Title 21, CFR, Section 1304 shall be available for inspection upon request for at least 3 years after the date of the inventory.

(Amended 9-11-2002)

1718.1 Manufacturer's Expiration Date

All prescription drugs not bearing a manufacturer's expiration date pursuant to Title 21, Code of Federal Regulations, section 211.137 are deemed to have expired and may not be manufactured, distributed, held for sale, or dispensed by any manufacturer, distributor, pharmacist, pharmacy or other person authorized to dispense such drugs in California.

Article 3. Pharmacist Candidates

1719. Recognized Schools of Pharmacy

As used in this division, "recognized school of pharmacy" means a school of pharmacy accredited, or granted candidate status, by the Accreditation Council for Pharmacy Education or otherwise recognized by the board.

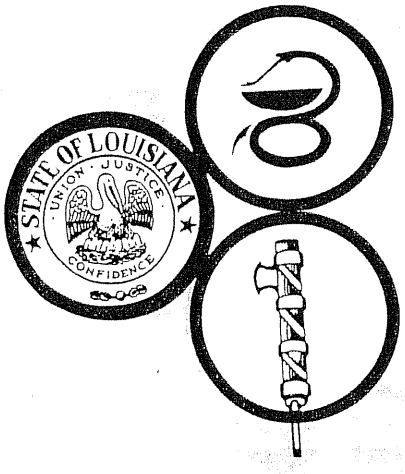
(Amended Effective 10-7-2005)

Attachment 2

Emergency Response Materials

July 2006

Emergency



Louisiana Board of Pharmacy

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Emergency Preparedness and Disaster Response (06-07-248)

As we enter a new hurricane season, the Lousiana Board of Pharmacy believes it worthwhile to review some of the lessons learned in the aftermath of Hurricanes Katrina and Rita in the summer and fall of 2005.

Preparations

- Help your patients prepare for the hurricane season by providing them with copies of their patient profiles, and encourage them to keep that profile with their critical documents during an evacuation. **Communicate before they evacuate!**
- Help your pharmacy prepare for the next emergency by reviewing your data security and environmental control policies and procedures. We know that you backup your electronic prescription data on an appropriate schedule; are any of those backup copies stored off site? If you need to close the pharmacy for evacuation, try to prepare multiple copies of your data, preferably on different media. This could be useful if you have an opportunity to re-open your pharmacy using different computer equipment.
- If your prescription drug inventory includes items labeled for storage at "controlled room temperature" (most non-refrigerated oral solid dosage forms), what measures do you have to ensure the continuity of those temperatures in the absence of electricity from your local electrical power generation or distribution company? Have you considered the use of supplemental electrical generators to ensure appropriate temperatures for the storage of prescription drugs? If you do use such devices, please adhere to the safety precautions affixed to those devices.

Responses

- If the emergency situation was serious enough to prompt the Office of the Governor to issue a proclamation declaring a State of Emergency for some or all of the state, and if your pharmacy is operating within the area under the declaration of emergency, please remember two standing rules already approved by the Board:
  1. Using sound professional judgment, a pharmacist may dispense a one-time emergency prescription for any medication, for up to a 30-day supply, **if**
     a. in the pharmacist's professional opinion, the medication is essential to life or the continuation of previously prescribed therapy, **and**
     b. the pharmacist prepares a written record marked "Emergency Prescription," and then files and maintains that record as required by law.
  2. If you are assisting a shelter or other relief effort, that organization may accept offers of assistance from pharmacists from other states, even if not licensed in Louisiana. They must present and retain on their person a copy of a valid license in another state.

  Remember, these rules are already in place; they are triggered by the governor's declaration of a State of Emergency.
- If you need to change the location of your pharmacy, please contact the Board office for assistance with that process. We may be able to streamline certain requirements for you.

102nd Annual Meeting CE Session Provides Disaster Planning Pointers to Boards

There has been a lot of talk in recent years about government emergency preparedness and disaster planning, talk that became all the more frequent and earnest after 9/11. And yet, when Hurricane Katrina slammed into the Gulf Coast last summer, the whole country witnessed a graphic demonstration of what we were prepared for – and what we were not.

Katrina proved a wake-up call for the public and private sectors alike. Since then, officials in business and government have sought to take the lessons gained from Katrina and apply them, so that the next widespread disaster, whatever it may be and whenever it may occur, will not be met unprepared.

Lessons learned from Katrina and the steps the boards of pharmacy can and should take to prepare themselves to handle emergencies was the topic of the two-part seminar, "Structuring an Effective Disaster Plan: Lessons Learned" at NABP's 102nd Annual Meeting in April 2006 in San Francisco, CA. During the seminar, which involved both presentations and a panel discussion, the speakers shared their own experiences in the aftermath of Katrina, noted what did and did not work during the crisis, what they think should be improved upon for next time, what to expect from the federal government in terms of response and assistance, and steps the boards should take in the vital task of developing their own disaster plans. The first half of the session was co-presented by Malcolm J. Broussard, executive director of the Louisiana Board of Pharmacy and a member of the NABP Executive Committee, and Robert J. "Bob" Dufour, a member of the Arkansas State Board of Pharmacy and pharmacy director, professional services, for Wal-Mart Stores, Inc.

What Happened

In the aftermath of Katrina, Dufour offered his services to the Louisiana Board of Pharmacy, which was asked to take on a whole new role from its usual one. "The number-one goal at the Louisiana Board of Pharmacy is to affect the public safety," he said. "This is usually done through regulations and enforcing those regulations. In this case, the Louisiana Board was asked to do something different. The governor and the Office of Emergency Preparedness . . . had their hands full . . . . They asked the Louisiana Board, 'Would you take care of the medication needs for the state of Louisiana?'"

The first thing the Lousiana Board had done, of course, was to coordinate with state officials and the federal disaster response team to assess the situation and set up a triage area. Within a couple of days of the levee breaches, the state's Department of Public Health's pharmacy department (responsible for disaster response, but hampered by the inoperability of its office in downtown New Orleans) opened an emergency operations center in Baton Rouge, eventually working out of the Board office itself. Immediate tasks included ramping up the communications systems, coordinating volunteer pharmacist staffing coverage, and establishing a medication distribution system for operating shelters.

In assessing the situation in the immediate hours and days after Katrina hit,

Disaster

(continued from page 145)

those participating in them were daunting, to say the least. Palombo related some of the factors his company faced in sending a mobile pharmacy to help a hospital near New Orleans. Medco sent two trailers, he said, one to serve as a pharmacy, the other as living quarters for the staff, as no other accommodations were available. The relief teams had to be self-sufficient; local resources were not an option. "[The trailers] were being shipped from Ohio, because there wasn't any local source," said Palombo. "We had to bring fuel in on a van."

The joint undertaking worked to a surprising degree. Thanks to ingenuity, communication, and unrelenting efforts from both the private and public sectors, and despite the fluid shelter situation and the constant movement of displaced residents, evacuees got their medications, and hospitals and nursing homes received appropriate medications and supplies.

Important Points

In their presentations, Dufour and Broussard highlighted a number of points important for boards to consider as they revamp or create their own disaster plans, as did the remaining speaker who joined in for the second half of the continuing education session: Captain Christopher Jones, regional emergency coordinator for the US Department of Health and Human Services' (HHS) Office of Public Health Emergency Preparedness.

With the overriding importance of communication and coordination in the face of a catastrophe, Boards should consider their relationships with those agencies charged with the medical aspects of disaster response – now, when things are calm, said Jones. "The last thing you want to do during a disaster is come to your state health department or to your state emergency management agency and pass your business card to them and tell them who you are and where you're from and try to begin to figure out at that juncture what you can do to help," he said. "What you really need to be doing is approaching the state health departments and the state emergency management agencies, but primarily the state health departments, because they're the ones who'll be coordinating the health and medical response, sitting down with them and figuring out how the state board of pharmacy can lend a hand and become integrated into the plans, adapt the plans to meet the capabilities and resources that the state boards of pharmacy bring."

Another, related and important step for Boards is to examine their current regulations, Broussard suggested. Louisiana's comparatively new section providing "state of emergency" capabilities to provide emergency medications and accept the help of pharmacists not licensed in the state proved vital to the Board's ability to help the thousands in need. While many states have 72-hour emergency prescribing provisions, few go beyond this.

State boards might want to consider other regulations as well, such as one recommended in the federal government's report, "Katrina – Lessons Learned" (available at www.whitehouse.gov/reports/katrina-lessons-learned). In Louisiana, Broussard noted, the Board had to remind pharmacists that medications stored above 104° F for more than 24 hours could no longer be dispensed – something of a problem in the heat of a Gulf Coast summer with no electricity in sight. The Bush Administration's report suggests that states enact legislation requiring pharmacies to have generators, at least partially addressing situations like this. (Fuel for the generators following a large-scale disaster? That is another question.)

While it is difficult to plan for a situation that has not occurred, boards should try to brainstorm the logistical issues that might be faced in any disaster, and work to address them, Dufour said. As they think through various disaster scenarios, boards should keep potential logistical problems in mind. As an example, he raised several questions: How does the current infrastructure work? If that infrastructure broke down, how could the logistical challenges be met? Where could medications be stored, and how would they be unloaded, stored, and distributed?

Boards also need to plan how they will communicate with pharmacists and, potentially, the public during a disaster. "You should have newspaper ads, radio ads, information you can put on your Web site," said Dufour. "Have that in the can now, so if something does hit, you're prepared."

The boards should not ignore their own needs. Broussard pointed out the importance of safeguarding board records, for example. "We need to be mindful of our duty to protect records so we have continuity of operations," he said.

As the session's speakers noted, and as is echoed in disaster plan advice from private, public, and non-profit experts alike, responses to disasters do not begin at the federal level. While some criticize this policy – in the federal government's Katrina report, the authors recommend, "In a catastrophic scenario that

overwhelms or incapacitates local and state incident command structures, the federal government must be prepared to assume incident command and get assistance to those in need until state and local authorities are reconstituted" – at present, said Jones, "The bottom line . . . is that during a disaster, all disasters are local disasters. The local emergency management agencies have the foremost responsibility in coordinating the response. It's only after the disaster exceeds their capabilities and capacity to respond that they'll ask for assistance from the state. Once the state determines that the magnitude of the event exceeds their resources to respond . . . they ask the federal government for assistance."

Indeed, Jones said, "Every community and every state should plan for the worst. If you plan to be able to initiate a response and sustain the support for that response for a week, you'll be in good stead. Prior to Katrina . . . I said plan to sustain a response for 72 hours . . . Katrina taught us a grave lesson, that in a catastrophic event that encompasses many communities over such a broad geographic area, there aren't enough federal resources to go around."

Beyond Hurricanes

Katrina taught everyone a lot about catastrophes and large-scale disasters as they pertain to hurricanes, but what about other types of disasters? How transferable are Katrina's lessons? The Department of Homeland Security's National Response Plan identifies 15 types of incidents that could be deemed disasters or emergencies. Any given locality may be subjected to a natural disaster, a terrorist attack, or even what Jones referred to as "technological disasters" and "immigration events."

While some response elements remain the same, one disaster that would require a different response in many ways than a hurricane is a flu pandemic. How would the board continue operations with significant absenteeism, such as could occur at the height of a pandemic? How could pharmacies continue to operate? How would large numbers of people receive vaccinations, antiviral drugs, or other measures that might be necessary on a large scale and in a hurry?

In light of immediate concerns raised by the avian flu pandemic and concerns that it will eventually make the leap to easy transmission by humans, HHS has provided extensive guidance on planning for a flu pandemic. (See www.hhs.gov/pandemicflu/plan and www.pandemicflu.gov for the HHS plan and guidance for state and local entities, state plans, and other useful information on the topic.) HHS has pledged to support affected states or areas by such measures as conducting outbreak investigations, working to produce and distribute vaccines, and providing guidance on such community containment strategies as quarantines or travel restrictions.

HHS also recommended that state and local governments establish a Pandemic Influenza Coordinating Committee representing a wide range of specialties in the public and private sectors "to oversee preparedness planning and ensure integration with other emergency planning efforts." HHS convened a meeting of local and state officials from across the country in December 2005, and since then has held pandemic planning summits across the country. Plans have been drawn up and are public record in at least draft form for each state. If they have not already been involved in such planning and coordination efforts, boards of pharmacy should begin participating as soon as possible.

A side benefit of the focus on pandemic flu preparations is the light they can shed on other planning efforts that may or may not be moving forward, particularly other infectious disease emergencies, including bioterrorism events. They also may facilitate the communication and coordination necessary for effective planning for other, less similar disasters.

Despite recent attention focused on the issue, particularly in relation to a flu pandemic, tight budgets and busy officials pushing the matter off in favor of items that seem more urgent mean that disaster plans in general are being talked about more then actually created (or old ones seriously reviewed). As a result of Resolution 102-4-06, Emergency Preparedness, Response, and the US Distribution System, which was adopted at the Association's 102nd Annual Meeting in April 2006, NABP will convene a task force to examine the disaster plan situation and offer more specific guidance to the Boards on the topic.

Hurricane Katrina pointed up many faults in local, state, and federal ability to respond effectively to an event of catastrophic proportions. But it also highlighted some positives: far-sighted, emergency-triggered regulations that facilitated assistance efforts; flexibility, ingenuity, and sacrifice on the part of numerous members of the public and private sectors; and close cooperation between regulators, retailers, wholesalers, and manufacturers that allowed victims (and rescuers) to access needed medications. With comprehensive and well-thought-out plans for every jurisdiction, these positive elements can make the next big disaster less tragic.

Thank you for the opportunity to speak with you today. My name is Dana Grau, Pharm.D. ; I am a Senior Pharmaceutical Consultant in the Emergency Pharmaceutical Services Unit of the California Department of Health Services, Emergency Preparedness Office. I am joined by Tom Ahrens, Pharm.D., Chief of Emergency Pharmaceutical Services and Louis Lallo, Pharm.D., a fellow Senior Pharmaceutical Consultant in our unit.

The mission of the Emergency Pharmaceutical Services Unit, like that of the Board of Pharmacy is to protect the health of the citizens of California. We are concerned with large-scale public health emergencies which include bioterrorism attacks, nuclear attacks, disease outbreaks such as pandemic influenza as well as natural disasters such as those caused by hurricanes and earthquakes. One of the primary missions of the Emergency Pharmaceutical Services Unit is to serve as a conduit receiving resources of the Strategic National Stockpile from the Centers for Disease Control and Prevention (CDC) on behalf of the state and delivering them from a single site within the state to our local affected communities.

The Strategic National Stockpile (SNS) is a national repository of antibiotic, chemical antidotes, antitoxin, life-support medications, IV administration, airway maintenance supplies, and medical/surgical items. The SNS is designed to supplement and re-supply state and local public health agencies in the event of a national emergency anywhere and at anytime within the United States.

The SNS is organized for flexible response. The first line of support lies within the immediate response 12-hour Push Packages. These 50 ton caches of pharmaceuticals, antidotes, and medical supplies are designed to provide rapid delivery of a broad spectrum of assets for an ill-defined threat in the early hours of an event. The Push Packages are positioned in strategically located, secure warehouses ready for immediate deployment to a designated site within 12 hours of the federal decision to deploy SNS assets.

If the incident requires additional pharmaceuticals and/or medical supplies, follow-on managed inventory will be shipped to arrive within 24 to 36 hours. If the agent is well defined, managed inventory can be tailored to provide pharmaceuticals, supplies and/or products specific to the suspected or confirmed agent.

The Strategic National Stockpile Program is committed to have 12-hour Push Packages delivered anywhere in the U.S. within 12 hours of a federal decision to deploy. The 12-hour Push Packages have been configured to be immediately loaded onto either trucks or commercial cargo aircraft for the most rapid transportation. Personnel from the Centers for Disease Control and Prevention will transfer custody of the SNS materiel to state authorities once it arrives at the designated single receiving and storage site within the state. State authorities will begin the breakdown of a Push Package for distribution to affected jurisdictions. The site of this single warehouse will depend on the location of the event. For security reasons these sites are not being identified to the public.

The Emergency Pharmaceutical Services Unit is also responsible for assisting Local Health Departments in developing plans for dispensing medications from Strategic National Stockpile assets to their populations. Some of these plans call for large numbers of licensed personnel such as pharmacists and nurses to provide the mass dispensing function. Other emergency plans are being developed to conduct mass dispensing with little or no medical oversight due to lack of availability of such personnel in sufficient numbers.

Mass dispensing occurs at sites we call Points of Dispensing (or POD's) which are a venue for dispensing medicine to large numbers (potentially millions) of people who have been exposed to a pathogenic biological agent in the area of risk. People who are asymptomatic will be asked to go to a POD location to receive life saving prophylactic medication. POD's will ensure that hospitals are able to continue treating their existing patients as well as anyone who becomes ill as a result of the emergency.

In order to minimize loss of life, local health departments are developing plans to dispense medications such as antibiotics to 100% of the identified population within 48 hours of a decision to do so. Meeting this need requires huge logistic, security, public communication and mass dispensing capabilities. (Other modalities that are being studied to achieve this 48 hour target include home delivery of antibiotics by the United States Postal Service, pre-deployment of community based caches of medications that might include churches, schools, large employers, etc., and pre-event dispensing to first responders, as well as pre-deployment of antibiotics directly to civilian populations.)

Of foremost concern is the ability to respond in a timely manner to a bioterrorism attack over a large geographic area such as an outdoor release of an aerosolized agent such as Bacillus anthracis, the organism that causes anthrax. In this case, antibiotics much reach the population within 24 to 48 hours to have the greatest life-saving effect. The plans noted above are being designed to improve the capability to receive, distribute, and dispense these SNS assets.

Getting these medications from the single state warehouse into the hands of the people who would need them is one of the greatest challenges we face in our efforts to prepare California for a public health emergency such as a bioterrorism attack.

As you can see, the public health response to a bioterrorism event or a large scale natural disaster requires the activation of contingency plans that call for activities well outside of the normal day to day practice of pharmacy in order to protect the health of the citizens of California.

We have identified a number of potential warehouse sites throughout California where we might receive assets from the SNS. The final selection of the site will depend on the location and scope of the emergency. Some of these sites do not currently meet required standards and none hold Wholesale Drug Permits. The permit for the selected site would only need to be activated upon a management decision within the Department of Health Services.

Local Health Departments are also locating potential sites that could be used to receive, store and stage drugs and medical supplies that would be delivered from the State warehouse site as well as locating Points of Dispensing (PODs) from which oral antibiotics or vaccines would be dispensed/administered to the public.

Section 4062 of the California Business and Professions Code was enacted to allow pharmacists to respond to these extraordinary events.

4062. (a) Notwithstanding Section 4059 or any other provision of law, a pharmacist may, in good faith, furnish a dangerous drug or dangerous device in reasonable quantities without a prescription during a federal, state, or local emergency, to further the health and safety of the public. A record containing the date, name, and address of the person to whom the

drug or device is furnished, and the name, strength, and quantity of the drug or device furnished shall be maintained. The pharmacist shall communicate this information to the patient's attending physician as soon as possible.

Notwithstanding Section 4060 or any other provision of law, a person may possess a dangerous drug or dangerous device furnished without a prescription pursuant to this section.

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

As I have mentioned, there will be the need, in the case of an outdoor release of a pathogenic biological agent where the need to provide prophylactic antibiotic medications to an entire exposed population (thousands to potentially millions of exposed persons). It would be necessary to dispense antibiotics within 48 hours of exposure to significantly decrease morbidity and mortality. To accomplish this, local Points of Dispensing (PODs) will be established where these antibiotics will be dispensed.

Through discussions in our unit and with pharmacists throughout the state we have identified questions and issues that are of concern such as the following:

1. Is it necessary for the CDHS or a local public heath department to obtain a wholesale drug permit for each potential location where emergency drug supplies, such as those from the SNS, would be stored or dispensed? None of these sites currently have such permits. Also, is there any permit/waiver necessary for the State warehouse or local warehouse or POD sites to obtain as a pre-event requirement so that no statutes or regulations will be broken if these locations are needed to be utilized to either receive and store or dispense drugs?

2. Will the Board require numerous State applications for temporary Wholesale Drug Permits, only one of which would be activated upon declaration of a public health emergency?

3. Would a standing order from the Governor (issued as part of a State of Emergency) be necessary to legally utilize these sites pending the Board issuing an emergency waiver?

4. What is the Board's position regarding non-licensed personnel dispensing drugs to the public during emergencies?

5. Is there a minimum number of registered pharmacists required to be present at a warehouse site or a POD under emergency situations where these locations are receiving and dispensing drugs?

6. To process oral antibiotic prophylaxis to huge populations, pharmacists and non-pharmacists (such as nurses) may need to supervise large number of unlicensed volunteers, far exceeding normal ratios of pharmacist to ancillary personnel, to assist in this effort.

7. Unlicensed personnel may take rudimentary patient information, perform screening using established algorithms, and dispense drugs.

8. These medications will not be labeled to current standards of practice in California. These prescription labels may only contain the name of the drug, its strength, lot number, quantity, and directions for use.

9. There will probably be only minimal patient consultation and then possibly only in a group setting. In some extreme cases, in order to save lives, no consultation or screening would be performed due to the number of persons exposed and the limited amount of time to get people started on antibiotics.

10. Repackaging of bulk medications may be necessary at central locations (such as the State Warehouse) for distribution to PODs. Packaging of oral antibiotics at such a site will not utilize child-resistant bottles, but rather the drugs will be placed into zip-lock baggies with a minimum of labeling as mentioned above.

11. Some local county health departments are federally required to develop plans for use of the US Postal Service, where the Postal Service would deliver one or two bottles of one antibiotic to each residence within an affected zip code along with minimal information regarding exposure to an infective microbe as well minimum labeling on antibiotic bottles (child-resistant).

Ultimately we want to be able to answer in the affirmative and with certainty when a pharmacist asks us: Does the application waiver described in Business & Professions Code 4062(b) cover such variations from normal day to day practices such as these during an emergency?

To successfully accomplish the distribution of SNS assets and mass prophylaxis will require the assistance of many, many pharmacists. Having practiced community pharmacy for over thirty years, I can fully appreciate my fellow pharmacists' reluctance to participate in a setting so far out of traditional boundaries of pharmacy practice and pharmacy rules and regulations.

Business and Professions Code Section 4062 allows the Board to waive regulations in an emergency. We appreciate and would like to continue this dialog with the Board to explain our vision in achieving the goal of providing mass prophylaxis to 100% of an identified population within 48 hours. It is important for our recruiting efforts to ensure any issues the Board may have are addressed before the event. We want to ensure there are no surprises for the Board when the Board is considering, perhaps retroactively, the enactment of Section 4062.

Further, we need the Board's support and assistance to be a partner with us in encouraging pharmacists, pharmacy students, and pharmacy technicians to join in this effort to protect the health of the citizens of California.

Thank you.

Strategic National Stockpile

April 14, 2005

The Strategic National Stockpile - What it means to you

CDC's Strategic National Stockpile (SNS) has large quantities of medicine and medical supplies to protect the American public if there is a public health emergency (terrorist attack, flu outbreak, earthquake) severe enough to cause local supplies to run out. Once Federal and local authorities agree that the SNS is needed, medicines will be delivered to any state in the U.S. within 12 hours. Each state has plans to receive and distribute SNS medicine and medical supplies to local communities as quickly as possible.

What should you know about the medicines in the SNS?

- The medicine in the SNS is FREE for everyone.
- The SNS has stockpiled enough medicine to protect people in several large cities at the same time.
- Federal, state and local community planners are working together to ensure that the SNS medicines will be delivered to the affected area to protect you and your family if there is a terrorist attack.

How will you get your medicine if the SNS is delivered to your area?

- Local communities are prepared to receive SNS medicine and medical supplies from the state to provide to everyone in the community who needs them.
- Find out about how to get medicine to protect you and your family by watching TV, listening to the radio, reading the newspaper, checking the community Web site on the Internet or learning from trusted community leaders.

More Detailed Information about the Stockpile

Helping State and Local Jurisdictions Prepare for a National Emergency

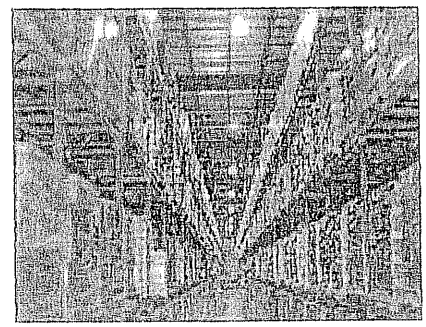
An act of terrorism (or a large scale natural disaster) targeting the U.S. civilian population will require rapid access to large quantities of pharmaceuticals and medical supplies. Such quantities may not be readily available unless special stockpiles are created. No one can anticipate exactly where a terrorist will strike and few state or local governments have the resources to create sufficient stockpiles on their own. Therefore, a national stockpile has been created as a resource for all.

In 1999 Congress charged the Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) with the establishment of the National Pharmaceutical Stockpile (NPS). The mission was to provide a re-supply of large quantities of

ssential medical materiel to states and communities during an emergency within twelve hours of the federal decision ɔ deploy.

'he Homeland Security Act of 2002 tasked the Department of Homeland Security (DHS) with defining the goals and ıerformance requirements of the SNS Program, as well as managing the actual deployment of assets. Effective on 1 Aarch 2003, the NPS became the Strategic National Stockpile (SNS) Program managed jointly by DHS and HHS. Vith the signing of the BioShield legislation, the SNS Program was returned to HHS for oversight and guidance. The SNS Program works with governmental and non-governmental partners to upgrade the nation's public health capacity o respond to a national emergency. Critical to the success of this initiative is ensuring capacity is developed at federal, tate, and local levels to receive, stage, and dispense SNS assets.

A National Repository of Life-Saving Pharmaceuticals and Medical Materiel

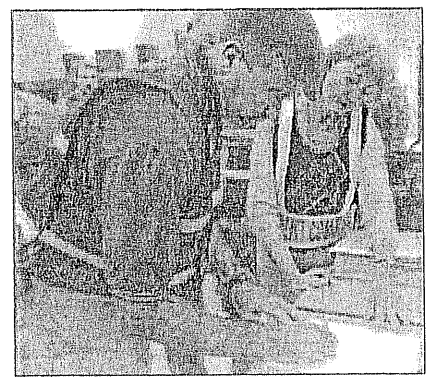


'he SNS is a national repository of antibiotics, chemical antidotes, antitoxins, life-support medications, IV administration, airway maintenance supplies, and nedical/surgical items. The SNS is designed to supplement and re-supply state and ocal public health agencies in the event of a national emergency anywhere and at nytime within the U.S. or its territories.

'he SNS is organized for flexible response. The first line of support lies within the mmediate response 12-hour Push Packages. These are caches of pharmaceuticals, ntidotes, and medical supplies designed to provide rapid delivery of a broad pectrum of assets for an ill defined threat in the early hours of an event. These Push Packages are positioned in trategically located, secure warehouses ready for immediate deployment to a designated site within 12 hours of the federal decision to deploy SNS assets.

If the incident requires additional pharmaceuticals and/or medical supplies, follow-on vendor managed inventory (VMI) supplies will be shipped to arrive within 24 to 36 hours. If the agent is well defined, VMI can be tailored to provide pharmaceuticals, supplies and/or products specific to the suspected or confirmed agent(s). In this case, the VMI could act as the first option for immediate response from the SNS Program.

Determining and Maintaining SNS Assets



To determine and review the composition of the SNS Program assets, HHS and CDC consider many factors, such as current biological and/or chemical threats, the availability of medical materiel, and the ease of dissemination of pharmaceuticals. One of the most significant factors in determining SNS composition, however, is the medical vulnerability of the U.S. civilian population.

The SNS Program ensures that the medical materiel stock is rotated and kept within potency shelf-life limits. This involves quarterly quality assurance/quality control checks (QA/QC's) on all 12-hour Push Packages, annual 100% inventory of all 12-hour Push Package items, and inspections of environmental conditions, security, and overall package maintenance.

Supplementing State and Local Resources

During a national emergency, state, local, and private stocks of medical materiel will be depleted quickly. State and local first responders and health officials can use the

;NS to bolster their response to a national emergency, with a 12-hour Push Package, VMI, or a combination of both, lepending on the situation. The SNS is not a first response tool.

Rapid Coordination & Transport

The SNS Program is committed to have 12-hour Push Packages delivered anywhere in the U.S. or its territories within 2 hours of a federal decision to deploy. The 12-hour Push Packages have been configured to be immediately loaded nto either trucks or commercial cargo aircraft for the most rapid transportation. Concurrent to SNS transport, the SNS Program will deploy its Technical Advisory Response Unit (TARU). The TARU staff will coordinate with state and ocal officials so that the SNS assets can be efficiently received and distributed upon arrival at the site.

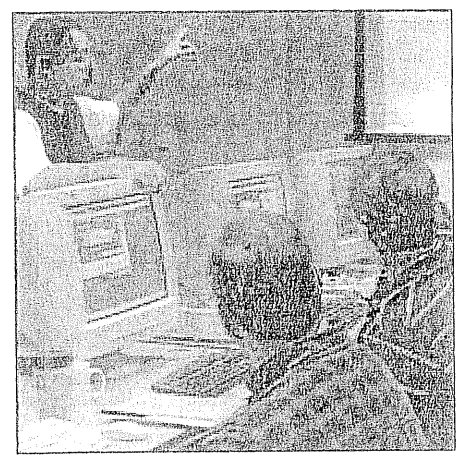
Transfer of SNS Assets to State and/or Local Authorities

HHS will transfer authority for the SNS materiel to the state and local authorities once it arrives at the designated eceiving and storage site. State and local authorities will then begin the breakdown of the 12-hour Push Package for listribution. SNS TARU members will remain on site in order to assist and advise state and local officials in putting he SNS assets to prompt and effective use.

When and How is the SNS Deployed?

The decision to deploy SNS assets may be based on evidence showing the overt release of an agent that might adversely affect public health. It is more likely, however, that subtle indicators, such as unusual morbidity and/or nortality identified through the nation's disease outbreak surveillance and epidemiology network, will alert health officials to the possibility (and confirmation) of a biological or chemical incident or a national emergency. To receive SNS assets, the affected state's governor's office will directly request the deployment of the SNS assets from CDC or HHS. HHS, CDC, and other federal officials will evaluate the situation and determine a prompt course of action.

Training and Education



The SNS Program is part of a nationwide preparedness training and education program for state and local health care providers, first responders, and governments (to include federal officials, governors' offices, state and local health departments, and emergency management agencies). This training not only explains the SNS Program's mission and operations, it alerts state and local emergency response officials to the important issues they must plan for in order to receive, secure, and distribute SNS assets.

To conduct this outreach and training, CDC and SNS Program staff are currently working with HHS, Regional Emergency Response Coordinators at all of the U.S. Public Health Service regional offices, state and local health departments, state emergency management offices, the Metropolitan Medical Response System cities, the Department of Veterans' Affairs, and the Department of Defense.

Archived Webcasts

Mass Antibiotic Dispensing: Streamlining POD Design & Operations
This April 14, 2005 webcast describes the methods of setting up & operating Points of Dispensing (PODs) to achieve maximum effectiveness.

Mass Antibiotic Dispensing: Managing Volunteer Staffing
This December 2, 2004 webcast highlights the essential elements of an effective volunteer program.

Mass Antibiotic Dispensing: A Primer
This June 24, 2004 webcast provides Strategic National Stockpile (SNS) planners with an overview of the critical aspects of a mass dispensing operation.

Page last modified April 14, 2005
Page Located on the Web at http://www.bt.cdc.gov/stockpile/

Attachment 3

Draft Policy Statement for Pharmacy Disaster Response

A draft statement is:

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 widespread health system and/or public response. In such events the skills, training, and capacities of board licensees will be an invaluable resource to those affected or to those responding. The board also wishes to encourage and ensure adequate response to any such circumstance that may affect residents of California, by welcoming wholesalers, pharmacies, or pharmacists licensed in good standing in other states to assist with appropriate health system and/or public response to residents of California.

To that end, the board encourages its licensees to become involved in local, state, or national emergency or disaster preparedness efforts. City and/or county health departments, fire departments, and other first responders will be able to provide information on local opportunities. The Emergency Preparedness Office of the California Department of Health Services is coordinating emergency preparedness and response at the state level, particularly with regard to health system response, drug distribution and dispensing, and immunization and prophylaxis in the event of an emergency. At the federal level, the contact agency is the Department of Homeland Security and its Federal Emergency Management Agency (FEMA). The board also continues to be involved in such planning efforts, at every level.

The board further encourages its licensees to assist in any way they can in any such emergency circumstance or disaster. Under such conditions, the goal must be protection of public health

and the provision of necessary patient care by the most expeditious and efficient means. Where declared emergency conditions prevail, the board recognizes that it may not always be possible or feasible to comply with all of the provisions of state or federal law governing the practice of pharmacy and/or the distribution or dispensing of potentially lifesaving medications.

It is therefore the policy of the board that in the event of a declared emergency or disaster, board licensees shall assist local officials in ensuring the distribution and dispensing of dangerous drugs under circumstances that will facilitate the treatment and delivery of health care to the public. In this task, board licensees may follow the direction of local health officials in providing necessary medication without meeting the usual legal requirements for same established in state and federal law, including: prescription requirements, record keeping requirements, labeling requirements, employee ratio requirements, consultation requirements, and other standard pharmacy practices and duties. The board expects that the professional judgment and training of pharmacists will focus on providing medication to patients, in the best interests of the patients. The board further expects that during the 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.

In the event of a declared disaster or emergency, the board expects to use all of its authority under the California Business and Professions Code, including under section 4062 thereof, to encourage and permit provision of care to patients by the most expeditious and efficient means, including by waiver of requirements that it may be impossible or implausible to meet under the circumstances. Its licensees should exercise their best judgment to respond to a need for their

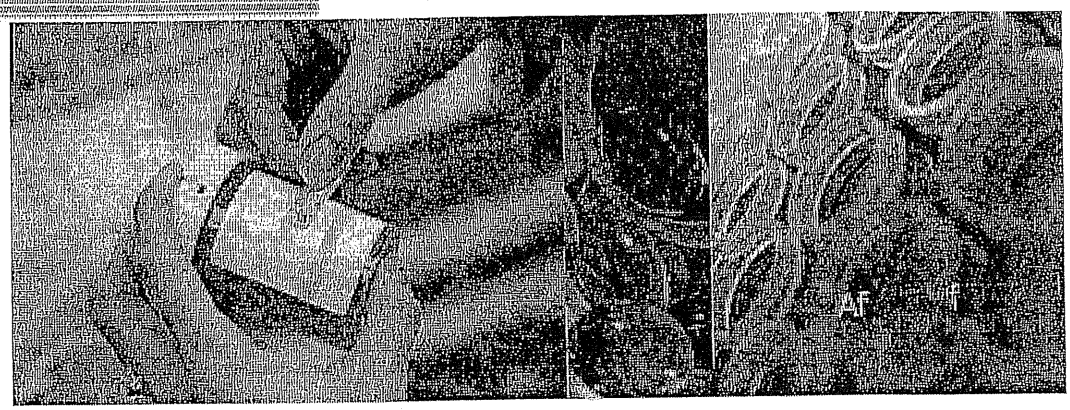
assistance, with circumstances dictating whether or to what extent such requirements can be met.

Furthermore, during such a period of declared disaster or emergency affecting the 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 disaster or emergency within California, the board will allow pharmacists who are not licensed in California, but who are licensed and in good standing in another state, to come to California to provide emergency pharmacy services. The board will also allow nonresident pharmacies and wholesalers who are not licensed in California but who are licensed in good standing elsewhere to ship medications to pharmacies, health professionals and other wholesalers in California. The board will also allow the use of temporary facilities to facilitate drug distribution. The board fully 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.

Attachment 4

ExCEPT Pharmacy Technician Certification Exam Materials

Exam for the Certification of Pharmacy Techinicans



Welcome to the Institute for the Certification of Pharmacy Technicians

The purpose of the Exam for the Certification of Pharmacy Technicians (ExCPT) is to help ensure that a minimum knowledge base or competency is possessed by pharmacy technicians who assist pharmacists in the preparation of prescriptions. The ExCPT is nationally recognized by the National Community Pharmacists Association and the National Association of Chain Drug Stores as a psychometrically sound pharmacy technician certification exam.

The ExCPT is offered by the Institute for the Certification of Pharmacy Technicians (ICPT), which has succeeded a former organization known as the Institute for the Advancement of Community Pharmacy (IACP). With this name change comes an expanded staff and additional resources to enable the ExCPT to be offered nationwide.

Read More!

Virginia Pharmacy Techs

Are you a pharmacy technician who is working in the state of Virginia?

Read More!

News and Boa Approvals

Frequently asked que

In which states can pharmacy tech the ExCPT?

Connecticut

New Jersey

Minnesota

Oregon

Virginia

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Exam for the Certification of Pharmacy Technicians

Frequently Asked Questions

Question:

In which states can pharmacy technicians take the ExCPT?

Answer:

Pharmacy technicians can take the Exam for the Certification of Pharmacy Technic (ExCPT) in almost every state. There are only a few states that actually require te be certified and all of them allow the Board of Pharmacy to approve more than on certification exam. The ExCPT will be applying to these states for approval.

There are 24 states that do not recognize certification at all. Technicians and empl a choice as to which national certification test (ExCPT or PTCB), if any, that they w Pharmacy technicians certified by either exam have the same rights and responsib

The other states that allow an exemption to the pharmacist-to-technician ratio for certified technicians do NOT require all technicians to be certified and many, if not technicians in these states practice without being certified. Many technicians in the chose to be ExCPT certified in order to enhance their credentials or further their ca of these states recognize both the ExCPT and PTCB on an equal basis. We expect f soon and more to follow.

Currently, ExCPT-Certified pharmacy technicians are practicing in 23 states and th Columbia. For information about the requirements in your state, contact the ExCP Education at ken@icptmail.org.

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ICPT is pleased to announce that the Pharmacy Certification Exam is now available computer at more than 700 testing centers nationwide. Using this option, test tak immediate test score results!

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Pricing:
$95 for the Pharmacy Exam
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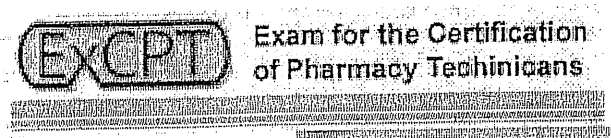

Privacy Policy Statement

This is the web site of **Institute for the Certification of Pharmacy Technician**

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314-442-6775.

For each visitor to our Website, our Web server automatically recognizes only the
domain name, but not the e-mail address (where possible). We do, however, colle
mail addresses of those who communicate with us via e-mail.

The information we collect is used to improve the content of our Website, is not sh
other organizations and is disclosed when legally required to do so, at the request
governmental authorities conducting an investigation, to verify or enforce compliai
policies governing our Website and applicable laws, or to protect against misuse o
unauthorized use of our Website.

With respect to cookies: We do not set any cookies.

If you do not want to receive e-mail from us in the future, please let us know by s
mail at the above address.

If you supply us with your postal address you may receive periodic mailings from
information on services. If you do not wish to receive such mailings, please let us
sending us e-mail at the above address.

Persons who supply us with their telephone numbers will only receive telephone c
us with information regarding the order they have placed.

With respect to Ad Servers: We do not partner with or have special relationships w
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From time to time, we may use customer information for new, unanticipated uses

previously disclosed in our privacy notice. If our information practices change at s
the future we will post the policy changes to our Website to notify you of these ch
provide you with the ability to opt out of these new uses. If you are concerned ab
information is used, you should check back at our Website periodically.

Customers may prevent their information from being used for purposes other than which it was originally collected by e-mailing us at the above address.

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Consumers can access this information by e-mail us at the above address.

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NEWS RELEASE

The Connecticut Commission on Pharmacy Approves the ExCPT Exam.

(Hartford, CT, July, 2006 – For Immediate Release) After an exhaustive 10-month investigation, **the Connecticut Board of Pharmacy confirmed on July 26 that the Exam for the Certification of Pharmacy Technicians (ExCPT) was equivalent to the PTCB exam** and approved it in the state of Connecticut. The Commission found that "The ExCPT exam is psychometrically sound, legally defensible and equivalent to the PTCB." Steven Beaudin, a public member of the Commission, said, "I'm glad that we now have two certification exams in Connecticut. Competition is a good thing."

To determine equivalency, the Commission compared, among other things, the content and rigor of the PTCB and ExCPT exams as well as the organization and governance of both organizations. The policies and procedures used for the practice analyses, test blueprints, item writing procedures, test assembly procedures, scoring, reports, security and quality assurance procedures were found to be equivalent. The Commission intends to continue monitoring and will compare both exams again in a year.

Kenneth W. Schafermeyer, Ph.D., R.P.h., Director of Education for the Institute for the Certification of Pharmacy Technicians (the sponsor of the ExCPT) said, "We are very pleased with this decision as we move forward with approval process of the ExCPT Exam in all applicable states and to be recognized by all pharmacy employers. The ExCPT Exam is offered in all LaserGrade testing centers 325+ days a year in every state throughout the U.S. at a technician-friendly cost of $95. We intend to provide every pharmacy technician superior educational and professional services as their career develops."

Connecticut regulations allow a 2:1 ratio of technicians to pharmacists but authorize the pharmacist to supervise one additional technician if he or she is certified. According to Connecticut statutes, "The department shall, upon authorization of the commission, certify as a pharmacy technician any person who meets the requirements for registration as a pharmacy technician . . . who holds a certification from the Pharmacy Technician Certification Board or any other equivalent pharmacy technician certification program approved by the department."

- more -

About ICPT

The Institute for the Certification of Pharmacy Technicians (ICPT) is operated by pharmacists for the pharmacy profession. The purpose of the Exam for the Certification of Pharmacy Technicians (ExCPT) is to help ensure that a minimum knowledge base or competency is possessed by pharmacy technicians who assist pharmacists in the preparation of prescriptions. The ExCPT is nationally recognized by the National Community Pharmacists Association and the National Association of Chain Drug Stores as a psychometrically sound pharmacy technician certification exam. The exam is offered in all 50 states and the District of Columbia.

Address: Institute for the Certification of Pharmacy Technicians (ICPT)
1816 Woodmark Rd
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Web site: www.nationaltechexam.org

Email: ken@icptmail.org
Office Phone: (314) 442-6775
Fax: (866) 203-9213
Mobile: (314) 609-1073

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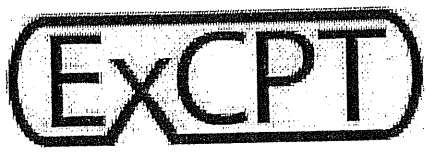
Specifications (v 1.4) of the Exam for the Certification of Pharmacy Technicians



Exam Specifications	
Eligibility	Candidates must be 18 or older with high school degree or GED. Candidates convicted of a drug-related felony may not be certified.
Test sites	Over 1,000 LaserGrade Test Centers located throughout the country.
Number of times per year that exam is offered	Over 300
Deadline for exam registration	Usually less than 48 hours
Deadline for notification of change of exam time or location	24 hours
Exam format	Secure computer-based exam
Number of questions	100 multiple-choice questions with choices a-e. (No questions have distracters worded "all the above.")
Passing score	Scaled scores range from 200 to 500. A 390 or higher is needed to pass.
Quality Assurance	
Exam based on comprehensive job analysis	Yes
Advice and oversight by panel of experts	Yes
Meets standards of the American Educational Research Association, American Psychological Association and National Council on Measurement in Education, *Standards for Educational and Psychological Testing*	Yes
Audited by independent experts in psychometrics	Yes
Exam items written by a panel of expert item writers	Yes
All test items field tested prior to use	Yes
Board given evidence of reliability	Yes
Board given evidence of validity	Yes

Exam Security	
Eligibility verified at time of exam.	Pre-registration required; approved identification must be shown at test center.
Exam items changed on periodic basis	Yes
Proctors thoroughly training to follow procedures and for handling emergency situations.	Yes
Stringent computer encryption programming used	Yes
Exams sent to testing site before exam	No
Extra printed exams that must be accounted for and destroyed if not used	Not necessary because of computer-based exam
Services for Candidates	
Diagnostic report offered to unsuccessful candidates	Yes
Candidates with disabilities accommodated in compliance with ADA	Yes
Study guide available on website	Yes
Practice exam questions Available free of charge	Yes
Website for exam information	Yes
Exam results reported to candidate	Immediate notification
Recertification	Required every two years. 20 hours of pharmacy-related continuing education (including at least one hour of law) required
Services for Board of Pharmacy	
Provides Board with performance bond	Yes
State-specific questions offered	Optional
Results of item analysis and test statistics reported to Board on a periodic basis.	Yes
Exam results reported directly to the Board of Pharmacy	Yes. Available via a secured private web site for the Boards of Pharmacy
Criminal background checks	Available for extra fee if Board elects

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NEWS RELEASE

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To determine equivalency, the Commission compared, among other things, the content and rigor of the PTCB and ExCPT exams as well as the organization and governance of both organizations. The policies and procedures used for the practice analyses, test blueprints, item writing procedures, test assembly procedures, scoring, reports, security and quality assurance procedures were found to be equivalent. The Commission intends to continue monitoring and will compare both exams again in a year.

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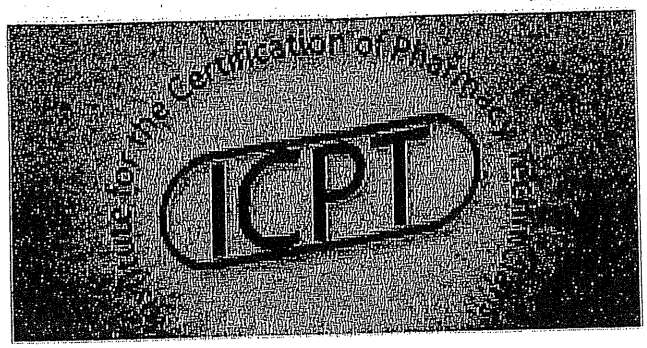

Institute for the Certification of Pharmacy Technicians

Report to Boards of Pharmacy

August 2006

The following report is based on information provided by the Institute for the Certification of Pharmacy Technicians in response to a Request for Information (RIF) from the Connecticut Commission on Pharmacy. After an exhaustive 10-month investigation, **the Connecticut Board of Pharmacy confirmed on July 26 that the Exam for the Certification of Pharmacy Technicians (ExCPT) was equivalent to the PTCB exam** and approved it in the state of Connecticut. Despite strong opposition from our competitor and its financial partners, the Commission still found that "The ExCPT exam is psychometrically sound, legally defensible and equivalent to the PTCB."

To determine equivalency, the Commission compared, among other things, the content and rigor of the exams as well as the organization and governance of the two companies, the policies and procedures used for the practice analyses, test blueprints, item writing procedures, test assembly procedures, scoring, reports, security and quality assurance procedures. This information is included in this report.

After careful review, I am confident that all Boards of Pharmacy will reach the same conclusion as the Connecticut Commission on Pharmacy that **the ExCPT is at least equivalent to the PTCB in rigor and superior with regard to access and cost.**

Kenneth W. Schafermeyer, R.Ph., Ph.D.
Director of Education
ken@icptmail.org
314-609-1073

List of Attachments

Institute for the Certification of Pharmacy Technicians

Report to Boards of Pharmacy
August 2006

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Report to Boards of Pharmacy

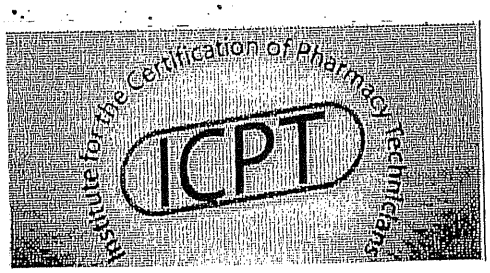
regarding

The Exam for the Certification of Pharmacy Technicians

provided by

The Institute for the Certification of Pharmacy Technicians

August 2006



All information is accurate as of the date written and may be subject to change. Additional details are available from the ICPT and LaserGrade websites. All questions about the ECPT should be referred to Kenneth W. Schafermeyer, R.Ph., Ph.D., Director of Education: ken@icptmail.org or 314-609-1073.

I. Governance

A. *Policies and Procedures*

ICPT policies and procedures are attached under Appendix1.

B. *Individuals or corporations having a financial interest in the test providers' organization, including providers of grants or financial support.*

The National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA) have a financial interest in the ExCPT. Depending on volume and expenses, these two organizations will split royalties that will range from 0% to 35% of exam fees. At this point, the royalties are still at 0%. ICPT's partner, LaserGrade receives approximately 42% of exam revenues.

II. Examination Generation, Validation, and Administration Process

A. *Practice analysis*

1. *Date performed.* The practice analysis for the ExCPT was completed in August 2005. A previous practice analysis was conducted for the Virginia Board of Pharmacy in February, 2003.

2. *Methodologies employed.* A survey questionnaire was mailed to a stratified random sample of 630 individuals (420 pharmacy managers and 210 pharmacy technicians). A reminder postcard and follow-up survey were also sent to non-respondents. Respondents were given a list of over 50 job functions and asked to indicate: (1) the importance of each pharmacy technician function with regard to promoting patient health and safety (with a Likert Scale responses ranging from very important [5] to not important [1]); (2) the frequency that pharmacy technicians perform each function on an average day; and (3) the relative amount of time that pharmacy technicians spend on each function (with a Likert Scale responses ranging from high to low). Fifty-six surveys were returned because of bad addresses. Of the 574 surveys delivered, 308 were returned but 20 were discarded as unusable. The overall response rate, therefore was 50.2%. The results were tabulated and ranked in descending order.

3. *Practice settings examined.* The pharmacy technician functions covered in the practice analysis included functions performed in all practice settings, including community and institutional practice.

Respondents practiced in a variety of practice settings: community (66%), hospital (23%), long-term care (8%); and other (3%).

4. *Conclusions or final determinations*. The ranking of the various practice functions is attached under Appendix2. These results were used by the Expert Panel, along with input from stakeholders, was used to design the exam blueprint.

   Although pharmacy technicians typically ranked most functions as slightly more important and performed slightly more frequently than did pharmacy managers, the rank order for the various functions was essentially the same for both groups. As would be expected, practitioners practicing in a given setting tended to value their functions as more important than those not practicing in that setting. Therefore, the results for practitioners from each practice setting were compared to assure that functions important to one type of setting were not unduly outweighed by those functions deemed to be more important by respondents from other types of settings. The exam blueprint, therefore, reflects pharmacy technician functions relevant to all major practice settings.

B. Test blueprint/plan

1. *Test purpose*. The purpose of the Exam for the Certification of Pharmacy Technicians (ExCPT) is to encourage pharmacy technicians to improve their knowledge and skills and to help ensure that a minimum knowledge base or competency is possessed by pharmacy technicians who assist pharmacists in the preparation of prescriptions.

2. *Target audience*. The target group for the ExCPT is pharmacy technicians from all practice settings throughout the United States. Stakeholders include individuals, companies, associations and government agencies that employ, supervise, train, regulate or receive services from pharmacy technicians.

3. *Covered content or performance areas*. Please see the Exam Blueprint at Appendix3.

4. *Number and types of questions to be written for each content or performance area*. Please see the Exam Blueprint at Appendix3.

5. *Scoring*. The ExCPT is scored immediately and successful candidates are given an official report by LaserGrade indicating that they passed the ExCPT immediately after completing the exam. Candidates may use this report to provide evidence to

employers or regulatory boards that they passed the ExCPT and are a certified pharmacy technician.

The purpose of the exam is to provide summative assessment (i.e., to determine whether an individual has achieved a certain level of competency). It is not designed for formative assessment (i.e., to give the candidate feedback). ICPT does, however, provide diagnostic reports to help unsuccessful candidates focus their study time so they can successfully retake the exam. Candidates can also get some formative feedback by answering the practice problems that are offered on the ICPT website.

Candidates who do not pass the ExCPT will be allowed to retake the exam after four weeks. Since there are multiple versions of the ExCPT, candidates who take retake the exam will receive a different, but equivalent, set of questions.

The passing score is established by the ICPT Expert Panel based on a standard of performance that experts in the profession have determined are acceptable for this certification program. Specifically, the Expert Panel uses a modified Angoff procedure (descried later in this document) to determine the passing score. The passing score is not based on a curve.

6. *Test administration method.* The ExCPT is a secure, computer-based exam offered during business hours and some evenings and weekends at over 1,000 LaserGrade Testing Centers throughout the United States. Candidates may register by calling the LaserGrade toll-free number. Candidate identification is verified at the LaserGrade Testing Center at the time of the test. The candidates have two hours to answer 110 multiple-choice questions. One question is presented on the screen at a time. Candidates may mark the answer or they can skip questions and come back later. Final answers are submitted when the candidate is finished and results are given immediately. A demonstration of the computer format used for exams administered by LaserGrade is shown on the LaserGrade website at www.lasergrade.com.

Candidates are given an opportunity to comment on any question that they believe is ambiguous, inaccurate or deficient. Candidates are also asked to complete a brief survey at the end of the exam to rate the exam registration procedures, the testing facility and general satisfaction with the testing experience. This information is reviewed by the Director of Education and referred t the Expert Panel for recommendations if necessary.

7. *Desired psychometric characteristics*. All items in the test bank are pretested to examine reliability, discrimination and validity. Items used on each exam are also examined to assure proper performance. Following is a discussion the desired characteristics with regard to reliability, discrimination and validity.

Reliability. Reliability refers to the accuracy (consistency and stability) of measurement by a test.[1] In other words, reliability is the extent to which test scores are free from errors in the measurement process. The most commonly used statistical index is the reliability coefficient. In numerical value, reliability coefficients are always between .00 and .99.[2] Values of 0.80 and above are considered good, but the closer the value of the reliability coefficient to the upper limit, the less measurement error and the greater the reliability. The statistical test used to produce the reliability coefficient for the ExCPT is the Kuder Richardson 20. This statistic provides an *overall measure* of the ability of test items to discriminate between high-scoring students and low-scoring students. (To test the ability of *individual* items to discriminate between high-scoring students and low-scoring students, discrimination analysis (see below) is used.) The formula for Kuder Richardson 20 is as follows:

$$KR = (N/(N-1)) * ((V - SUM (p_i q_i))/V)$$

KR = Kuder Richardson 20
N = Number of items in the test
V = Variance of the raw scores, or $(\text{Standard Deviation})^2$
p_i = Proportion of correct answers of question i, or (number of correct answers/total number of responses)
q_i = proportion of incorrect answers of question i, or (i - p)

The reliability coefficient for the ExCPT has consistently remained at 0.90 or higher. This provides strong evidence that the ExCPT meets the criteria for reliability.

Discrimination Analysis. Discrimination analysis is a type of multiple-regression analysis commonly used in calculating test statistics for multiple-choice examinations. In this case, one

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1 Isaac S and Michael WB, *Handbook in Research and Evaluation, Second Edition* (San Diego: Edits Publishers, 1985): 123-126.

2 National Computer Systems, *MicroTEST Score II User's Guide* (Minneapolis: National Computer Systems, 1988): 5-11, B-6.

measure of the performance of an individual item is the discrimination – the extent to which persons who perform well on the entire exam do well on an individual item, and vice versa.[3] The discrimination analysis separates individuals into quartiles according to their scores. The high quartile and low quartile are then compared for each exam item. In other words, to discriminate properly between people who will do well on an exam and those who do not, individuals selecting the correct answer for a particular question should show a modest to high correlation with the "pass rate" for the overall exam. Likewise, an exam item discriminates properly if those individuals selecting incorrect answers correlate negatively with the pass rate for the overall exam. The formula used to calculate the discrimination index for each response alternative is as follows:

$$DI = (a - b) / c$$

DI = Discrimination Index
a = Response frequency of the upper quartile
b = Response frequency of the lower quartile
c = Number of respondents in the upper quartile[4]

Discrimination scores range from -1.0 to 1.0.[5] For each question correct answers should have a positive discrimination (items greater than 0.1 are generally considered acceptable; 2.0 or higher is considered good) and incorrect answers should have a zero or negative discrimination. An exception to this rule occurs when a large percentage of examinees (e.g., over 90 percent) answer a question correctly. In this case, the question would not be able to discriminate much and, therefore, the discrimination index would be close to zero. Since there should be some variance in the degree of difficulty of the individual items in a given exam, it can be expected that there may be some questions on a minimum competency exam that will be answered correctly by the great majority of examinees and, consequently, would have low discrimination indices. Items that are answered correctly by more than 90 percent of the candidates, however, are generally replaced in order to encourage more discrimination among candidates.

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3 Norman G and Streiner D, *Biostatistics: The Bare Essentials* (St. Louis: Mosby, 1994); 178.

4 National Computer Systems, *MicroTEST Score II User's Guide* (Minneapolis: National Computer Systems, 1988): B-4.

5 Kerlinger FN, *Foundations of Behavioral Research, Third Edition* (New York: Holt, Rinehart and Winston, Inc., 1986): 562.

When reviewing the computerized item analysis of pilot exams, ICPT looks for several types of problems. First, the discrimination analysis is studied to ensure there are no questions in which the correct answer has a negative discrimination index. Second, the statistics are studied further to assure that no distracters (i.e., the answer choices that are not correct) have a positive discrimination index. If either of these two problems were to occur, the exam item will either be revised and retested or deleted from the test bank. Thirdly, ICPT looks at degree of difficulty. A generally accepted method of exam construction is known as the "rule of thirds" – one third of the questions would be relatively difficult, one-third moderate difficulty and one-third easier. Effort is made to achieve an acceptable balance of item difficulty.

Validity. There are three major types of validity measurements: (1) content validity, (2) criterion validity and (3) construct validity. Content validity is often referred to as "face validity." This measurement is an index of whether the exam is really measuring what it claims to measure and whether the exam provides an adequate sample of that kind of behavior.[6] Content validity is ultimately a matter of judgment. In the case of the ExCPT, content validity was determined by the Expert Panel. It was the professional judgment of the Panel members that the ExCPT adequately measures the content needed to work as a pharmacy technician. The opinion of members of the Stakeholder's Council will be sought and considered on an on-going basis.

The second type of validity, criterion validity, is studied by comparing test or scale scores on the new test with one or more external variables, or criteria, known or believed to measure the attribute under study.[7] Measuring the same skill with two different tests should produce the same results (i.e., pass or fail) if there is criterion validity. Employers using the ExCPT have indicated that those who pass the ExCPT perform adequately in practice and those who fail do not and often need additional training. Periodic stakeholders meetings are scheduled to determine, in part, whether testing content continues to be valid for the work environment of pharmacy technicians.

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6 Bailey KD, *Methods of Social Research, Third Edition* (New York: The Free Press, 1987): 67-68.

7 Kerlinger FN, *Foundations of Behavioral Research, Third Edition* (New York: Holt, Rinehart and Winston, Inc., 1986): 418-419.

The third type, of validity, construct validity, seeks to explain individual differences in test scores. For example, it would not be expected that exam scores would vary according to age or gender; they would, however, be expected to vary according to experience or level of education. By collecting demographic data from each ExCPT examinee, it was determined that correlations among exam scores and age, gender, practice site, hours worked per week and educational level were not statistically significant. There was, however, a moderate relationship between test performance and years of practice when comparing less than one year to more than one year.

One way that the Test of English as a Foreign Language (TOEFL) measures construct validity of its exam as a measure of English language proficiency is to compare scores of native speakers to those of nonnative speakers. Native speakers find the TOEFL quite easy and their scores are homogeneously high; and a high proportion of them earned maximum or near-maximum scores. Performance of nonnative examinees was lower and more widely distributed.[8] A comparison of scores of pharmacists with those of pharmacy technicians would show uniformly high scores by pharmacists (compared to the lower and more widely distributed scores of technicians) and this would provide additional evidence of construct validity.

8. *Competency statements*. Please see the statements included in the practice analysis and the content of the exam blueprint (Tabs 2 and 3, respectively).

C. *Item writing procedures*

1. *Item writers and their respective areas of expertise*. Item writers include pharmacy and pharmacy technician educators and practitioners who have practiced in many different states and in many different practice settings including community, hospital, long-term care and home health care. A list of item writers is included under Appendix4.

2. *Any item writing training administered to writers*. Item writers and Expert Panel members are given written materials and oral instructions on writing acceptable multiple-choice items. An exercise as a part of this training involves providing these individuals with a set of multiple-choice practice questions for

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8 Educational Testing Service, *TOEFL Test & Score Manual* (Princeton, NJ: Educational Testing Service, 1997): 36.

critique and discussion. The guidelines used in this training are from a well-known text by Gronlund.[9]

3. *Qualifications of trainers.* The trainers were Drs. Kenneth Schafermeyer and Dana Hammer. Both have extensive experience at educational design and assessments. CVs of both are available on request. Reference letters for Dr. Hammer are included under Appendix5.

4. *Description of testing standards employed.* The ExCPT follows and meets standards of the American Educational Research Association, American Psychological Association and National Council on Measurement in Education, *Standards for Educational and Psychological Testing.* The ExCPT also employs the standards established for certification programs by the National Commission for Certifying Agencies (NCCA).

D. *Exam items and questions*

1. *Test format.* The ExCPT is a secure, psychometrically sound computer-based exam that consists of 110 multiple-choice questions, of which ten are pretest questions that are not scored.

2. *Item validation process.* This was discussed in the previous section titled "Desired Psychometric Characteristics."

3. *Field testing and review process.* This process is discussed in the following section titled "New item field testing procedures."

4. *Item pool depth and rotation.* The testbank consists of just over 3,000 items. New items are being added on a regular basis with about 300 new items expected to be added during the last half of this year. With three versions of the exam, any candidates retaking the exam would be assured of seeing a different set of questions the following month when they are eligible to register again. At least 20 questions are changed each month. Those items that are rotated off the exam may be reused at some point. To avoid overexposure, items will be retired as new items are adopted. All versions of the exam, however, will be consistent with the exam blueprint. In addition to rotating and retiring test items, the order of test items and answers are scrambled and numbers for calculation questions are changed on a frequent basis.

Freq of Items used Regularly

9 Gronlund NE, *How to Make Achievement Tests and Assessments, Fifth Edition* (Boston: Allyn and Bacon, 1993).

E. *Item analysis*

1. *New item field testing procedures.* Pretesting new questions before they are used as scored questions on the ExCPT is necessary to assure that all items perform properly and that new versions of the exam can be created in the future. As with all standardized tests, the ExCPT contains some questions that are being pretested for possible use on future exams. Specifically, the ExCPT consists of 110 questions, of which ten are pretest questions that are not scored. The pretest items are randomly interspersed throughout the exam and are not identified for the candidate in order to assure that test statistics are valid. When a sufficient amount of data is obtained (usually 50 to 100 data elements), these pretest questions are pulled from the ExCPT and new pretest questions are substituted. All pretest items are analyzed carefully for difficulty, reliability, discrimination and validity and are approved by the Expert Panel before they are used as scored questions on future versions of the ExCPT.

2. *Item performance analysis method.* All items are carefully reviewed through a process known as an item analysis. This item analysis consists of statistical procedures to determine the difficulty, discrimination, reliability and validity of each item before they are used as scored questions in the ExCPT and again on a regular basis while items are being used. A description of these statistical procedures was described in the previous section titled "Desired Psychometric Characteristics."

3. *Item ongoing performance review and recall process.* The Director of Education receives weekly reports from LaserGrade indicating the score earned on each exam taken during the week as well as the answers given for each item – both scored items and pretest items. Results are reviewed for unexpected difficulty, unusual patterns and other potential problems. For example, if a new item had been miskeyed, the problem would be detected immediately and scores adjusted accordingly. Items that are determined by the Director of Education to be too easy, too difficult, outdated or fail to discriminate properly are either removed from the testbank for future editing or retired. The Expert Panel also reviews performance of the items on a regular basis and can determine whether certain items should be recalled. As explained previously, items are rotated often but are eventually retired and replaced with new items.

F. *Examination review committee*

1. *Member names.* The members of the Expert Panel are included under Appendix6.

2. *Areas of expertise.* Please see Appendix6.

3. *Current employment.* Please see Appendix6.

4. *Tenure on the Committee.* Individuals on the Expert Panel serve three-year terms with terms staggered to assure continuity.

G. ***Description of test assembly procedures***

1. *Exam consistency between administrations.* To protect the integrity of the exam, multiple versions of the ExCPT are used and the sample of questions taken from the test bank changes continuously as well. Because different administrations of the ExCPT are made up of different combinations of questions, it is important to assure that these different versions provide an equal challenge to everyone. The careful selection of items assures that different versions of the exam test the same content areas. The Expert Panel establishes the passing score using the modified Angoff procedure in which each panelist independently estimates the percentage of qualified candidates who would correctly answer each item. The panelists' ratings are averaged to determine the passing score (also known as the "cut score"). With a relatively large panel of ten members, it is advisable to decrease variance by deleting the extreme high and extreme low estimates. This, of course, does not affect the median score—only the variance. The overall passing score is determined by averaging the individual ratings. Although care is taken to make each version equivalent, the ExCPT is now using statistical methods to equate and scale exam scores.

   Equating is essentially a statistical method of selecting the raw score on each test that would provide the same probability of passing. In other words, it is a way of calibrating different versions of the exam to assure that they provide an equal challenge. For example, a raw score of 75 may be determined to be a passing score on one version of the exam and a 74 may be determined to be the equivalent passing score on a more difficult version.

   A scale is a score-reporting technique that translates the different raw scores into a standard score. For example, the scores that may be earned on the ExCPT range from 200 to 500 and the passing score is 390. The minimum passing raw scores are then converted

to 390 for all versions of the exam. If two different versions of the exam have different cut scores (e.g., a raw score of 75 on one version and a raw score of 74 on another) then both are converted so that 390 is the passing score. Reporting only raw scores could cause confusion because the results of one test administration may be difficult to compare with another that does not have exactly the same difficulty or same cut score. Equating and scaling procedures are used in most certification programs because they are easy and reliable, commonly accepted as standard procedures in certification programs, psychometrically sound and are legally defensible.

2. *Correlation of the passing score with the practice analysis findings.* Scores for each content area of the exam are reviewed to determine which areas are most difficult. Experience with the ExCPT shows that the most difficult area for candidates continues to be pharmacy calculations. Fortunately, candidates performed better on those content areas that were rated higher in the practice analysis in terms of criticality and frequency of performance. ICPT is collecting performance data in order to encourage candidates to give particular attention to studying the more difficult content areas that were rated high in the practice analysis.

3. *Effective discrimination between candidates who perform well and those who perform poorly.* Evidence reported in the item analysis helps assure that items discriminate properly so that the exam does too. The cut score effectively discriminates between the group which performed satisfactorily from that which did not.

4. *Psychometric standards employed in exam assembly.* The ExCPT employs the both the APA and NCCA standards discussed previously. These standards require certain procedures to be followed, including the practice analysis, Expert Panel, item writing, item review, item pretesting and item writing, which were all described previously.

H. *Test form*

1. *Testing media design.* The ExCPT is a secure, proctored, computer-based exam offered at LaserGrade Testing Centers throughout the United States.

2. *Number of test forms employed per administration.* Three equated versions of the ExCPT are available. The exam form to be administered to a given candidate will be randomly selected.

Unsuccessful candidates retaking the ExCPT will be given a different version.

3. *Method of assuring exam construction consistency between test forms or computer iterations.* All exam forms are equated to assure that they provide the same challenge to all candidates. As explained previously in Section I-G (1), establishing cut scores, equating and scaling are used to assure continuity. The item analysis provides statistics demonstrating that different forms of the exam are consistent with regard to the challenge presented to candidates.

4. *Security procedures to preserve test integrity and limit item exposure.* Policies and procedures regarding confidentiality and cheating are outlined in Section 7 of the ICPT Policies and Procedures. (Please see Appendix1.) Policies and procedures related to registration, identification, and security procedures at the LaserGrade Testing Center are explained in Section 8 of the ICPT Policies and Procedures. (Please see Appendix1.) LaserGrade requirements for security and supervision at the Test Centers are outlined in Section 5 of the "LaserGrade Testing Center Requirements" found under Appendix7.

   The computer-based exam available through LaserGrade is far more secure than a paper-and-pencil exam. The LaserGrade Test Center Specialist must enter an individual password to gain access to the on-site computer. The text for the questions and the candidate's answers are encrypted and sent to the Test Center computer after the candidate is admitted and shows proper identification. When the candidate has completed the ExCPT, the test report is printed and the candidate's encrypted results are sent to LaserGrade and the Test Center's copy of the exam is written over and erased. Exams are never left on the Test Center Computers. The exam also times out after two hours.

   All individuals associated with the ExCPT, including members of the Board of Directors, item writers, Expert Panel members and staff sign a confidentiality agreement that requires them to hold any and all information about items on the ExCPT completely confidential. This agreement remains in effect for three years after the individual's service to ICPT.

I. *Scoring*

1. *Description of scoring employed.* Scoring is described in Sections II-B (5), II-B (7), and II-G above and in Section 9 of the ICPT Policies and Procedures. This topic was discussed previously.

2. *Rationale for scoring type used.* This topic was also discussed previously in Section II-G (1). This commonly used scoring procedure is consistent with standards for certification programs and is legally defensible.

III. Reports

ICPT creates a number of reports; some of which are public and some fomr internal purposes only. The public reports will be posted on the ICPT website and the private reports are used by the board of directors, Expert Panel and Stakeholders Council as needed.

A. *Passing score*

1. *Frequency of report.* As described previously, ICPT receives weekly score reports from LaserGrade, which are carefully reviewed by the Director of Education. Results are compared to the results from the cut score analysis (described previously) to assure that exams and individual items are performing as expected. Bimonthly score reports include test statistics such as the mean, median, pass rate, range, minimum, maximum, standard deviation, standard error, reliability coefficient and reliability index. Results are reported to the Expert Panel, which helps provide oversight and quality assurance. The overall pass rate will be published on the IPCT website.

2. *Process for determining passing score.* This topic was described previously in Sections II-B (5) and II-G above.

B. *Technical reports*

Technical reports used to monitor the exam, establish the cut scores and analyze results are available to stakeholders as needed.

1. *Frequency of report.* Update reports are received by ICPT weekly; complete statistical analyses are received on an as-needed basis – no less than bimonthly. Additional special reports are received on an as-requested basis. Reports on pass scores and general exam information are reported on the ICPT website and other relevant

information will be reported to the board, Expert Panel and Stakeholders Council as needed.

2. *Administration operational information.* Relevant operational information such as policies and procedures, staff contact information, Expert Panel members, etc. will be kept up to date on the website.

3. *Description of test assembly procedures.* The procedure used to assemble the test will be published on the website. A database program for the test bank will be available for internal use only and used to categorize questions according to topic and degree of difficulty. This database also records, among other things, a number for each item, the item writer, the date adopted, the date pretested, the difficulty, discrimination, versions of the exam that used the item, and an indicator of "bad pairs" (i.e., the number of other items that should not appear on the same exam). This database helps the Expert Panel to assemble new versions of the exam in compliance with the test blueprint. The database also helps the Expert Panel to record item performance. An analysis of individual ratings under the modified Angoff method is used to help establish passing scores.

4. *Reliability and validity information.* Reliability data is included with each complete statistical report and item analysis that is received at least bimonthly. Procedures for establishing validity are described above.

5. *Test equating methods.* The procedures for equating exams was described in Section II-G (1) and will be reported on the ICPT website. The weekly reports received from LaserGrade are reviewed carefully by the Director of Education and Expert Panel to assure that the exam and exam items are performing as expected. The complete statistical report and item analysis is also checked to assure that the equating method is working properly.

6. *Scoring tables and procedures.* Although the procedures are published on the website, the actual scoring tables for developing passing scores are used internally by the Expert Panel.

7. *Statistical summary information.* Pass rates and reliability statistics for the ExCPT will be published continuously on the ICPT website. Information about individual items, of course, are only used internally.

C. *Score reports to examinees and the Commission*

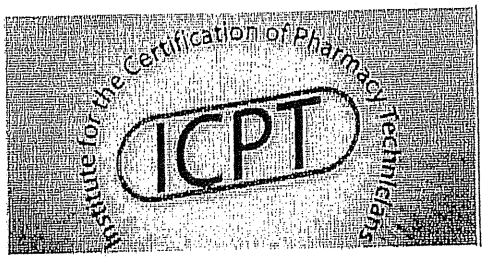
1. *Availability of diagnostic information for failing candidates.* Diagnostic reports are provided to unsuccessful candidates immediately upon completion of the ExCPT. This report indicates those content areas that should be studied more carefully by the candidate.

2. *Possibilities for Commission report customization.* Boards of pharmacy have access to a password-protected website that contains a complete set of up-to-date ExCPT records. A board of pharmacy staff member will be given a password and training to check the website for score reports and exam statistics. Although the database allows boards to make queries and print reports, ICPT is committed to providing information needed by the board and will consider producing periodic or special reports as needed.

3. *Pass/fail report to the Commission.* This information is also included in the secure online website and is updated daily.

4. *Frequency of reporting to the Commission.* The board can access the database whenever it wants and as often as it wants.

Appendix 1



Institute for the Certification of Pharmacy Technicians

Policies and Procedures

1. Eligibity Requirments

To be eligible to take the *ExCPT*, a candidate must: (1) be at least 18 years of age, (2) have a high school diploma or GED and (3) have never been convicted of a felony. Candidates will be required to provide an attestation stating that they meet these criteria and recognize that ICPT will revoke certification if any false information is provided by the candidate. ICPT reserves the right to investigate criminal background and verify candidate eligibility. Candidates must provide a government-issued photo identification at the time of the exam to verify identity.

2. Registration

Contacting LaserGrade. The *ExCPT* is offered over 300 days per year at over 1,000 LaserGrade Testing Centers throughout the United States. Candidates may register by calling the LaserGrade toll-free number 1-800-211-2754 to arrange a test date, time and location. By providing a zip code, the candidate will be informed of the closest LaserGrade Testing Centers. Alternatively, these locations can be found on the Web at www.lasergrade.com. Exams can usually be taken within 24 to 48 hours of registration.

Information required. Candidates must give their full name, address, Social Security Number, telephone number, email address (if applicable) and demographic information such as date of birth, gender, employer, type of practice site, type of training, years of practice and hours worked per week. Candidates should also indicate whether they qualify for special accommodations under the Americans with Disabilities Act. (See the following section.) These data are used to analyze test results and produce reports. Date of birth also helps verify identification at the test center.

Payment. The *ExCPT* costs $95 and it is payable by credit card at the time the candidate calls LaserGrade. Candidates who do not have credit cards can send LaserGrade a check or money order. When the check clears LaserGrade will contact the individual to arrange the test date. Employers may prepay for a specified number of candidates by making

arrangements directly with LaserGrade. Registered candidates who need to change an exam time for any reason must contact the LaserGrade call center at least 24 hours in advance to reschedule or cancel an exam without penalty.

3. Americans with Disabilities Act

General policy. Candidates with documented disabilities (including learning disabilities, reading disabilities, visual impairment, hearing impairment, or other physical or mental disabilities) will be given special accommodations upon request, in conformance with the Americans with Disabilities Act (ADA).

Procedure for requesting special accommodations. Documentation must be provided at the time of the request and must provide a specific description of the candidate's needs. Candidates must indicate the name of a physician or other professional who can verify the disability or provide further information in support of the request. The candidate may include a letter from an appropriate professional on official stationalry that provides evidence of a prior diagnosis or accommodation (e.g., special education services). Previous school records may also be submitted to document a disability. This documentation letter must describe the specific disability/diagnosis, the approximate date when the disability was first diagnosed, the method used to confirm the diagnosis, a brief description of the disability, and the type of accommodation needed by the candidate. The letter must be signed by the professional. Candidates requesting accommodation because of an emotional disability must have a SSM-IV classification of the diagnosis specified in the letter.

The candidate will need to provide authorization for the physician or other professional to share protected health information as described in the Heath Insurance Portability and Accountability Act (HIPAA). This physician or other professional may be contacted by ICPT to verify information or provide clarification of any information with regard to the disability or testing needs. ICPT will respond to the candidate within ten business days. Some states may also require approval by the Board of Pharmacy.

ICPT will respond to the request for accommodation as quickly as possible; generally within 10 business days of the request.

4. Affirmative Action

The ICPT and LaserGrade Testing Centers do not discriminate against any individual because of age, disability, gender, national origin, race, religion, sexual orientation, or veteran status. ICPT and LaserGrade endorse and adhere to the principles of equal opportunity.

5. Cancellation of Scheduled Exam

Notification by candidate. Candidates who are unable to take the ExCPT at the scheduled time should notify LaserGrade at least 24 hours in advance to avoid penalties. Refunds are not provided but credit will be given for a future exam appointment. If an

exam appointment is cancelled by the candidate within 24 hours or the candidate does not arrive during the scheduled time, the exam fee will be forfeited. Cancellation notices will only be accepted from the candidate; employers, family members or other individuals may not request a cancellation on behalf of candidates. An exception to this rule may be made by an employer who originally registered the candidate with LaserGrade and directly paid the examination fee.

Cancellation by LaserGrade. LaserGrade Testing Centers may close without notice in the case of inclement weather, a state of emergency or other unforeseen event. In this case, the candidate will be allowed to reschedule at a convenient time and location with the exam fee credited to the future exam appointment. Candidates may verify that the LaserGrade Test Center is open by calling the center directly shortly before the appointed time.

6. Examination Rules of Conduct and Confidentiality

Passing the ExCPT is a big step in a pharmacy technician's career. Understandably, candidates will want to take advantage of all available resources when preparing for this important examination. It is *illegal and unethical to* recall (memorize) and share questions that are on the ExCPT or to solicit questions that are on the ExCPT from candidates who have taken the exam. ITEMS FROM THE EXAMINATION ARE NOT TO BE RECALLED FOR ANY PURPOSE.

Soliciting recalled questions from candidates who have previously taken the examination is unethical for several reasons. The first is obvious; candidates are expected to pass the test based on their own merit without assistance. The members of the public who will entrust certified technicians with their well-being expect that that they are trustworthy and competent individuals. Secondly, the purpose of the ExCPT is to protect the public by ensuring that candidates for licensure have achieved entry-level competence. By asking previous test takers to share questions, candidates are undermining the very purpose of the examination. Lastly, soliciting questions from previous test takers who have agreed to the Candidate Attestation would be encouraging candidates to commit illegal acts. ITEMS FROM THE EXAMINATION ARE NOT TO BE SOLICITED FOR ANY PURPOSE.

ICPT will actively prosecute individuals who violate the Attestation Agreement. The Institute will also report any incidents of students requesting questions or sharing questions to their licensing jurisdiction. Candidates who are prosecuted by ICPT or who are reported to a licensing jurisdiction for soliciting or sharing questions may severely damage their chances of achieving certification.

Before taking the ExCPT, Candidates must agree to comply with the following attestation:

Candidate Attestation

As a condition for taking the ExCPT, I certify that I have read, understand and agree with the following statements:

1. The ExCPT and its test items are the exclusive property of the Institute for the Certification of Pharmacy Technicians and are protected by copyright.
2. The ExCPT and its test items are valuable proprietary information and are understood to be confidential. The loss or outside disclosure of these materials or the information contained herein would harm ICPT economically and would subject the perpetrator to severe civil and criminal penalties as well as invalidation of certification
3. Candidates may not cheat or violate the confidentiality of the exam. Cheating or violation of confidentiality may be defined as, but not necessarily limited to the following:

    - obtaining help from any other person during an examination
    - communicating with or giving help to another candidate during and examination
    - using notes, books, or any other sources of information during an examination
    - using electronic programmable devices, such as calculators, cell phones, and PDAs during an examination
    - reproducing or making copies of the ExCPT or test items by any means
    - memorizing test items
    - discussing or disclosing the contents of the examination by any means
    - providing false or purposely misleading information when applying for or registering for the exam

4. I agree that any claim I may have related to the good-faith enforcement of these policies or the unintentional damage or loss of my exam records will not exceed the amount of my application fee for this examination.

Procedure for Handling Suspected Cheating Incidents. Candidates will be notified through a "Candidate Attestation" at the time they register and/or take the test that cheating will not be tolerated and that there will be appropriate penalties.

When cheating is detected, the LaserGrade Testing Center Specialist (TCS) will, in most circumstances, allow the candidate to finish taking the exam. However, the TCS will stop the exam if the candidate: (a) becomes unruly, (b) is interfering with other candidates, or (c) is copying questions on the exam. In all cases the TCS will secure the exam and a copy of the videotape and any other evidence.

The LaserGrade TCS will then write an incident report and send it to ICPT within 24 hours. The report will include the following information: date, time, location, proctor

name, candidate's name, candidate's Social Security Number, test version, a full description of the incident and a list of the evidence supporting the allegation.

LaserGrade will report the candidate's grade as "pending." Candidates will be notified that the ICPT investigation may take up to 30 days. If ICPT determines that the candidate violated the ICPT policies on cheating and confidentiality, it may seek a range of remedies depending upon the severity of the case, including but not limited to taking civil or criminal action against the candidate, suspending eligibility, and/or referring information about said misconduct to the respective board(s) of pharmacy Candidates will be given due process to appeal this decision before a member of the ICPT Board of Directors and two other qualified, unbiased individuals.

8. Taking the Exam

Identification required. In order to take the exam, candidates are required to present government-issued photo identification, such as a valid passport, driver's license, US Armed Forces photo identification or a non-driver's identification issued by a state department of motor vehicles. The identification must be clear and legible. The name on the photo identification must be the same as on the original registration. If the names are different then a certified or notarized copy of a marriage license, divorce decree, adoption papers or other legal documentation of name change. If the address on the government-issued photo identification is different from that supplied at the time of registration, the candidate must show proof of address, such as a current utility bill.

Prohibited items. Candidates may not bring any paper, books, cell phones, calculators, pagers, scanners, cameras or PDAs with them into the examining room. Candidates may be inspected for such materials prior to the exam. All purses, brief cases and other personal items will be securely locked up during the exam. The testing session may be videotaped for additional security.

Materials supplied. Candidates will be supplied with two blank sheets of paper and a pencil. The paper must be returned to the proctor at the end of the exam. A calculator will be available on the computer. Easy instructions on using this calculator and for navigating through the exam items and submitting the final answers will be given at the time of the exam. Candidates may also preview these instructions on the LaserGrade website at www.lasergrade.com.

Questions. No questions concerning the content of the examination may be asked during the testing period.

Comments. Candidates will be given the opportunity to comment on any question that they believe is ambiguous, inaccurate or deficient. A comment section for this purpose is provided at the end of the exam. All comments submitted will be reviewed by the ICPT Expert Panel. Responses are not provided to individual comments. Candidates will also be asked to complete a brief survey at the end of the exam to rate the exam registration procedures, the testing facility and general satisfaction with the testing experience.

9. Scoring Exams and Reporting Results

Exam results for successful candidates. The ExCPT is scored immediately and successful candidates are given an official report by LaserGrade indicating that they passed the ExCPT immediately after completing the exam. Candidates may use this report to provide evidence to employers or regulatory boards that they passed the ExCPT and are a certified pharmacy technician.

Exam results for unsuccessful candidates. The purpose of the exam is to provide summative assessment (i.e., to determine whether an individual has achieved a certain level of competency). It is not designed for formative assessment (i.e., to give the candidate feedback). ICPT does, however, provide diagnostic reports to help unsuccessful candidates focus their study time so they can successfully retake the exam. Candidates can also get some formative feedback by answering the practice problems that are offered on the ICPT website.

Candidates who do not pass the Exam will be allowed to retake the exam after four weeks. Since there are multiple versions of the Exam, candidates who take retake the Exam will receive a different, but equivalent, set of questions.
Passing score. The passing score is established by the ICPT Expert Panel based on a standard of performance that experts in the profession have determined are acceptable for this certification program. Specifically, the Expert Panel uses a modified Angoff procedure to determine the passing score. With this method each panelist independently estimates the percentage of qualified candidates who would correctly answer each item. The panelists' ratings are averaged to determine the passing score (also known as the "cut score"). The overall passing score is determined by averaging the individual ratings. The extreme high and low ratings can be deleted to decrease the variance without affecting the median score. The passing score is not based on a curve.
Recognition of certification. Pharmacy technicians who successfully pass the *ExCPT* are considered Certified Pharmacy Technicians and will receive a certificate suitable for framing.

Confidentiality of scores. Exam results for successful candidates will be available to state boards of pharmacy and, if authorized by the candidate, may be made available to employers as well. A list of Certified Pharmacy Technicians who passed the ExCPT will be available to the public. Unless authorized by the candidate, scores will not be released nor the identity revealed of candidates who do not pass the ExCPT.

Appeals and rescoring. Candidates who wish to appeal their test results or a specific test item will be allowed to do so by completing an appeal form and remitting a nominal examination review fee. The appeal form is available from the Director of Education and is used to record these requests and keep track of the reasons for the request as well as the results of the review. The Director of Education, with consultation from the Expert Panel if necessary, will respond to the candidate within ten working days.

Requests for duplicate certificates. Candidates who need a duplicate certificate may obtain one for a nominal charge by completing a request form available on the ICPT website. Individuals requesting a name change must provide notarized proof of the name change.

Reexamination. Candidates who do not pass the ExCPT will be allowed to retake the exam after four weeks. Since there are multiple versions of the ExCPT, candidates who take retake the exam will receive a different, but equivalent, set of questions.

10. Standards for Assuring Quality of the ExCPT

APA Standards. The ExCPT meets the standards of the American Educational Research Association, American Psychological Association and National Council on Measurement in Education, *Standards for Educational and Psychological Testing.*

NCCA Standards. The ExCPT follows the standards of the National Commission for Certifying Agencies (NCCA), the accreditation body of the National Organization for Competency Assessment. These standards for certification programs are considered to be more demanding than the APA standards. Our audit by an independent expert in psychometrics used these standards in her audit of the exam.

Development of exam. The above-referenced standards require that certain steps be followed to assure the psychometric soundness of a certification exam. These steps include the following:

- *Practice analysis.* A comprehensive job/practice analysis is conducted to clearly delineate performance domains and tasks and the associated knowledge and skill sets for pharmacy technicians. Among other things, respondents indicate the criticality and amount of time spent by technicians on various job tasks. Individuals are surveyed from a stratified sample of pharmacy technicians as well as technician supervisors and trainers from all practice settings. The sample size is large enough to give sufficient statistical power and to make proper inferences from the data and appropriate subsets of the data, New practice analyses are conducted on a periodic basis, usually every two years.

- *Exam blueprint.* The results of the practice analysis and input from stakeholders are used by the Expert Panel to determine the content areas to be tested on the exam and the weight given to each of these content areas. The result is the production of a document known as the exam blueprint, which will be available to all stakeholders. The ExCPT consists of 110 multiple-choice questions, including 10 pilot questions. Exam questions fall into three general areas: (1) Regulation and Technician Duties (~25%), (2) Drugs and Drug Products (~25%); and (3) The Dispensing Process (~50%).

- *Item writing.* A panel of volunteer item writers from a wide range of pharmacy practice settings are used to submit exam items. These item writers include

pharmacy college professors, pharmacists and certified pharmacy technicians who have strong expertise in specific pharmacy practice settings. All item writers are instructed on the standards for writing acceptable multiple-choice exam items. All items submitted are numbered, categorized according to topic and coded to identify the writer. All items are submitted to an extensive review process before being adopted as a part of the ExCPT exam test bank.

- *Expert panel review*. A panel of five to ten highly qualified individuals from a diverse set of practice settings are appointed to the Expert Panel to review all items submitted by item writers. The panel accepts those items that meet the standards and either amend or reject other items. All items accepted must first be pretested before being used in an exam. The Expert Panel also reviews results of the practice analysis, establishes the exam blueprint, sets the passing score and approves the equating and scaling procedures.

- *Pilot testing*. As with all standardized tests, the *ExCPT* contains some questions that are being pretested for possible use on future exams. Pretesting additional questions is necessary to assure that all items perform properly and that new versions of the Exam can be used in the future. The pretest items are interspersed throughout the exam and are not be identified for the candidate in order to assure that test statistics are valid.

- *Item analysis*. All items are submitted to an extensive process known as an item analysis. This item analysis consists of statistical procedures to determine the difficulty, discrimination, reliability and validity of all items before they are used as scored questions in the ExCPT. Item analyses are conducted on a regular basis, at least bimonthly.

- *Passing scores*. See the discussion in the previous section.

- *Equating and scaling*. To protect the integrity of the exam, multiple versions of the ExCPT are used. Candidates are randomly assigned to take one of the versions of the exam. If candidates need to retake the ExCPT, they are assigned to a different version of the exam. The various versions are carefully equated to assure that all offer the same challenge. Equating is essentially a statistical method of selecting the raw score on each test that would provide the same probability of passing. In other words, it is a way of calibrating different versions of the exam to assure that they provide an equal challenge. For example, a raw score of 75 may be determined to be a passing score on one version of the exam and a 74 may be determined by the Expert Panel to be the equivalent passing score on a more difficult version.

  To assure consistency among various versions of the exam, scores are converted to a scaled score instead of a raw score. A scale is a score-reporting technique that translates the different raw scores into a standard score. For example, the scores that may be earned on the ExCPT range from 200 to 500 and the passing

score is 390. The minimum passing raw scores are then converted to 390 for all versions of the exam. If two different versions of the exam have different cut scores (e.g., a raw score of 75 on one version and a raw score of 74 on another) then both are converted so that 390 is the passing score. Reporting only raw scores could cause confusion because the results of one test administration may be difficult to compare with another that does not have exactly the same difficulty or same cut score. Equating and scaling procedures are used in most certification programs because they are easy and reliable, commonly accepted as standard procedures in certification programs, psychometrically sound and are legally defensible.

- *Rotating and retiring test items*. The integrity of the exam is further protected by rotating and retiring test items on a regular basis. Candidates who have to retake the exam several times would not see the same exam again because they would be assigned to all of the different versions before they could retake the same version. During the time before retaking the same version, most of the questions would have changed. All versions of the exam, however, will be consistent with the exam blueprint and will be equated. In addition to rotating and retiring test items, the order of test items and answers are scrambled and numbers for calculation questions are changed on a frequent basis. Questions that are retired from the exam can be used later as practice questions.

- *Independent audit by expert in psychometrics*. An independent, unbiased expert in psychometrics is retained to audit the ExCPT procedures, content and exam items. An audit of the exam developed for the Virginia Board of Pharmacy follows all ExCPT test procedures and was audited by Dr. Dana Hammer of the University of Washington in February 2004. A more recent audit of the ExCPT content and procedures was conducted by Dr. Hammer in February 2006. Dr. Hammer used the certification standards and guidelines established by the National Commission for Certifying Agencies. Dr. Hammer's opinion was that the exam meets the standards for certification programs and is psychometrically sound. It is the intent of ICPT to continue conducting independent audits of the ExCPT.

11. Services to Boards of Pharmacy

Reporting and maintaining results. Exam results are posted on a secure website designed specifically for board of pharmacy use. With a password, authorized board of pharmacy staff members may check ExCPT records to determine whether specified pharmacy technicians are certified by ExCPT. ExCPT records can also be used to update board records and to generate reports from the certification database. An online users manual is provided to help boards of pharacy to make optimal use of the website.

Reciprocity. Boards of pharmacy can use the secure website to verify certification the current status of all ExCPT-certified pharmacy technicians for purposes of reciprocity.

Boards can also be notified of any pharmacy technicians whose certification has been revoked.

12. Revocation

ICPT may revoke the certification of a pharmacy technician for any of the following reasons:

- Submission of false or misleading information in connection with certification or recertification;
- Violation of any of ICPT's policies on exam cheating or exam confidentiality or failure to cooperate with ICPT in the investigation of any such incident by another candidate.
- Conviction of a felony or a crime involving prescription medications or controlled substances (including but not limited to the illegal use, sale or distribution of prescription medications or controlled substances);
- Revocation or suspension of a pharmacy technician registration or license by a state board of pharmacy;
- Documentation of gross misconduct or gross negligence of duties to a state board of pharmacy.

13. Recertification

Application. The first ExCPT Certified Pharmacy Technicians were issued certificates in October, 2005. Since certification expires after two years, these individuals will be the first to recertify starting in October 2007. During the two-year period prior to recertification, certified pharmacy technicians must participate in at least 20 hours of continuing education (CE), including at least one hour of pharmacy law. To recertify, technicians must use the ICPT recertification application form and may file either online or by regular mail. Complete instructions will be provided with the form. Address changes should be sent to the Institute so that we may send a recertification application approximately 60 days prior to the expiration date. Technicians will be allowed to recertify up to 90 days after expiration of their certification but cannot include CE credit earned during this grace period. After this 90-day period, there will be a late fee.
Continuing education. To be approved, CE credit must be related to pharmacy technician practice. Acceptable topics include, but are not limited to: drug distribution, inventory control, managed health care, drug products, therapeutic issues, patient interaction, communication and interpersonal skills, pharmacy operations, prescription compounding, calculations, pharmacy law, preparation of sterile products and drug repackaging.

Certificates of participation must be obtained for each CE program. This certificate must include the name of the participant, the title of the program, date of the program, number of contact hours, the name of the sponsor and the signature of a person responsible for the program.

CE programs offered by national and state pharmacy associations and pharmacy technician associations will generally be acceptable if related to pharmacy technician practice. Applicable college courses with a grade of "C" or better will also be eligible for CE credit at the rate of 15 CE hours for each a 3credit-hour course offered on a semester basis (i.e., three hours a week for 15 weeks). Courses offered on a quarter basis will be credited for 15 hours for a 4 credit-hour course (i.e, four hours per week for approximately 11 weeks). The maximum number of CE credits earned through college courses during a two-year period is 15. Recertification may be conducted on-line or by mail beginning in October 2007.

Appendix 2

ExCPT Practice Analysis
List of Pharmacy Technicians Practice Functions

Question	Mean Importance	Relative Frequency	Relative Time
Understand the necessity of having a pharmacist check all work performed by the technician.	4.91	1.00	1.00
Use proper procedures to avoid prescription errors.	4.88	1.00	1.00
Use proper procedure to assure delivery of the correct prescriptions to patients.	4.83	1.00	1.00
Properly count, measure or compound the drug to be dispensed.	4.82	0.98	0.98
Accurately enter prescription information and drug history into the computer.	4.82	1.00	1.00
Demonstrate a clear knowledge of the line between tasks that may be performed by a pharmacy technician and those that must be performed by pharmacist.	4.82	1.00	1.00
Use correct procedures in preparing prescriptions for dispensing.	4.80	1.00	0.98
Describe the functions that a pharmacy technician cannot perform	4.80	0.75	0.72
Properly process third-party prescriptions.	4.79	0.56	0.49
Maintain HIPAA compliance while communicating with patients.	4.74	0.97	0.80
Correctly translate a prescriber's directions for use into accurate and complete directions for the patient.	4.74	0.99	0.99
Follow the proper rules and regulations when filling prescriptions.	4.73	1.00	0.83
Use the proper DAW code when entering prescription data.	4.72	0.52	0.52
Prepare prescription labels or patient information.	4.72	1.00	1.00
Correctly calculate prescription quanties and days supply.	4.69	0.83	0.87
Properly label drug products packaged in approved containers or, when appropriate, in original containers.	4.67	0.99	0.99
Properly package the drug to be dispensed in child-resistant containers or other approved containers as required.	4.67	0.99	0.99
Take proper action when a compliance alert is noted when entering a prescription.	4.65	0.80	0.81

Demonstrate knowledge of abbreviations used on prescriptions and familiarity with the ways in which abbreviations can be misinterpreted.	4.64	0.99	0.99
Communicate accurately and appropriately with patients.	4.62	1.00	0.98
Follow the proper rules and regulations when handling refills, partial filling and transfers of controlled substances among pharmacies.	4.53	1.00	0.90
Properly repackage drug products and label correctly and, in the case of repackaged medications, include the correct expiration date.	4.47	0.91	0.86
Identify which reject codes returned by third-party processors can be handled by a technician.	4.45	0.48	0.46
Properly file prescriptions	4.41	0.97	0.97
Demonstrate awareness of the compliance/interaction checks that a pharmacy computer performs.	4.38	0.90	0.83
Describe what information is required on completed prescription forms and how to gather any information that is missing.	4.35	0.93	0.93
Assist with inventory control and maintenance.	4.31	0.70	0.59
Follow the correct procedures for handling patient requests for pseudoephedrine.	4.31	0.27	0.19
Describe the purpose of patient profiles and how to enter, update, and maintain them.	4.26	0.78	0.76
Explain HIPPA requirements to patients (e.g., why they have to sign for prescriptions when picked up).	4.26	0.47	0.19
Identify the therapeutic class for commonly used durgs (e.g., analgesic, antibiotic, etc.)	4.21	0.68	0.62
Describe the difference between prescription and OTC medications and describe major theraputic classes of the latter	4.20	0.79	0.65
Describe strategies for avoiding mix-ups among easily confused products.	4.19	0.11	0.15
Identify and interpret the various methods used to indicate the quantity of medications to dispense.	4.17	0.87	0.85
Properly stock automated dispensing devices or other devices used in the dispensing process.	4.16	0.55	0.29
Assist in proper inventory maintenance.	4.15	0.90	0.89
Demonstrate knowledge of federal and state laws and regulations affecting pharmacy.	4.15	0.65	0.29
Use aseptic technique to prepare parenteral medications	4.15	0.30	0.27

Accept refill authorizations from prescribers or their authorized agents, provided there is no change to the original prescription.	4.15	0.78	0.19
Describe the different types of information conveyed on prescription labels and receipts.	4.13	1.00	1.00
Identify the brand and generic names of the most commonly used prescription drugs.	4.13	0.89	0.92
Compound intravenous medications and TPN	4.10	0.35	0.38
Understand proper use of auxiliary labels.	4.09	0.76	0.72
Help maintain the security of the pharmacy department	4.09	0.90	0.81
Demonstrate knowledge of terms and units of measurement in each of the systems of measurements and the ability to convert from one system to another.	4.08	0.72	0.74
Properly handle real or perceived medication errors.	4.07	0.87	0.83
Follow the correct procedures for handling Schedule V sales without a prescription.	4.05	0.42	0.21
Compound liquid, solid and semi-solid dosage forms	4.03	0.40	0.18
Demonstrate knowledge of record-keeping requirements.	4.02	0.99	0.97
Understand laws and regulations regarding generic substitution	4.00	0.80	0.51
Cite rules and regulations regarding time limits for refilling prescriptions.	3.99	0.94	0.92
Cite information required on completed prescription forms.	3.99	0.89	0.82
Assure maintenance of adequate supplies of prescription vials, caps, bottles, and other supplies.	3.89	0.96	0.77
Explain what generic drugs are and how they compare to brand-name medications.	3.85	0.40	0.27
Describe the state law regarding the substitution of generic equivalents.	3.78	0.52	0.22
Answer patients' questions about prescription coverage under the Medicare Modernization Act.	3.75	0.68	0.49
Differentiate among the controlled substances schedules.	3.56	0.96	0.32
Identify the types of information found on medication stock bottles.	3.53	0.77	0.17
Identify the most common indication for the most commonly used prescription drugs.	3.40	0.96	0.93
Demonstrate familiarity with the characteristics of and cite examples from each of the four major categories of dosage forms.	3.32	0.15	0.15

Demonstrate a working knowledge of different types of drug dispensing systems (e.g., multidose vials, punch cards, and unit-dose packaging.)	3.27	0.68	0.47
List the practitioners who are authorized to prescribe medications.	3.21	0.23	0.17
Recognize common and severe adverse drug reactions, contraindications and drug interactions.	3.09	0.20	0.19
Understand the role of federal agencies such as FDA and DEA	3.00	0.25	0.02
Explain the role of the state board of pharmacy.	2.87	0.04	0.04
Describe the mechanism of action of various drug classes	2.23	0.04	0.04

Appendix 3

Exam for the Certification of Pharmacy Technicians

Exam Content (v1.4)

(valid through Sept. 30, 2006)

1. Regulations and Technician Duties (~25% of exam)

Overview of technician duties and general information

- The role of pharmacists and pharmacy technicians
- Functions that a technician may and may not perform
- Prescription department layout and workflow
- Pharmacy security
- Role of government agencies (Board of Pharmacy, DEA, FDA, etc.)
- Inventory control
- Stocking medications
- Identifying expired products

Controlled substances

- Difference among the controlled substances schedules
- Laws governing refills, partial refills, filing, and transfers of controlled substances
- Correct procedures for handling Schedule V sales

Other laws and regulations

- Federal privacy act (operational procedures, communications, incidental disclosures and patient rights)
- Laws and regulations regarding generic substitution (incl. differences between brand and generic products)
- Professionals with prescribing authority (and acronyms)

2. Drugs and drug products (~25% of exam)

Drug Classification

- Major drug classes (e.g., analgesics, anesthetics, antibiotics, antiseptics, etc.)
- Basic mechanism of action and indications
- Dosage forms (types, characteristics and uses)

Most frequently prescribed medications

- Brand and generic names
- Drug class
- Primary indications
- NDC number
- Avoiding dispensing errors (e.g., sound-alike and look-alike drug names)
- Common adverse drug reactions, drug interactions, contraindications and side effects

3. Dispensing Process (~50% of exam)

Preparing prescriptions

- Information required on a valid prescription form
- Telephoned and faxed prescriptions
- Refill requirements
- Patient information (age, gender, etc.)
- Interpreting prescribers' directions for prescription labels
- Recognizing and using common prescription and medical abbreviations

Dispensing prescriptions

- Avoiding errors (e.g., sound-alike/look-alike names, other common errors)
- Systems for checking prescriptions
- Automated dispensing systems (including quality control)
- Correct procedures to prepare prescriptions and enter information in the computer
- Labeling prescriptions properly
- The purpose and use of patient records
- Proper packaging and storage
- Child-resistant containers
- Managed care prescriptions (submitting claims, reimbursement, reconciliation, partial fills, chargebacks and verifying delivery to the patient)

Calculations

- Systems of measurement used in pharmacy
- Calculating the amounts of prescription ingredients
- Calculating quantity or days supply to be dispensed

- Calculations use in compounding (e.g., ratio strength, w/w%, w/v, v/v, dilution/concentration, mEq, etc.)
- Calculating administration rates for IVs

Sterile products, unit dose and repackaging

- Drug distribution systems used in hospitals and nursing homes (e.g., unit dose)
- Procedures for repackaging medications
- Prescription compliance aids
- Aseptic technique and the use of laminar flow hoods
- Special procedures for chemotherapy
- Routes of administration for parenteral products
- Types of sterile products
- Correct procedures for maintaining the sterile product environment
- Accurate compounding and labeling of sterile product prescriptions
- Calculation of dosages and administration rates

Appendix 4

Exam for the Certification of Pharmacy Technicians

Partial List of Item Writers and

Their Respective Areas of Expertise

Name	Location	Expertise
Kelly Burch, Pharm.D.	St. Louis, MO	Hospital practice and home health care
Manisha Chander, Pharm.D.	Morton Grove, IL	IV infusion and home health care
Rasma Chereson, R.Ph., Ph.D.	St. Louis, MO	Community practice, compounding, parenteral therapy kinetics and pharmaceutics
Laura Cranston, R.Ph.	Fairfax Station, VA	Community practice
Eric Hobson, Ph.D.	Savannah, GA	Patient interaction and communication, pharmacy education
Douglas Hoey, R.Ph.	Alexandria, VA	Community practice
Delphine Knop, Pharm.D.	Des Plaines, IL	Hospital practice
Tejal Pandya, Pharm.D.	Schaumburg, IL	Long-term care
Dan Pepe, PhD,	San Antonio, TX	Hospital practice
Donald Rickert, R.Ph., Ph.D.	Belleville, IL	Hospital practice, pharmacy law
Elizabeth S. Russell, R.Ph.	Richmond, VA	Pharmacy law
Kenneth W. Schafermeyer, R.Ph., Ph.D.	University City, MO	Community practice, pharmacy education
Walter Thomas Smith, Pharm.D., J.D.	St. Louis, MO	Home health care, compounding, calculations and law
Peggy Summers, R.Ph.	Lake Jackson, TX	Community and hospital
Tasha Williams, Pharm.D.	Chicago, IL	Community pharmacy

Brandon Williams, Pharmacy Technician	Collinsville, IL	Community pharmacy
Dan Yee, Pharm.D.	Orlando FL,	Hospital, medical writer, clinical coordinator
New members to be added:		
Anita Benavidez, CPhT	Phoenix, AZ	Hospital and pharmacy benefit management
Ray Tanaka, R.Ph.	Elmhurst, IL	Health system pharmacy and nuclear pharmacy

Appendix 5

Letters of Reference for Independent Expert in Psychometrics, Dr. Dana Hammer, who audited the ExCPT

1. Dr. Eric Hobson, Associate Dean, South University College of Pharmacy
2. Dr. Robert McCarthy, Dean, University of Connecticut College of Pharmacy

SouthUniversity
School of Pharmacy
709 Mall Boulevard
Savannah, GA 31406-4881
(912) 201-8120

Members of the Connecticut Commission of Pharmacy
c/o William J. Summa, Jr., Chairman
Department of Consumer Protection
Commission of Pharmacy
165 Capitol Ave.
Hartford, CT 06106

25 March 2006

Members of the Connecticut Commission of Pharmacy & William J. Summa, Jr., Chairman:

At the request of Kenneth Schafermeyer, Ph.D., and the Institute for the Certification of Pharmacy Technicians, I offer the following assessment of the appropriateness of the use of Dana P. Hammer, Ph.D. to carry out a detailed audit of the Virginia Pharmacy Technician Exam (audit report filed in February 2005). As part of this assessment, I have reviewed the following: Dr. Hammer's February 2005 audit report, Dr. Hammer's CV, NCCA Standards and Essential Elements. Additionally, I bring to this assessment 15 years experience in pharmacy education, expertise in outcomes definition and assessment, psychometrics, test design and administration, awareness of the pharmacy education community's confidence in Dr. Hammer's work, and my respect for Dr. Hammer's accomplishments.

My review of these materials leads me to concur with Dr. Hammer's assessment that the Virginia Pharmacy Technician Exam is psychometrically sound and offers a reliable tool for ascertaining the performance capabilities of individuals who sit this examination.

Assessments offered by Dr. Hammer are impeccable. Her work is consistently sound, accurate, and conforms to the highest standards of practice. Invariably, Dr. Hammer's work sets standards for others to emulate. Her audit of the Virginia Pharmacy Technician Exam addresses every question that I would have asked had I carried out a review of the exam in question. Likewise, the analyses she used are appropriate and allow for a fine-grained analysis of macro- and micro-level issues related to construct validity, consistency across offerings, item strength and higher-order outcomes assessment. This audit is a fine piece of work.

Dr. Dana P. Hammer is uniquely qualified to carry out a detailed assessment of evaluation tools used to determine pharmacy-related knowledge, skill, and attitudinal competence. Her graduate-level training is unique: she completed the Doctor of Philosophy degree option in pharmacy offered at Purdue University, the only program of its type designed to provide pharmacy with highly-trained educators. This doctoral program requires extensive coursework linked to research-based practice activities that ensure that individuals in this program have mastered such topics as research design, educational assessment theory and methods, analytical methodology in clinical and educational practice, and high-stakes testing.

The pharmacy education community recognizes Dr. Hammer's expertise and capability. She is called upon routinely to consult with the development of educational curricula in didactic and practice situations. She serves as a regular faculty member at the American Association of Colleges of Pharmacy Summer Institutes on Curricular Design and Assessment, staffs the intensive program for new faculty and preceptors offered by the American College of Clinical Pharmacy, and is leading nation-wide efforts to develop systematic approaches to pharmacy preceptor training.

Dr. Hammer's high standing in the pharmacy education community is further supported by the fact that, to date, she has twice been awarded the Rufus Lyman Award for significant contribution to the pharmacy education literature. Few pharmacy educators have been thus recognized. I expect that she will receive this award more than once again based upon the strength of her assessment-focused research projects that are currently underway or in the planning stages. My appreciation of Dr. Hammer's skills runs deep: she is one of two or three professional peers to whom I turn when I need to better understand complex educational issues, discuss assessment methodology, or get a trusted peer review of assessment tools or research design protocols.

Should you or your colleagues require further comment about this particular issue, please feel free to contact me. Email is the most convenient method and can allow us to arrange a time to talk in detail.

Collegially yours,

Eric H. Hobson, Ph.D.
Associate Dean for Academic Affairs and Assessment
Professor of Pharmacy Practice
(912) 201-8125
ehobson@southuniversity.edu

University of Connecticut
School of Pharmacy

March 24, 2006

William Summa, R.Ph.
President
Connecticut Pharmacy Commission
Hartford

Dear Billy:

I wanted to drop a short note to you and your fellow Commission members regarding two of my long-time colleagues, Drs. Kenneth Schafermeyer and Dana Hammer. I know that Dr. Schafermeyer will be appearing before you next week regarding an alternative pharmacy technician exam; Dr. Hammer, as I understand it, conducted an audit of the exam.

Both Drs. Schafermeyer and Hammer are highly regarded by their faculty peers around the country and particularly by those of us within the social and administrative sciences discipline. The quality of their research is superb and their perspective is valued by those of us in the academy. Equally important, they are known as individuals of high integrity. I can assure you that they are honest, forthright, and not known for hyperbole. Though one may disagree with their perspective, you can be assured that their conclusions have followed careful analysis and study.

It's not appropriate for me to offer an opinion of the proposed alternate test; I have not studied it sufficiently to do so. I ask only that you listen to Dr. Schafermeyer's presentation with an open mind, confident that he will present a qualified, honest assessment of the alternate test.

Many thanks,

Robert L. McCarthy, Ph.D.
Dean and Professor

Appendix 6

Exam for the Certification of Pharmacy Technicians

Expert Panel Members (05/2006)

Name	Position	Location	Practice Experience	Other Expertise
Anita V. Benavidez, BS, CPhT	• Former Analyst, United Health Group • Former instructor, Midwestern University College of Pharmacy	Phoenix, Arizona	• Hospital Pharmacy Technician • Pharmacy Education • Managed Care	• PTCB-Certified Pharmacy Technician • PCCA compounding and aseptic technique certificates • Pharmacy benefit management
Bette Cataldo, Pharm.D.	• Clinical Pharmacist, Missouri Baptist Hospital (ret.) • Assistant Pharmacy Director, St. Louis University Hospital (ret.)	St. Louis, Missouri	• Hospital Pharmacy • Home Health Care • Technician Training	• Pharmacy compounding • Home IV preparation
Rasma Chereson, R.Ph., Ph.D.	• Professor of Pharmaceutics, St. Louis College of Pharmacy • Community pharmacy practitioner, Medicine Shoppe International	University City, Missouri	• Pharmacy Education • Community Pharmacy	• Teacher of : > Pharmacokinetics > Pharmacy Compounding > Parenteral Therapy > Pharmacy Dispensing

Dana P. Hammer, R.Ph., Ph.D.	• Psychometrician and Director of the Bracken Pharmaceutical Care Learning Center, University of Washington College of Pharmacy	Seattle, Washington	• Pharmacy Education • Community Pharmacy • Hospital Pharmacy	• Expert psychometrician. • Teacher of: > Advanced Compounding Skills > Educational Design > Pharmacy Practice Laboratory
Timothy R. Koch, R.Ph.	• Government Relations Manager, Wal-Mart Pharmacies • Former Vice President, MO Board of Pharmacy	Bentonville, Arkansas	• Hospital Pharmacy • Community Pharmacy • Board of Pharmacy	• Pharmacy laws and regulations
Justin Lusk	• Pharmacy technician and 2nd Lt. USAF	Jackson, Missouri	• Community Pharmacy (technician)	
Merry Lynn Schmittgens, R.Ph.	• Owner, Medicine Shoppe Pharmacy • Instructor of Pharmacy, St. Louis College of Pharmacy	Affton, Missouri	• Hospital Pharmacy • Community Pharmacy • Pharmacy Education	• Pharmacy compounding
Mayur Shah, Pharm.D.	• Owner, MRxI, Inc. • Owner, Broadway Avenue Pharmacy	Chicago, Illinois	• Hospital Pharmacy • Community Pharmacy • Pharmacy Benefit Management	• Oncology/hematology specialist • Pain management specialist • Chemotherapy compounding
Walter Thomas Smith, Pharm.D., J.D.	• Assistant Professor of Pharmaceutical Sciences, St. Louis College of Pharmacy	St. Louis, Missouri	• Home Health Care / Long-Term Care • Pharmacy Education	• Teacher of: > Introduction to Pharmacy Practice > Pharmacy Calculations. > Biomedical Ethics • Sterile product compounding • Pharmacy law

Note: This Expert Panel represents a diverse range of pharmacy practice settings, experiences and locations. Members have practice experience from all over the United States including: Alaska, Arizona, Arkansas, Colorado, Illinois, Indiana, Kansas, Massachusetts, Michigan, Missouri, Nebraska, Oregon, Tennessee, Texas, Virginia, and Washington.

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Appendix 7

LaserGrade Test Center Requirements

1. GENERAL

A. Testing Center must conform with local building, sanitation, and health codes.
B. Building and grounds must be clean and in good condition.
C. The exits must be clearly marked and unobstructed.
D. Fire extinguishers, when required, must be in working order, the location well marked, and easily accessible.
E. Emergency exits must be clearly identified and clear of obstructions.
F. Emergency first-aid kits, if required, must be stocked and easily accessible.
G. Restrooms must be clean, supplied with towels, etc., and in working order.
H. Restrooms must be located in the same building as the testing center.
I. Adequate parking must be available, near the testing center location.

2. TEST ROOM ENVIRONMENT

A. Temperature must be consistent and comfortable.
B. Testing room must be well-ventilated, with continuous air circulation.
C. Testing room must be lit so that the candidate at each terminal can read all diagrams, charts, etc., and read the computer screen without difficulty.

3. TEST ROOM PHYSICAL SPACE

A. Testing room must be large enough to comfortably place the testing station(s), computer tables, chairs, and printer stand. Generally speaking, 120 square feet or larger is adequate.
B. Each testing terminal must be separated with a suitable partition or spaced five feet apart.
C. There must be enough table space for the computer monitor, keyboard, mouse pad and testing materials the candidate will be issued. A recommended table size is 42" X 30".

4. TESTING ATMOSPHERE

A. Testing area should be located so candidates will not be disturbed by foot traffic, loud conversation or outside noise.
B. Testing rooms shall be free from any other activity during testing sessions; during non-testing times, the testing room may be available for other uses.
C. In general, the testing center should provide a pleasant and comfortable atmosphere and be conducive to a good testing environment.

5. SECURITY and SUPERVISION

A. Testing must take place in a separate room with a closeable door.
B. Testing room must have a window, video surveillance system, or seating for an in-room proctor for test supervision. All must allow an unobstructed view of each candidate within the testing room.
C. Testing room door must be lockable. Access to this room must be strictly monitored. Only authorized personnel are permitted.
D. All testing materials must be secured when not in use. A locking file cabinet may be used for this purpose.
E. The testing room may be used for other purposes when not being used for testing.

6. REQUIRED EQUIPMENT and SUPPLIES

A. Copy machine or scanner to provide copies of candidate IDs and test eligibility for testing center files.
B. Facsimile machine allowing receipt of transmitted documents 24 hours per day.
C. A locking file cabinet to secure test materials and to store candidate files.
D. A printer stand for the testing center printer.
E. Clipboards for keeping candidate papers together before filing.
F. Three ring binders to organize testing material.
G. A spare printer cartridge.
H. A ream of scratch paper for the candidates. (Two sheets to each candidate)
I. Supply of #2 pencils. (Two are issued to each candidate)
J. Test report embosser, if required. (Supplied by LaserGrade)
K. Test supplement books, if required. These books contain graphs, charts and diagrams used in the computer test.
L. Pre-printed test report forms. (Supplied by LaserGrade)
M. Testing center procedures manual. (Supplied by LaserGrade)

LaserGrade Computer Specifications			
	LaserGrade Engine	MOS Engine	APTC Engine

	MHz At least 256 MB RAM Must have a CD-ROM	MHz At least 256 MB RAM	RAM
Operating System	Windows 98 or higher, networked or stand-alone.	Windows 98/2000	Windows NT or Novell network, or Windows 98/2000 stand alone or peer to peer
Network	Optional. We support NT and peer to peer. No wireless networks.	Simple LAN, peer to peer	Windows 2000 Pro optional
Telecom	Internet - DSL or higher	Optional, only necessary if needed for internet connection	External 56 Kbps modem
Printer	100% compatible with HP series of Inkjet or Laser printers.	300 DPI printer with Windows 95/98 support – must be installed as a DEFAULT printer on ALL MOS Workstations	Administrator and testing workstations must have access to an inkjet/laseror bubblejet printer with at least 600 DPI capabilities
Hard Drive	Minimum 5 Gig available space	250 MB available after installing Office 97	2 GB
Video	17" SVGA .28 pitch, displaying 256 colors on a 1024x768	Color VGA video display set to 640x480 resolution	SVGA color monitor and video card with 1 MB RAM and capable of 256 colors

	screen. Video card compatible with Trident 9440 with 2 Mb RAM, displaying 256 colors in both 1024x768 & 640x480		
Pointing Device	Microsoft or compatible mouse	Microsoft or compatible mouse	Microsoft or compatible mouse
Internet Access	All testing stations must have internet access.	Internet access via dial-up, network, or proxy server	Optional
Installed Applications	Internet Explorer 5.0 or higher. Adobe Acrobat Reader	Microsoft Office 2000 or XP Professional Edition– full installation	None required.

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Attachment 5

AB 595 and Texas District Court Decision Regarding FDA's Regulation of Compounding

AMENDED IN SENATE AUGUST 24, 2006

AMENDED IN SENATE MAY 26, 2005

AMENDED IN ASSEMBLY APRIL 18, 2005

AMENDED IN ASSEMBLY MARCH 29, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 595

Introduced by Assembly Member Negrete McLeod

February 17, 2005

An act to amend Section ~~4051~~ *4033* of, to add Section 4019.5 to, ~~to repeal Section 4033 of,~~ and to repeal and add Section 4123 of, the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 595, as amended, Negrete McLeod. Pharmacy: compounding of prescription drugs.

Existing law, the Pharmacy Law, provides for the licensing and regulation by the California State Board of Pharmacy of pharmacists, pharmacies, and other related practices and makes a violation of that law a crime. The Pharmacy Law defines various terms for its purposes, including *"manufacturer" and provides specified exceptions from the definition of a* "manufacturer."

This bill would ~~delete~~ *revise* the definition of manufacturer *to except only pharmacies that compound or otherwise manufacture on the immediate premises where the drug or device is sold to the ultimate consumer and pharmacies compounding pursuant to a contract with another pharmacy, and would except those pharmacies from registration or licensing as a manufacturer or otherwise complying*

with federal or state laws regulating manufacturers, unless otherwise determined by a federal or state agency regulating manufacturers. The bill would define compounding of a prescription drug for the purposes of the Pharmacy Law and would ~~make other related changes in that regard~~ *impose specified requirements on dispensing of compounded drugs. The bill would authorize a pharmacy to contract with another pharmacy to compound products on behalf of its patients, subject to specified requirements. The bill would also impose requirements with respect to recalling a compounded drug product.* Because the bill would specify requirements for compounded drug products under the Pharmacy Law, *the violation of which would be a crime,* it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 4019.5 is added to the Business and
2 Professions Code, to read:
3 4019.5. (a) "Compounding" means any of the following
4 activities occurring in a pharmacy pursuant to a prescription:
5 (1) Altering the dosage form or delivery system of a drug.
6 (2) Altering the strength of a drug.
7 (3) Combining components or active ingredients.
8 (4) Preparing a drug product from bulk chemicals.
9 (b) "Compounding" shall not include the reconstitution of a
10 drug pursuant to the manufacturer's direction for oral, rectal, or
11 topical administration.
12 ~~SEC. 2. Section 4033 of the Business and Professions Code is~~
13 ~~repealed.~~
14 ~~SEC. 3. Section 4051 of the Business and Professions Code is~~
15 ~~amended to read:~~
16 ~~4051. (a) Except as otherwise provided in this chapter, it is~~
17 ~~unlawful for any person to compound, furnish, sell, or dispense~~

~~any dangerous drug or dangerous device, or to dispense or compound any prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist under this chapter.~~

~~(b) Notwithstanding any other law, a pharmacist may authorize the initiation of a prescription, pursuant to Section 4052, and otherwise provide clinical advice or information or patient consultation if all of the following conditions are met:~~

~~(1) The clinical advice or information or patient consultation is provided to a health care professional or to a patient.~~

~~(2) The pharmacist has access to prescription, patient profile, or other relevant medical information for purposes of patient and clinical consultation and advice.~~

~~(3) Access to the information described in paragraph (2) is secure from unauthorized access and use.~~

SEC. 2. Section 4033 of the Business and Professions Code is amended to read:

4033. ~~(a)~~ "Manufacturer" means and includes every person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufactures on the immediate premises where the drug or device is sold to the ultimate consumer *or a pharmacy compounding pursuant to a contract as provided in Section 4123. Any excepted compounding pharmacy shall not be required to register as a manufacturer with, or seek licensure by, any federal or state agency regulating manufacturers or otherwise comply with any federal or state law regarding manufacturers, absent a determination by a federal or state agency regulating manufacturers that the pharmacy must do so. Neither this definition nor any other provision of this chapter shall impair the authority of a federal or state agency regulating manufacturers to apply laws regulating manufacturers to a pharmacy.*

~~(b) Notwithstanding subdivision (a), "manufacturer" shall not mean a pharmacy compounding a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy for the purpose of delivering or administering the drug to the patient or patients named in the prescription, provided that neither the components for the drug nor the drug are compounded, fabricated, packaged, or otherwise prepared prior to receipt of the prescription.~~

~~(c) Notwithstanding subdivision (a), "manufacturer" shall not mean a pharmacy that, at a patient's request, repackages a drug previously dispensed to the patient, or to the patient's agent, pursuant to a prescription.~~

~~SEC. 4.~~

SEC. 3. Section 4123 of the Business and Professions Code is repealed.

~~SEC. 5.~~

SEC. 4. Section 4123 is added to the Business and Professions Code, to read:

4123. (a) A compounded drug product shall only be dispensed or furnished to a patient pursuant to a prescription meeting the requirements of Section 4040.

(b) A compounded drug product shall only be dispensed or furnished to a patient where the prescription has been generated solely within an established professional relationship between the prescriber, patient, and dispensing pharmacy.

(c) A pharmacy may conduct anticipatory compounding of a drug product in limited quantity, as defined by regulation of the board, before receipt of a prescription order for that drug product, where the quantity of each drug product compounded in anticipation of receipt of prescription orders is based on a documented history of receipt of prescription orders generated solely within an established professional relationship between prescribers, patients of the pharmacy, and the pharmacy.

(d) A pharmacy may contract with another pharmacy to compound drug products on behalf of its patients, *provided that all of the following requirements are met:*

(1) Any pharmacy that compounds a drug product for another pharmacy shall report that contractual arrangement to the board. The information shall be reported by the pharmacy performing the compounding services within 30 days of commencing that compounding.

(2) The drug product shall not be compounded prior to receipt of the prescription by the pharmacy doing the compounding.

(3) Both the pharmacist that compounds the drug product and the pharmacist that dispenses or furnishes the compounded drug product to the patient pursuant to a prescription shall have access to and appropriately review the patient's medication profile and other pertinent patient information prior to

compounding and prior to dispensing or furnishing the drug product to the patient.

(4) Both the pharmacy that compounds the drug product and the pharmacy under contract that dispenses or furnishes the compounded drug product to the patient pursuant to a prescription shall maintain complete and adequate records of the required drug therapy review performed by each prior to compounding, dispensing, or furnishing the drug product.

(5) The pharmacy that compounds the drug product shall supply the pharmacy under contract that dispenses or furnishes the compounded drug product to the patient with documentation regarding the compounded drug product sufficient to enable the pharmacist dispensing or furnishing the compounded drug product to the patient to both adequately perform the required drug therapy review and provide consultation to the patient, as required by regulation of the board.

(6) Both the pharmacy that compounds the drug product and the pharmacy under contract that dispenses or furnishes the compounded drug product to the patient shall retain on the licensed premises in a readily retrievable form for a period of three years from the date of creation all records of the required drug utilization review performed by each pharmacy, as well as all documentation regarding the compounded drug product shared between the two pharmacies.

(7) The pharmacy that compounds the drug product and the pharmacy that dispenses or furnishes the compounded drug product to the patient shall both be responsible for ensuring that the prescription has been properly filled and that the compounded drug product has been safely delivered to the patient.

(e) A pharmacy may only base its anticipatory compounding on a documented history of prescription orders received for its own patients or customers, and not those patients or customers of pharmacies with which it has a contractual relationship.

(f) Notwithstanding any other provision of this chapter, a pharmacist may ~~do both of the following:~~

~~(1) Compound a drug product pursuant to a prescription, for delivery to another pharmacy pursuant to a contract for the purpose of dispensing or furnishing the drug product to the~~

~~patient named in the prescription, provided that the drug is not compounded prior to the receipt of the prescription.~~

~~(2) Repackage~~ *repackage* a drug previously dispensed to the patient at the request of the patient or the patient's agent.

(g) A pharmacy shall recall a compounded drug product that is misbranded, adulterated, or has the potential for adverse effects or patient harm with continued use of the drug product. Within two business days of discovery of a drug product that is misbranded, adulterated, or has the potential for adverse effects or patient harm, the pharmacy shall notify the prescriber and patient of the nature of the recall, the problems identified, and any recommended actions to ensure patient safety. Any recall that is initiated by a pharmacy pursuant to this section shall also be reported to the board and to the Food and Drug Branch of the State Department of Health Services within two business days.

~~SEC. 6.~~

SEC. 5. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
MIDLAND-ODESSA DIVISION

FILED
AUG 3 0 2006
CLERK, U.S. DISTRICT COURT
WESTERN DISTRICT OF TEXAS
BY DEPUTY CLERK

MEDICAL CENTER PHARMACY, *et al.*	§	
Plaintiffs	§	
	§	
v.	§	**MO-04-CV-130**
	§	
GONZALES, *et al.*	§	
Defendants	§	

ORDER GRANTING IN PART PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND GRANTING IN PART DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

Before the Court are Plaintiffs' Motion for Summary Judgment, filed March 31, 2006; Defendants' Motion for Summary Judgment, filed March 31, 2006; and numerous responses, replies, and supplemental briefs. On May 25, 2006, the Court held a hearing over the parties' Motions for Summary Judgment. After due consideration, and in accordance with the oral pronouncement made at the hearing, the Court finds the following order shall now enter.

FACTUAL AND PROCEDURAL BACKGROUND

Plaintiffs are a group of ten state-licensed pharmacies that specialize in compounding prescription drugs for humans and non-food animals. Although the Food, Drug and Cosmetic Act ("the Act"), 21 U.S.C. § 301, *et seq.*, does not define the terms compounding or compounded drug, the practice has been generally defined as the process by which "a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 360–61 (2002). These hybrid drugs are typically created in the absence of a commercially available drug which would serve a similar purpose, or where a commercially available drug contains ingredients to which the patient is allergic. The practice of compounding drugs from approved ingredients saves time

and money for patients and physicians. Every state legislature has authorized the compounding of drugs, and state governments continue to regulate the practice.

On September 27, 2004, Plaintiffs filed the instant lawsuit challenging the authority of the FDA to regulate compounded drugs and to inspect state-licensed retail pharmacies under the Act. On January 27, 2005, Defendants filed a Motion to Dismiss, seeking dismissal of the case for failure to state a claim upon which relief can be granted. At a hearing on May 23, 2005, this Court denied, without prejudice, Defendants' Motion to Dismiss and both parties engaged in discovery. On February 24, 2006, Plaintiffs' Motion for Leave to File an Amended Complaint was granted. The Amended Complaint sought declaratory and injunctive relief on seven counts. Specifically, Plaintiffs requested (1) declaratory judgment under the new drug definitions found in 21 U.S.C. §§ 321(p)(1) and (v)(1), (2) injunctive relief under the new drug definitions, (3) declaratory judgment under the exemption contained in 21 U.S.C. § 374(a)(1), (4) injunctive relief under the exemption contained in 21 U.S.C. § 374(a)(1), (5) declaratory judgment regarding the FDA's policy that compounding from bulk ingredients for non-food animals is illegal, (6) injunctive relief regarding Compliance Policy Guideline 608.400, and (7) injunctive relief under 21 U.S.C. § 331(f).

Thereafter, on March 31, 2006, Plaintiffs and Defendants filed competing Motions for Summary Judgment. In their Motion for Summary Judgment, Plaintiffs seek:

1. a declaration that drugs compounded by licensed pharmacists are not "new drugs" or "new animal drugs" *per se* under 21 U.S.C. §§ 321(p)(1) and (v)(1);

2. an injunction that prevents the FDA from declaring that compounded drugs are "new drugs" or "new animal drugs" under 21 U.S.C. §§ 321(p)(1) or (v)(1) and therefore subject to the requirements and prohibitions imposed upon such drugs under the Act;

3. an injunction that prevents the FDA from enforcing its position that compounded drugs are "new drugs" or "new animal drugs" under 21 U.S.C. §§ 321(p)(1) or (v)(1) and therefore subject to the requirements and prohibitions imposed upon such drugs under the Act;

4. a declaration that the FDA is prohibited from compelling inspections that exceed the grounds enunciated in the first sentence of 21 U.S.C. § 374(a)(1) of pharmacies like Plaintiffs that comply with the requirements of 21 U.S.C. § 374(a)(2)(A);

5. an injunction that prevents the FDA from engaging in inspections that exceed the subjects enunciated in the first sentence of 21 U.S.C. § 374(a)(1) of pharmacies that are in good standing with their respective State boards of pharmacy and have met the Exemption Criteria;

6. a declaration that Compliance Policy Guideline 608.400 and the Notice are unenforceable;

7. a declaration that the FDA does not have the authority to declare compounding from bulk ingredients for non-food animals illegal;

8. an injunction that prevents the FDA from enforcing its current Compliance Policy Guideline which unilaterally declares that compounding from bulk ingredients for non-food animals is illegal;

9. an order requiring the FDA to rescind the Notice at issue in this case;

10. an order requiring the FDA to publish a copy of the Court's order on its website;

11. an injunction that prevents the FDA from prohibiting Plaintiffs or similarly situated pharmacies from receiving bulk ingredients;

12. an injunction that prevents the FDA from bringing prosecutorial, enforcement or punitive actions against any Plaintiffs for refusing to allow the FDA to conduct inspections exceeding the first sentence of 21 U.S.C. § 374(a)(1) of their pharmacies, pursuant to 21 U.S.C. § 374(a)(2)(A), absent independent evidence from the relevant State boards of pharmacy that Plaintiffs are non-compliant; and

13. any and all other relief, in law or in equity, as may be just.

Plaintiffs filed a Response to Defendants' Motion on April 20, 2006, and Defendants' Reply was filed on April 21, 2006. Thereafter on May 25, 2006, this Court held a hearing over

the Motions for Summary Judgment. At the conclusion of the hearing, the Court orally granted Plaintiffs' Motion for Summary Judgment in part, and took several remaining issues under advisement. After the hearing, both parties filed supplemental briefs, which this Court has duly considered.

STANDARD OF REVIEW

Summary judgment should be granted only where "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." FED. R. CIV. P. 56(c). In this case, Plaintiffs and Defendants represent to the Court that no genuine issues of material fact exist. They both filed Motions for Summary Judgment and agree that adjudication based on the summary judgment motions is proper.

DISCUSSION

In their Motion for Summary Judgment, Plaintiffs argue they are entitled to declaratory and injunctive relief on several grounds, as enumerated above. The Court finds that the requested relief can be grouped into the following topics: (1) Compounded Drugs, (2) Inspections, (3) Compounding from Bulk Ingredients for Non-Food Animals, (4) Compliance Policy Guideline 608.400 and the Notice, and (5) Injunctions. Each topic shall be examined individually below.

(1) Compounded Drugs

Plaintiffs first contend that compounded drugs, prepared by pharmacists in the regular course of their business pursuant to a prescription from a licensed practitioner are not new drugs

under the Act. However, Defendants maintain that compounded drugs fall within the definitions of new drugs found at 21 U.S.C. §§ 321(p)(1) and (v)(1).[1] The new drug definitions state:

> "(p) The term "new drug" means –
>
> (1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof..."

21 U.S.C. § 321(p)(1).

> "(v) The term "new animal drug" means any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed, –
>
> (1) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof..."

21 U.S.C. § 321(v)(1). Taken alone, the new drug definitions might seem to indicate that compound drugs fall within their provisions. However, after examining relevant case and

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[1] When reviewing an agency's interpretation of a statute, a court should look to the plain language of the statute and determine whether the agency construction conflicts with the text. *Supreme Beef Processors, Inc. v. United States Dept. of Ag.*, 275 F.3d 432, 438 (5th Cir. 2001) (citing *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984). Then, "[i]f the agency interpretation is not in conflict with the plain language of the statute, deference is due." *Id.* Additionally, "[t]he judiciary is the final authority on issues of statutory construction and must reject administrative constructions which are contrary to clear congressional intent." *Chevron U.S.A.*, 467 U.S. at 843 n. 9. This Court has afforded the appropriate deference to the FDA's interpretation of the statutory provisions at issue in this case. For the reasons contained in this Order, however, this Court rejects the FDA's construction of those statutes.

statutory law, as well as legislative intent, this Court finds that compound drugs are implicitly exempt from the new drug definitions contained in § 321.

a. 21 U.S.C. § 353a

In 1997, Congress enacted the Food and Drug Administration Modernization Act of 1997 ("FDAMA"). In doing so, § 127(a) of FDAMA was codified and added to the Act under 21 U.S.C. § 353a. At the time it was enacted, Section 353a declared:

"a) In general

> Sections 351(a)(2)(B), 352(f)(1), and 355 of this title shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the unsolicited receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient, if the drug product meets the requirements of this section, and if the compounding –
>
> (1) is by –
>
> > (A) a licensed pharmacist in a State licensed pharmacy or a Federal facility, or
> >
> > (B) a licensed physician,
> >
> > on the prescription order for such individual patient made by a licensed physician or other licensed practitioner authorized by State law to prescribe drugs; or
>
> (2) (A) is by a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient; and
>
> > (B) is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between –
> >
> > > (I) the licensed pharmacist or licensed physician; and
> > >
> > > (ii) (I) such individual patient for whom the prescription order will be provided; or

(II) the physician or other licensed practitioner who will write such prescription order.

(b) Compounded drug

(1) Licensed pharmacist and licensed physician

A drug product may be compounded under subsection (a) of this section if the licensed pharmacist or licensed physician –

(A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of Title 21 of the Code of Federal Regulations –

(I) that –

(I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

(II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or

(III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (d) of this section;

(ii) that are manufactured by an establishment that is registered under section 360 of this title (including a foreign establishment that is registered under section 360(I) of this title); and

(iii) that are accompanied by valid certificates of analysis for each bulk drug substance;

(B) compounds the drug product using ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

(C) does not compound a drug product that appears on a list published by the Secretary in the Federal Register of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective; and

(D) does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product.

(2) Definition

For purposes of paragraph (1)(D), the term "essentially a copy of a commercially available drug product" does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product.

(3) Drug product

A drug product may be compounded under subsection (a) only if –

(A) such drug product is not a drug product identified by the Secretary by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product; and

(B) such drug product is compounded in a State –

(I) that has entered into a memorandum of understanding with the Secretary which addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State; or

(ii) that has not entered into the memorandum of understanding described in clause (I) and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician.

The Secretary shall, in consultation with the National Association of Boards of Pharmacy, develop a standard memorandum of understanding for use by the States in complying with subparagraph (B)(I).

(c) Advertising and promotion

A drug may be compounded under subsection (a) of this section only if the pharmacy, licensed pharmacist, or licensed physician does not advertise or promote the compounding of any particular drug, class of drug, or type of drug. The pharmacy, licensed pharmacist, or licensed physician may advertise and promote the compounding service provided by the licensed pharmacist or licensed physician.

(d) Regulations

(1) In general

The Secretary shall issue regulations to implement this section. Before issuing regulations to implement subsections (b)(1)(A)(i)(III), (b)(1)(C), or (b)(3)(A) of this section, the Secretary shall convene and consult an advisory committee on compounding unless the Secretary determines that the issuance of such regulations before consultation is necessary to protect the public health. The advisory committee shall include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopoeia, pharmacy, physician, and consumer organizations, and other experts selected by the Secretary.

(2) Limiting compounding

The Secretary, in consultation with the United States Pharmacopoeia Convention, Incorporated, shall promulgate regulations identifying drug substances that may be used in compounding under subsection (b)(1)(A)(i)(III) of this section for which a monograph does not exist or which are not components of drug products approved by the Secretary. The Secretary shall include in the regulation the criteria for such substances, which shall include historical use, reports in peer reviewed medical literature, or other criteria the Secretary may identify.

(e) Application

This section shall not apply to –

(1) compounded positron emission tomography drugs as defined in section 321(ii) of this title; or

(2) radiopharmaceuticals.

(f) "Compounding" defined

As used in this section, the term "compounding" does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling."

Thus, when enacted, § 353a exempted compounded drugs from the FDA's drug approval process, provided that drug compounders complied with various restrictions. These restrictions included refraining from advertising or promoting certain compounded drugs. *See* 21 U.S.C. §§ 353a(a), (c). After the passage of FDAMA, a group of pharmacies that specialized in compounding filed suit, complaining that the provisions of § 353a that restricted advertising and solicitation violated the free speech guarantee provided by the First Amendment to the United States Constitution. *See W. States Med. Ctr. v. Shalala*, 69 F.Supp.2d 1288 (D. Nev. 1999). The District Court for the District of Nevada found that the relevant provisions did violate the First Amendment, however it severed the remaining portions of the statute. *Id.* On appeal, the Ninth Circuit Court of Appeals affirmed in part and reversed in part, holding that the advertisement and solicitation provisions were unconstitutional, but they were not severable from the remainder of the section. *See W. States Med. Ctr. v. Shalala*, 238 F.3d 1090 (9th Cir. 2001). The United States Supreme Court then granted certiorari, however it only reviewed the free speech issue of the case as the severability issue was not raised before it. *See Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (2002).

Upon review of the case, the Supreme Court found that subsections (a) and (c) of § 353a did violate the free speech guarantee of the Constitution of the United States. *Id.* However, the Court unequivocally stated that it was not reviewing the Court of Appeals' conclusion regarding severability. *See* 535 U.S. at 360 ("We therefore only address the constitutional question, having

no occasion to review the Court of Appeals' severability determination"); *Id.* at 366 ("Because neither party petitioned for certiorari on the severability issue, we have no occasion to review that portion of the Court of Appeals' decision"). Moreover, the majority's concluding sentence of the opinion declared "we affirm the Court of Appeals' judgment that the speech-related provisions of FDAMA § 127(a) are unconstitutional." *Id.* at 377. The holding of the Supreme Court was limited to adjudging §§ 353a(a) and (c) unconstitutional, and the issue of whether the remainder of the statute was severable was not considered. Thus, the last court to rule on the severability issue was the Ninth Circuit Court of Appeals.

Although the Ninth Circuit ruled that the remaining portions of § 353a were not severable from the provisions regarding solicitation and advertising, this Court is not bound by that determination as "the Fifth Circuit is in no way bound by decisions rendered by other circuits." *United States v. Dawson*, 576 F.2d 656, 659 (5th Cir. 1978). Rather, the opinions of sister circuits are only considered persuasive authority. *Id.* Additionally, this Court is not alone in recognizing that § 353a has not been declared invalid in its entirety by the Supreme Court. *See United States v. Livdahl*, 2005 WL 3970828 at *8 n. 4 (S.D. Fla. 2005) ("This Circuit has not addressed the issue of whether § 353a is invalid in its entirety based on the unconstitutionality of §§ 353a(a) and (c)"). Therefore, because this Court is not bound by the Ninth Circuit's ruling on severability, it shall now consider whether the remaining provisions of § 353a are still intact.

It is well established that "a court should refrain from invalidating more of the statute than is necessary." *Regan v. Time, Inc.*, 468 U.S. 641, 652 (1984)(plurality opinion). If a statute contains provisions that are severable from the unconstitutional portions, a court shall maintain the statute "so far as it is valid." *Id.* When determining if a statute is severable, a court shall examine the statute to see if the constitutionally permissible portions are "fully operative as a

law." *I.N.S. v. Chadha*, 462 U.S. 919, 934 (1983). If the permissible portions are fully operative as law, any offending portions should be severed "[u]nless it is evident that the Legislature would not have enacted those provisions which are within its power, independently of that which is not." *Id.* In making this determination, a court shall evaluate "whether the statute will function in a *manner* consistent with the intent of Congress." *Alaska Airlines v. Brock*, 480 U.S. 678, 685 (1987). Therefore, a court may invalidate an entire statute only if the remaining portions of the statute cannot operate independently or there is clear evidence that Congress would not have enacted the statute without the portions that have been declared unconstitutional.

However, if Congress has explicitly provided for severance through the inclusion of a severability clause, "the inquiry is eased." *Id.* at 686. The inclusion of a severability clause "creates a presumption that Congress did not intend the validity of the statute in question to depend on the validity of the constitutionally offensive provision." *Id.* (citations omitted). "This presumption may be overcome only by 'strong evidence' that Congress would not have enacted the law without the invalidated portions of the statute." *Koog v. United States*, 79 F.3d 452, 462 (5th Cir. 1996) (citing *Alaska Airlines*, 480 U.S. at 686).

In the Act, Congress included a severability clause which clearly dictates the course of action should part of a statute contained therein be declared unconstitutional. Found in § 391, the severability clause states: "[i]f any provision of this chapter is declared unconstitutional, or the applicability thereof to any person or circumstances is held invalid, the constitutionality of the remainder of the chapter and the applicability thereof to other persons and circumstances shall not be affected thereby." *See* 21 U.S.C. § 391. The existence of this clause creates a presumption that Congress intended the rest of a provision contained within the Act would remain valid if a portion was declared unconstitutional.

In making its determination, the Ninth Circuit relied heavily on the legislative history attached to the passage of FDAMA. However, in the Fifth Circuit, a court "cannot search legislative history for congressional intent unless [it finds] the statute unclear or ambiguous." *In re Abott Labs.*, 51 F.3d 524, 528 (5th Cir. 1995); *see also United States v. Missouri Pac. R.R. Co.*, 278 U.S. 269, 278 (1929) ("[W]here the language of an enactment is clear, and construction according to its terms does not lead to absurd or impracticable consequences, the words employed are to be taken as the final expression of the meaning intended."). In this case, the language of the severability statute contained in the Act is clear and unambiguous. Therefore, the Court finds that the severability statute must be given its full effect. The offending portions of § 353a are severed and the remainder of the statute remains in full effect.[2]

After subsection (a) and (c) of § 353a are severed, the remaining provisions of the section demonstrate that Congress intended to declare that compounding is an approved and legal practice. The existence of the remaining portions of the statute permit pharmacies to compound drugs. Because pharmacies are permitted to compound, this Court finds that any drugs created by the compounding process are authorized under § 353a and are therefore implicitly exempt from the new drug approval process and the definitions found in 21 U.S.C. § 321 (p)(1) and (v)(1).

However, the Court notes that the FDA has raised valid concerns regarding pharmacies that claim to be compounding but in actuality are manufacturing drugs. Thus, pursuant to guidance from the FDA found in Compliance Policy Guideline 460.200, discussed in more detail *infra*, the Court finds that the exemption for compounded drugs from the new drug definition is

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[2] Even assuming *arguendo* that the severability provision in the Act does not control in this case, the Court finds after reviewing the relevant legislative history that its decision would not be altered. The legislative history tied to the passage of § 353a does not overcome the presumption of severability that is created through the existence of the severability clause.

limited to compounds which are made in reasonable quantities upon receipt of a valid prescription for an individual patient from a licensed practitioner. Drugs that are compounded in large quantities before a prescription is received from a doctor do not fall within the narrow exemption this Court finds exists.

b. *Western States*

Although this Court has not been presented with a single case which explicitly declares that compounding is either legal or prohibited, the Supreme Court recognized the practice of compounding in *Western States*. Therein, the Court outlined the history of compounding and acknowledged the importance of the process. Specifically, the Court stated:

> "The Government also has an important interest, however, in permitting the continuation of the practice of compounding so that patients with particular needs may obtain medications suited to those needs. And it would not make sense to require compounded drugs created to meet the unique needs of patients to undergo the testing required for the new drug approval process. Pharmacists do not make enough money from small-scale compounding to make safety and efficacy testing of their compounded drugs economically feasible, so *requiring such testing would force pharmacists to stop providing compounded drugs*."

W. States, 535 U.S. at 369-70 (emphasis added). The language of this case expresses the Supreme Court's acknowledgment of the importance of compounding and the reasons why it is not practical for compounded drugs to be subject to the new drug approval process.

The Court finds that the language of *Western States* demonstrates that compounding is a process that has been approved by the Supreme Court, albeit in dicta. Further, this Court finds that if compounding is a legal activity, then any drugs created through the compounding process must be exempt from the new drug definitions found in the Act. If compounded drugs are not exempt, the drugs would be required to undergo the new drug approval process, which as recognized by the Supreme Court in *Western States*, is not a viable option for compounded drugs.

c. Compliance Policy Guideline 460.200

After the Supreme Court's decision in *Western States*, the FDA issued a revised Compliance Policy Guideline ("CPG") that governed compounding and pharmacies. *See* CPG 460.200. Although CPG 460.200 is more specific than FDAMA, they contain similar provisions. *Wedgewood Village Pharmacy, Inc. v. United States*, 421 F.3d 263, 272 (3rd Cir. 2005). In the CPG, the FDA reiterates its long-standing position that it would not attempt to regulate traditional compounding practices. *See* CPG 460.200. Specifically, the CPG states the "FDA recognizes that pharmacists traditionally have extemporaneously compounded and manipulated reasonable quantities of human drugs upon receipt of a valid prescription for an individually identified patient from a licensed practitioner." *Id.* The CPG further states that this traditional compounding activity is not the subject of this guidance. *Id.* Rather, the CPG focuses on the regulation of pharmacies who manufacture drugs under the guise of compounding. *Id.* Pursuant to the CPG, the FDA shall consider nine different factors in deciding whether an enforcement action is appropriate for a pharmacy that claims it is compounding, but is actually manufacturing. *Id.* The language in CPG 460.200 demonstrates that the FDA draws a line between compounding for an individual patient pursuant to a prescription from a licensed practitioner and compounding that rises to the level of manufacturing. The Court finds this distinction further supports the exemption of compounded drugs from the new drug definitions, if the drugs are created for an individual patient on the basis of a prescription from a licensed practitioner.

d. 21 U.S.C. § 374

Another factor supporting the exemption of drugs that are compounded for an individual patient pursuant to a licensed practitioner's prescription is found in the Act under § 374. Section

374, examined in greater detail *infra*, provides the FDA with authority to inspect pharmacies to insure they are complying with the law. *See* 21 U.S.C. § 374. However, there is an explicit exemption from the inspection of all materials found in a pharmacy if the pharmacy is in compliance with local laws, dispensing drugs pursuant to a prescription from a licensed practitioner in the course of his or her professional practice, and compounding in the regular course of its business. *Id.* The Court finds this freedom from inspections of all materials for pharmacies that compound in the regular course of business demonstrates Congress' intent to carve out a niche for compounded drugs.

e. Public Policy

Finally, public policy supports exempting compounded drugs from the new drug definitions. If compounded drugs were required to undergo the new drug approval process, the result would be that patients needing individually tailored prescriptions would not be able to receive the necessary medication due to the cost and time associated with obtaining approval. When a licensed practitioner writes a prescription for a compounded drug for a patient, the medication is normally needed soon thereafter. It is not feasible, either economically or time-wise, for the needed medications to be subjected to the FDA approval process. It is in the best interest of public health to recognize an exemption for compounded drugs that are created based on a prescription written for an individual patient by a licensed practitioner.

f. Conclusion

In conclusion, this Court finds that compounded drugs, when created for an individual patient pursuant to a prescription from a licensed practitioner, are implicitly exempt from the new drug definitions contained in 21 U.S.C. §§ 321(p)(1) and (v)(1). Plaintiff's Motion for

Summary Judgment is granted on its claim that compounded drugs do not fall under the new drug definitions.

(2) Inspections

Plaintiffs next contend that they, as pharmacies who comply with 21 U.S.C. § 374(a)(2)(A), are exempt from inspections that exceed what is permitted by 21 U.S.C. § 374(a)(1). Further, they request the FDA be banned from bringing prosecutorial, enforcement or punitive actions against any Plaintiff for refusing to allow the FDA to conduct an inspection that exceeds the first sentence of 21 U.S.C. § 374(a)(1). In response, Defendants argue that the Act unequivocally authorizes the FDA to inspect pharmacies.

Section 374(a) of the Act provides that:

> "officers or employees designated by the Secretary....are authorized to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce;...and to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment....and all pertinent equipment, finished and unfinished materials, containers, and labeling therein."

See 21 U.S.C. § 374(a)(1). Additionally, the section provides:

> "[i]n the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, or restricted devices are manufactured, processed, packed, or held, the inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, or restricted devices which are adulterated or misbranded within the meaning of this chapter, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this chapter, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this chapter."

Id. This additional inspection authority is often referred to as the "records provision." *Wedgewood Vill. Pharmacy, Inc.*, 421 F.3d at 269. The records provision authorizes the FDA to search not just records, but any files, papers, processes, controls or facilities if a pharmacy is engaging in certain designated activities. *Id.* However, Congress has specifically exempted certain pharmacies from the enhanced inspection authority contained within the records provision. *Id.* The exemption provides:

> "(2) The provisions of the third sentence of paragraph (1) [the records provision] shall not apply to –
>
> (A) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail..."

Id. § 374(a)(2).

The first sentence of § 374 provides the FDA with a general inspection authority, while the records provision found in the third sentence allows the FDA to engage in enhanced inspections when pharmacies are adulterating or misbranding drugs or restricted devices or otherwise violating the Act. Congress created an exemption from the records provision, though, for pharmacies that (1) conform to applicable local laws that regulate pharmacy, (2) are regularly engaged in dispensing drugs or devices upon receipt of a prescription from a licensed practitioner in the course of his or her practice, and (3) only manufacture, prepare, propagate, *compound*, or process drugs or devices in the regular course of their business of dispensing or selling drugs at retail. *See id.* (emphasis added).

Pursuant to the language of § 374, the FDA has the authority to conduct limited inspections of all pertinent equipment, finished and unfinished materials, containers, and labeling found in pharmacies. However, if a pharmacy is compliant with local laws, and dispenses drugs pursuant to the receipt of a prescription from a licensed practitioner, and compounds in the regular course of its own individualized business, the pharmacy is exempt from the more detailed inspection of the records found in the third sentence of the section. In order to conduct a third sentence inspection of a pharmacy who meets the requirements found in the exemption, the FDA must demonstrate why the pharmacy does not qualify for the exemption.

In this case, the FDA has not demonstrated that any of the ten Plaintiff pharmacies do not qualify for the exemption. Rather, the evidence before the Court establishes that Plaintiff pharmacies all conform with the applicable local laws, dispense drugs pursuant to prescriptions from licensed practitioners and compound drugs in the regular course of their business. Because Plaintiff pharmacies meet the requirements of the exemption, the FDA cannot conduct inspections that exceed the authority granted in the first sentence of 21 U.S.C. § 374. In other words, the FDA is not authorized to carry out the more intrusive records inspection against Plaintiffs unless it demonstrates that they are no longer meeting the requirements set forth in the exemption.[3] Additionally, as long as the pharmacies involved in this case as Plaintiffs continue to meet the requirements of the exemption, the FDA shall not bring prosecutorial, enforcement or punitive actions against them for refusing to allow the FDA to conduct an inspection that exceeds the first sentence of 21 U.S.C. § 374(a)(1). Accordingly, Plaintiff's request for a declaration that the FDA is prohibited from compelling inspections that exceed the grounds set

[3] In making this ruling, the Court limits its holding to the pharmacies involved as Plaintiffs in this case, who have demonstrated that they each comply with the exemption requirements. The ruling does not extend to pharmacies who have not shown they meet the exemption.

forth in the first sentence of 21 U.S.C. § 374(a)(1) of pharmacies that comply with the requirements of 21 U.S.C. § 374(a)(2)(A) is granted only as to the pharmacies who are Plaintiffs in this cause of action.

(3) Compounding from Bulk Ingredients for Non-Food Animals

Plaintiffs maintain that nothing in the Act prohibits them from compounding drugs from bulk ingredients for non-food producing animals. Further, Plaintiffs declare this is an area of regulation for the states. In response, Defendants declare that the use of bulk active pharmaceutical ingredients in the compounding process as it relates to non-food producing animals creates a new drug that is unsafe, adulterated and misbranded under the Act.[4]

a. Unsafe and Adulterated Drugs

Defendants first contend that drugs compounded for non-food animals from bulk ingredients are unsafe under 21 U.S.C. § 360b, and hence adulterated under 21 U.S.C. § 351. Section 360b states "[a] new animal drug shall, with respect to any particular use or intended use of such drug, be deemed unsafe for purposes of section 351(a)(5) of this title unless..." certain requirements related to the filing of a new drug application are met. Section 351(a)(5) declares "[a] drug or device shall be deemed to be adulterated...if it is a new animal drug which is unsafe within the meaning of section 360b of this title."

As this Court declared in the discussion *supra*, compounded drugs do not fall within the new animal drug definition. Because drugs compounded for animal use are not new animal drugs, they do not fall under the provisions of 21 U.S.C. § 360b and thus are not unsafe.

---

[4] Initially, Defendants maintained that the Animal Medicinal Drug Use Clarification Act of 1994 ("AMDUCA") prohibited compounding from bulk ingredients for animal drugs. At the summary judgment stage, however, Defendants abandoned this argument. Therefore, the Court shall not address this issue in depth, other than to recognize that AMDUCA does not prohibit the compounding of animal drugs from bulk-drug ingredients. Rather, AMDUCA permits the extra-label use of certain approved animal drugs.

Moreover, because animal drugs which have been compounded are not unsafe under 21 U.S.C. § 360b, they are not adulterated under 21 U.S.C. § 351.

b. Misbranded Drugs

Next, Defendants declare that drugs compounded from bulk ingredients for non-food animals are prohibited because bulk ingredients are drugs under 21 U.S.C. § 321(g)(1)(D) which are misbranded under 21 U.S.C. § 352. Defendants maintain the drugs are misbranded because they fail to bear adequate directions for use. However, as Defendants recognize in their Motion for Summary Judgment, there is an exemption found in the Regulations relating to the use of bulk ingredients. The regulation found at 21 C.F.R. § 201.122 exempts bulk ingredients from the Act's adequate directions for use requirement unless the finished product is a new drug. This Court found *supra* that drugs compounded for animal use are not new drugs. Thus, 21 C.F.R. § 201.122 exempts the bulk ingredients used in compounding drugs for non-food animals. As such, the Court finds that the Act does not contain a prohibition that prevents the use of bulk ingredients in drugs compounded for non-food animals.

Additionally, the Court finds it should be noted that the misbranding provision found in 21 U.S.C. § 352 does not automatically apply to Plaintiff pharmacies in this case because the evidence demonstrates they are:

> "pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail..."

21 U.S.C. § 360(g)(1). Because Plaintiff pharmacies are compliant, they are not required to register with the Secretary nor are they automatically subject to the misbranding provision. *See* 21 U.S.C. § 352(o).

c. *Containers* and *Algon*

Finally, the parties debate at length whether the cases of *United States v. 9-1 Kg. Containers*, 854 F.2d 173 (7th Cir. 1988) and *United States v. Algon Chem., Inc.*, 879 F.2d 1154 (3rd Cir. 1989) prevent pharmacies that are deemed compliant under 21 § U.S.C. 360(g)(1) from compounding using bulk ingredients. After duly considering both cases, this Court finds that *Containers* and *Algon* are distinguishable from the case now before it. Those cases involved bulk drug suppliers who were providing bulk drugs directly to veterinarians. Suppliers and veterinarians are not afforded the protections that compliant, compounding pharmacies are given under the Act. As long as compliant pharmacies are compounding drugs for non-food animals with legal bulk ingredients, they comport with the Act. That is the case with Plaintiffs in this case, who are all compliant pharmacies. If, however, pharmacies use illegal bulk ingredients when compounding for non-food animals, they lose the protections afforded by the Act and are subject to enforcement actions.

d. Conclusion

In conclusion, this Court finds that pharmacies may compound drugs for non-food animals from legal bulk ingredients. Drugs compounded from legal bulk ingredients do not violate the Act's unsafe, adulterated or misbranded provisions. Plaintiffs' Motion for Summary Judgment is accordingly granted on this claim.

(4) Compliance Policy Guideline 608.400 and the Notice

Plaintiffs assert that the CPG and Notice at issue in this case misstate the law and violate the Administrative Procedures Act. To the contrary, Defendants contend that the CPG and the Notice are not substantive rules and therefore do not require notice and comment rulemaking. The specific CPG about which Plaintiffs complain in this case is CPG 608.400. CPG 608.400 prohibits the compounding of drugs for non-food animals from bulk ingredients. The Notice at issue was sent on April 2, 2004, to all United States Boards of Pharmacy from the Director of the Office of Compliance for the FDA Center for Veterinary Medicine. The Notice declared that pharmacy compounding from bulk ingredients for non-food animals is illegal.

The Administrative Procedures Act requires that substantive or legislative rules, which have the force and effect of law, are subject to the APA's notice-and-comment rulemaking requirements. *See* 5 U.S.C. § 553(b). Exempt from the notice-and-comment requirements are "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice." 5 U.S.C. § 553(b)(A). However, "if a rule is 'substantive,' the exemption is inapplicable, and the full panoply of notice-and-comment requirements must be adhered to scrupulously. The 'APA's notice and comment exemptions must be narrowly construed.'" *Prof'ls and Patients for Customized Care v. Shalala*, 56 F.3d 592, 595 (5th Cir. 1995). Courts of the Fifth Circuit have long recognized that CPG's are not substantive rules, and thus are exempt from the notice-and-comment requirements. *See Prof'ls and Patients for Customized Care; Se. Minerals, Inc. v. Harris*, 622 F.2d 758 (5th Cir. 1980); and *Cowdin v. Young*, 681 F.Supp. 366, 370 (W.D. La. 1987).

After careful consideration of CPG 608.400 and the Notice, this Court finds that they are not substantive rules. The CPG clearly states that it is not binding on the FDA or the public, and

that it merely reflects the FDA's current thinking on what might be subject to an enforcement action. Similarly, the Notice was issued to the States as a request for assistance with potential FDA inspections of pharmacies. The Court finds that neither of these documents contain new substantive rules, and thus neither were subject to the APA's notice-and-comment procedures.

However, despite the fact that CPG 608.400 and the Notice were not subject to notice-and-comment, and therefore will neither will be stricken, the Court finds that they do not fully comport with the instant Order. To the extent that they contradict the rulings contained herein, the FDA shall no longer be permitted to enforce those portions of CPG 608.400 and the Notice. The balance of the CPG and the Notice shall remain in effect. Thus, the Defendants' Motion for Summary Judgment is granted in part, as the Court finds the CPG and Notice were not subject to the APA's notice-and-comment procedures. Plaintiffs' Motion for Summary Judgment is granted in part, as the Defendants shall no longer be permitted to enforce the portions of the CPG and Notice which conflict with the instant Order.

(5) Injunctions

Plaintiffs have requested injunctions against Defendants to prevent them from (1) declaring that compounded drugs are new drugs or new animal drugs, (2) engaging in inspections that exceed the subjects enunciated in the first sentence of 21 U.S.C. § 374(a)(1) of pharmacies that are in good standing with their respective State boards of pharmacy and have met the Exemption Criteria, (3) enforcing its current Compliance Policy Guideline which unilaterally declares that compounding from bulk ingredients for non-food animals is illegal, (4) prohibiting Plaintiffs or similarly situated pharmacies from receiving bulk ingredients, and (5) bringing prosecutorial, enforcement or punitive actions against any Plaintiffs for refusing to allow the FDA to conduct inspections exceeding the first sentence of 21 U.S.C. § 374(a)(1) of

their pharmacies, pursuant to 21 U.S.C. § 374(a)(2)(A), absent independent evidence from the relevant State boards of pharmacy that Plaintiffs are non-compliant. Defendants, in response, argue that there is no legal or factual basis to support the entering of any injunction in this case.

At this time, the Court finds that it is not appropriate to enter injunctions that would amount to pre-enforcement review of FDA actions. *See Southeastern Minerals, Inc. v. Harris*, 622 F.2d 758 (5th Cir. 1980). However, the parties are advised that Plaintiffs' requests for injunctions are denied without prejudice. If in the future Defendants continue to violate the Act, Plaintiffs may re-urge their requests for injunctions and the Court shall consider the petition at that time. Therefore, Plaintiffs' requests for an injunction, contained within their Motion for Summary Judgment, is denied without prejudice. Defendants' request that the injunctions be denied is granted, with the caveat that Plaintiffs shall be permitted to resubmit their requests for injunctions if Defendants continue to violate the Act.

CONCLUSION

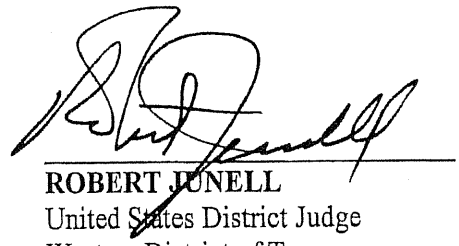
Based on the above-stated reasoning, Plaintiffs' Motion for Summary Judgment is granted in part and denied in part, and Defendants' Motion for Summary Judgment is granted in part and denied in part. Accordingly,

It is **HEREBY ORDERED** that Plaintiffs' Motion Summary Judgment is **GRANTED IN PART**.

It is **FURTHER ORDERED** that Plaintiffs' Motion for Summary Judgment is **DENIED IN PART**, in that the requests for injunctions are denied without prejudice.

It is **FURTHER ORDERED** that Defendants' Motion for Summary Judgment is **GRANTED IN PART AND DENIED IN PART.**

SIGNED this 30 day of **AUGUST, 2006.**



ROBERT JUNELL
United States District Judge
Western District of Texas

Attachment 6

Transfer of NAPLEX Scores to Other States

nabp

National Association of Boards of Pharmacy

1600 Feehanville Drive • Mount Prospect, IL 60056-6014
Tel: 847/391-4406 • Fax: 847/391-4502
Web Site: www.nabp.net

TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: Mary A. Dickson, Associate Executive Director MAD

DATE: March 31, 2006

RE: State Restrictions for Licensure Transfer

As a follow-up to the Licensure Transfer Process Memo sent on March 10, 2006, NABP would like to take this opportunity to share restrictions that apply to an applicant when reciprocating to a jurisdiction using a particular license. Most states **do** reciprocate with each other; however, several states do not allow an applicant to transfer when using a particular license for the basis of transfer.

Currently the following 17 jurisdictions do **not** allow transfer when using a **Florida** license for the basis of transfer:

Alabama	Louisiana	Oregon
Arkansas	Minnesota	Tennessee
Connecticut	Nevada	West Virginia
Georgia	North Carolina	Wyoming
Hawaii	Ohio	
Idaho	Oklahoma	

Currently the following 26 jurisdictions do **not** allow transfer when using a **California** license for the basis of transfer:

Alabama	Idaho	Maryland	Oklahoma	West Virginia
Arkansas	Indiana	Mississippi	Pennsylvania	Wyoming
Colorado	Iowa	Montana	Rhode Island	
Connecticut	Kentucky	Nevada	Utah	
District of Columbia	Louisiana	New Jersey	Vermont	
Georgia	Maine	North Carolina	Washington	

With the recent Bylaw change (effective May 23, 2005); licensure transfer applicants will no longer be required to maintain the license that was required by original examination in order to transfer into some jurisdictions. A recent survey conducted by NABP on September 16, 2005, indicates that this is not the case for all jurisdictions.

Currently the following 20 jurisdictions will require licensure transfer applicants to maintain their license by original examination:

Alabama	District of Columbia	Missouri	New York	South Carolina
Alaska	Kentucky	Nevada	North Dakota	South Dakota
Arizona	Louisiana	New Hampshire	Oklahoma	West Virginia
Arkansas	Maine	New Jersey	Oregon	Wyoming

* Please note: not all jurisdictions replied to the survey, and some decisions are pending.

Currently the following 21 jurisdictions will not require licensure transfer applicants to maintain their license by original examination, but the licensure transfer applicant must have a license in good standing from a member board of pharmacy and transferred their license through the NABP Clearinghouse:

California	Illinois	Massachusetts	Nebraska	Texas	Wisconsin
Delaware	Indiana	Minnesota	Ohio	Utah	
Georgia	Iowa	Mississippi	Puerto Rico	Vermont	
Idaho	Maryland	Montana	Rhode Island	Virginia	

* Please note: not all jurisdictions replied to the survey, and some decisions are pending.

We hope you find this information helpful to understanding the license transfer restrictions posed on licensure transfer applicants. If you have any questions about the restrictions, please contact me via phone at 847/391-4400 or 1-800/774-6227 or via e-mail at mdickson@nabp.net. Thank you.

cc: NABP Executive Committee
Carmen A. Catizone, Executive Director/Secretary

Attachment 7

Summary of the Licensing Committee Meeting of September 20, 2006

California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
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www.pharmacy.ca.gov

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

Licensing Committee

Meeting Summary
September 20, 2006

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

Present: Ruth Conroy, PharmD, Chairperson
Clarence Hiura, PharmD, Board Member
Susan Ravnan, PharmD, Board Member

Virginia Herold, Interim Executive Officer
Karen Cates, Assistant Executive Officer
Joshua Room, Deputy Attorney General
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Joan Coyne, Supervising Inspector

Chairperson Conroy called the meeting to order at 9:30 a.m.

ACPE Celebrates Its75 Birthday

The committee viewed a brief video-montage DVD prepared by the Accreditation Council for Pharmacy Education, showing the history of this organization since its formation 75 years ago. The pictorial review showed changes in pharmacy over this period.

Request to Add the Exam for the Certification of Pharmacy Technicians as a Qualifying Methods for Pharmacy Technician Registration

Kenneth W. Schafermeyer, PhD, RPh, Director of Education for the Institute for the Certification of Pharmacy Technicians, provided an overview of the development of a new certification examination for pharmacy technicians.

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.

A new pharmacy technician examination has been brought to the board's attention, the Exam for the Certification of Pharmacy Technicians (ExCPT).

The ExCPT is now accepted by Connecticut, New Jersey, Minnesota, Oregon and Virginia as a qualifying route for registration. The exam is computer administered six or seven days a week in 700 locations nationwide. The National Community Pharmacists Association and the National Association of Chain Drug Stores support use of the exam, and were involved in its development.

Dr. Schafermeyer distributed a number of documents describing the ExCPT. He stated that of the 26 states that require registration of pharmacy technicians, 11 have agreed to use the ExCPT examination as a qualifying route to registration (in several of these states the approval is proceeding but is still pending).

Dr. Schafermeyer stated that the ExCPT is a 100-question, multiple-choice examination. He described how the ExCPT is developed and validated using a job analysis and content outline. He identified the expert examiners for the test, and stated that the exam is psychometrically validated. He said that individuals can apply to take the examination approximately 48 hours before actually taking it at a scheduled time and location, and they must be at least 18 and have a high school diploma or GED. Candidates with a drug-related felony cannot be certified.

Board members and those in the audience asked a number of questions about the ExCPT, which is a competing exam of the PTCB exam.

The committee asked staff to review the ExCPT and see if it meets the requirements of Business and Professions Code section 139, which establishes requirements for examination programs for California-licensed occupations.

Staff will collect and compile this information and provide a report to a future meeting of the Licensing Committee. Meanwhile Dr. Schafermeyer will be offered the opportunity to present an overview of the examination to the board at the October 25th meeting.

Should the board approve the use of the ExCPT, a statutory modification to Business and Professions Code section 4202 would be required.

Emergency Preparedness for California Pharmacy

Dana Grau, PharmD, of the Emergency Preparedness Office, Emergency Pharmaceutical Services Unit in the Department of Health Services, provided

information about planning and preparing for disaster response. His office exists to protect the health of Californians against large-scale public health emergences, including bioterrorism attacks, nuclear attacks, disease outbreaks such as pandemic influenza as well as natural disasters such as those caused by hurricanes and earthquakes. Dr. Grau stated that his office is a conduit for the receiving resources of the Strategic National Stockpile from the Centers for Disease Control.

Dr. Grau described the Strategic National Stockpile as a national repository of antibiotics, chemical antidotes, antitoxins, life-support medications, IV administration, airway maintenance supplies and medical /surgical items. The stockpile will supplement and re-supply state and public agencies for any emergency, anywhere at anytime within the US. The stockpile is shipped to the designated location within 12 hours. Additional shipments arrive, if needed, within 24 to 36 hours. When necessary, the inventory of the stockpile can be modified to contain only several pharmaceuticals.

These drugs will need to be stored in a single state warehouse, depending upon where the disaster is located, and the DHS wants to be certain that the location, which would be secret, would be licensed.

In the event of a bioterrorism event, mass dispensing of medications to large numbers of asymptomatic people will occur at points of dispensing (PODs), allowing hospitals to treat the ill. Plans are to provide medications, such as antibiotics, to 100 percent of the identified population within 48 hours.

Large numbers of licensed individuals, such as pharmacists and nurses will be used to provide mass dispensing of the medications.

Dr. Grau stated that getting medications from the single state warehouse into the hands of the people who need them is a tremendous challenge to protect the public.

Dr. Grau stated that the DHS has identified potential warehouse locations throughout California from which the Strategic National Stockpile can be deployed. The actual site used will depend on the location and scope of the emergency. None of these sites is yet licensed as a drug wholesaler, and some may not meet all requirements of a licensed wholesaler. The permit for the site would be requested for activation upon the management decision of the DHS.

Additionally, local health departments are locating potential sites that can be used to receive, store and stage drugs and medical supplies delivered from the state warehouse site and to the PODs.

The DHS provided a list of 11 questions to frame the discussion for a system under which medications can be shipped, stored and distributed in the event of a declared disaster, most of which are not authorized within existing law for nonemergency drug distribution. These questions will be explored with the DHS and in a future Licensing Committee meeting.

Dr. Grau also asked for the board's assistance in publicizing training and preregistration of pharmacists, pharmacy technicians and pharmacist interns for disaster response. Concern about possible liability and violating state pharmacy laws is a concern keeping many pharmacists from becoming involved in this area.

The committee strongly noted its support to work with the DHS to aid in planning for disaster response. The first step will be the development of a policy statement that will be publicly released, placed on the board's Web site and highlighted in the next board newsletter.

The committee directed that this statement be provided to the board for action at the October meeting.

An Overview of 340B Drug Programs

Chairperson Conroy directed the committee to materials in the packet describing 340 B Drugs. The material was provided for information only, and was not an endorsement of the provider's program.

Transfers of NAPLEX Scores to Other States

At the July Board Meeting, the board directed that staff determine why 26 states will not accept NAPLEX scores earned in California if later the pharmacists wish to transfer the score to become licensed in that state.

Ms. Herold stated the review has not yet been started but will be completed and shared with the committee in December. Ms. Herold added that she had contacted the NABP for its insight, and was advised that::

1. California's acceptance of NAPLEX scores only if earned after January 1, 2004, may account for much of the reason why California scores are not accepted by these states; essentially because California does not fully accept NAPLEX scores earned by their pharmacists, but instead requires retaking the NAPLEX for many of a state's already licensed pharmacists.
2. Misunderstanding about what exams California will accept from their states (e.g., requiring passing of the old California licensure exam).

The NABP believes that education about California's requirements may help resolve some of this problem. Ms. Herold will contact these states one at a time to conduct the survey and hopes to provide education as well as obtain information.

Foreign Pharmacy Graduate Equivalency Commission Certifications

California law requires foreign-educated pharmacists to be certified by the Foreign Graduate Equivalency Commission (FPGEC) to satisfy the educational equivalency requirement with that of domestic pharmacy school graduates.

Since 1991, California has required foreign-educated pharmacists to pass the Test of Spoken English (TSE) as a condition of taking the pharmacist licensure examination. The TSE is administered by Educational Testing Service worldwide, and has been validated to assess the spoken English proficiency of those for whom English is not their original language.

In 1997, the FPGEC began requiring a TSE score of 50 as a component of FPGEC certification. Recognizing the duplication of this requirement with California's requirement, California law was amended in the late 1990s to require foreign-educated candidates who became FPGEC certified before January 1, 1998 to continue to provide a passing score on the TSE, but those certified after this date need to provide a TSE score directly to the board (due to the FPGEC's TSE requirement).

In a few months, Educational Testing Service will no longer administer the TSE, but instead rolled these requirements into the TOEFL iBT exam. The FPGEC has begun accepting the TOEFL iBT exam as part of its requirements to become FPGEC certified.

However, in recent months, the board has heard from several foreign-educated pharmacists who became FPGEC certified before 1998, and thus are required to complete the TSE requirement. However, these applicants have been unable to pass the TSE. The applicants have expressed concern about how they will qualify to take the pharmacist licensure examination in California if the TSE is no longer administered.

The FPGEC has agreed to recertify these individuals who have not earned a passing TSE upon passage of the TOEFL iBT.

Update on AB 595 on Compounding by Pharmacies and Recent Action by the US District Court, Western District of Texas

Ms. Herold updated the committee on the status of AB 595 – and why the bill was dropped in the closing moments of the 2006 Legislative Session. Assembly Bill 595 was sponsored by the board, and would have established requirements for pharmacies that compound medication. One provision would have allowed pharmacies to contract with other pharmacies to obtain compounded medication, if the pharmacy had a patient-specific prescription for the compounded medication. The Department of Health Services was opposed to this provision, and in May submitted amendments that would have required a separate licensure program with annual inspections for any pharmacy that compounded medications for another pharmacy pursuant to a contract. Instead, the board developed amendments in attempts to remove the opposition of the DHS that were amended into the bill formally in late August. However, once the amendments appeared in print, Kaiser Permanente, the California Pharmacists Association and Grandpa's Pharmacy opposed the bill. At this point, AB 595 was dropped. Meanwhile in Texas, a US District Court decision restricted the FDA's regulation of pharmacy compounding based on a lawsuit filed by several Texas pharmacies.

During the Licensing Committee Meeting, Deputy Attorney General Joshua Room provided an overview of the likely minimal impact the Texas decision might have upon California. He walked the committee through the decision and the somewhat confusing law as to pharmacy compounding, an area of overlapping and complementary jurisdictions between the federal government (which licenses and regulates manufacturers, along with counterparts in the states) and the states (which license and regulate pharmacies and pharmacists).

> In a decision on cross-summary judgment motions issued August 30, 2006, U.S. District Court Judge Hon. Robert Junell (Western District of Texas) reached three primary conclusions: (a) drugs compounded by a pharmacist for an individual patient pursuant to a prescription from a licensed practitioner are implicitly exempt from the definitions of "new drug" in 21 U.S.C. § 321(p)(1) and (v)(1) (and are therefore not required to be the subject of new drug applications/approvals before being provided to patients); (b) so long as the compounding pharmacies (1) conform to applicable local laws that regulate pharmacy, (2) are regularly engaged in dispensing drugs or devices upon receipt of a prescription from a licensed practitioner in the course of his or her practice, and (3) only manufacture, prepare, propagate, compound, or process drugs/devices in the regular course of their business of dispensing or selling drugs at retail, they are exempted by the language of 21 U.S.C. § 374(a)(2) from the more detailed inspection of records authorized by the third sentence of 21 U.S.C. § 374 (the "records inspection"), though they are still subject to the more general (facilities) inspection authorized by the first sentence of 21 U.S.C. § 374; and (c) pharmacies may compound drugs for non-food animals from legal bulk ingredients (contrary to FDA CPG 608.400 and a Notice distributed to Boards of Pharmacy by the FDA on April 2, 2004).
>
> For conclusions (a) and (c), Judge Junell relied heavily on language in 21 U.S.C. § 353a exempting those drugs compounded by pharmacists under the conditions outlined in Section 353a (basically, pursuant to an individual prescription arising from an established physician-patient relationship) from the requirements of Sections 351(a)(2)(B) [drug adulterated if not produced in conformity with good manufacturing practices], 352(f)(1) [drug misbranded unless label has adequate directions for use], and 355 [necessity of new drug application before introducing new drug into interstate commerce]. Section 353a was added in 1997 by the Food and Drug Modernization Act (FDAMA). As enacted, Section 353a also included prohibitions on pharmacy or pharmacist advertising or promotion of compounded drugs. Those prohibitions were almost immediately struck down by a federal District Court on First Amendment grounds, though at the District Court level the remainder of Section 353a was left standing (severed). However, when the case got to the Ninth Circuit U.S. Court of Appeal (which

covers California, Nevada, Oregon, Washington, etc.), the Ninth Circuit said these provisions were not severable and invalidated ALL of Section 353a. The case was subsequently appealed to the U.S. Supreme Court (Thompson v. Western States Medical Center, 535 U.S. 357 (2002)), but ONLY on the question of the validity of the provisions struck down (and not on the severability question). The U.S. Supreme Court affirmed the invalidation of the prohibitions on advertising and promotion on First Amendment grounds, but did not address the question of severability of these provisions from the remainder of Section 353a.

So, the continuing validity of Section 353a is left in a somewhat confusing limbo, as it has been invalidated entirely within the Ninth Circuit (the Ninth Circuit's decision is binding on any federal court in California, Nevada, etc.), but not elsewhere. The Western District of Texas is within the jurisdiction of the Fifth Circuit U.S. Court of Appeal. As Judge Junell pointed out, he was not bound to abide by the Ninth Circuit's invalidation of ALL of Section 353a. He chose not to follow that decision, and concluded that the provisions of Section 353a other than the prohibitions on advertising and promotion were severable, and remained in effect. It was in reliance on those "other" provisions that he reached the conclusions that he did.

Within California (or elsewhere within Ninth Circuit jurisdiction), however, Judge Junell's decision is of limited effect. First, as a general rule, a federal District Court order is enforceable and binding only as to the case in which the order is issued, and as to the parties involved in that case. Though it might be PERSUASIVE to another District Court hearing a similar case, in the absence of some special circumstances (e.g., a nationwide class action, or order otherwise applied more generally), an order by a District Court is not binding even on another Judge in the same District Court, let alone on a Court in another jurisdiction, for instance in California. There is nothing in this order that suggests this order is binding on anyone other than these ten plaintiffs, and the FDA with regard to its interpretation or enforcement of the laws as to these ten plaintiffs.

Second, application of this decision as even PERSUASIVE authority in a federal District Court in California (or elsewhere in the Ninth Circuit) is very unlikely given that the decision relies on a rejection of the Ninth Circuit's decision not to sever the rest of Section 353a from the provisions found to violate the First Amendment. A District Court anywhere in the Ninth Circuit would not have that option, as it would be bound to follow the Ninth Circuit's decision invalidating all of Section 353a. Though it is possible that a District Court could conclude that Section 353a, despite its invalidation, reflects Congressional intent and

thus should be used as a tool for interpreting other sections within the FDA's jurisdiction (e.g., 21 U.S.C. § 321), that is unlikely.

Therefore, if a similar case were to arise in a District Court in California (or anywhere in the country, including in the Western District of Texas), there is no requirement that the Judge in that case follow the decision issued by Judge Junell. This is not to say that this decision may not be persuasive to another judge facing a similar issue. However, this decision is not "law" within the State of California, and on the same facts another judge might reach the opposite conclusion. Likewise, there is at least theoretically nothing preventing the FDA, despite this decision, from seeking to enforce "new drug" provisions against a compounding pharmacy in California or attempting to pursue inspections under the "records provision" of 21 U.S.C. § 374. However, the FDA will probably take this decision into account in deciding whether to do so, because it will almost certainly be raised by any pharmacy challenging such action as persuasive authority as to the FDA's action(s).

Doug Wills of Grandpa's Pharmacy, asked for the board's assistance in pursuing enactment of a new version of AB 595 in the next Legislative Session. Ms. Herold stated that the board would review and take a position on the bill that the profession introduces and sponsors. She added that the board still has regulations pending that were developed in 2004 as part of the Compounding Task Force that the board may take up in the interim.

Competency Committee Report

Ms. Herold stated that a quality assurance review of the exam started in mid-August and should be completed before mid-October, when release of CPJE scores will resume.

The Department of Consumer Affairs has a contract for test administration services used by a number of regulatory entities in the department for occupational license testing. It is through this contract that the board administers the CPJE. The contract is set to expire in December 2006, but monthly extensions will be available for several months. Unless a new contract is in place, the board may be unable to use these test facilities for the CPJE after all extensions have run out (Spring 2007). A new request for proposals has been released, and a contract should be awarded on October 20; however, several prior contracts awarded for this service have been appealed and the contracting process has been invalidated. The board continues to watch this process closely.

The Competency Committee met for its annual work and planning session in August. New members have been added to the committee so that the committee could be split into two groups. This will reduce the time commitment and work required of each

committee member, who have actually had to work more to produce the new CPJE exam than they did on the old exam.

Attachment 8

CPJE Test Scores
April 1 – September 30, 2006

Board Data for All CPJE Candidates taking examination 4/1/06 through 9/30/06

Overall Pass Rates

CPJE

		Frequency	Percent
Valid	F	196	19.8
	P	796	80.2
	Total	992	100.0

NAPLEX

		Frequency	Percent
Valid	F	53	5.5
	P	905	94.5
	Total	958	100.0

Location of School

CPJE

			JPE		JPE Total	NAPLEX		NAPLEX Total
			Fail	Pass		Fail	Pass	
School	California	Count	38	548	586	5	575	580
		% within PF	6.5%	93.5%	100.0%	0.9%	99.1%	100.0%
	Other US	Count	99	199	298	28	249	277
		% within PF	33.2%	66.8%	100.0%	10.1%	89.9%	100.0%
	Foreign	Count	58	49	107	19	81	100
		% within PF	54.2%	45.8%	100.0%	19.0%	81.0%	100.0%
	Unclassified	Count	1	0	1	1	0	1
		% within PF	100.0 %	.0%	100.0%	100.0%	.0%	100.0%
Total		Count	196	796	992	53	905	958
		% within PF	19.8%	80.2%	100.0%	5.5%	94.5%	100.0%

Gender

			JPE pass fail status		JPE Total	NAPLEX pass fail status		NAPLEX Total
			Fail	Pass		Fail	Pass	
gender	F	Count	122	562	684	31	638	669
		% within PF	17.8%	82.2%	100.0%	4.6%	95.4%	100.0%
	M	Count	74	234	308	22	267	289
		% within PF	24.0%	76.0%	100.0%	7.6%	92.4%	100.0%
Total		Count	196	796	992	53	905	958
		% within PF	19.8%	80.2%	100.0%	5.5%	94.5%	100.0%

Degree

			JPE pass fail status		JPE Total	NAPLEX pass fail status		NAPLEX Total
			Fail	Pass		Fail	Pass	
degree awarded	BS Pharmacy	Count	69	54	123	24	90	114
		% within PF	56.1%	43.9%	100.0%	21.1%	78.9%	100.0%
	Pharm D.	Count	127	742	869	29	815	844
		% within PF	14.6%	85.4%	100.0%	3.4%	96.6%	100.0%
Total		Count	196	796	992	53	905	958
		% within PF	19.8%	80.2%	100.0%	5.5%	94.5%	100.0%

California Schools

			JPE pass fail status		JPE Total	NAPLEX pass fail status		NAPLEX Total
			Fail	Pass		Fail	Pass	
school	UCSF	Count	9	110	119	0	118	118
		% within PF	7.6%	92.4%	100.0%	.0%	100.0%	100.0%
	UOP	Count	12	150	162	2	157	159
		% within PF	7.4%	92.6%	100.0%	1.3%	98.7%	100.0%
	USC	Count	8	155	163	1	160	161
		% within PF	5.0%	95.0%	100.0%	0.6%	99.4%	100.0%
	Western	Count	6	91	97	2	95	97
		% within PF	6.2%	93.8%	100.0%	2.1%	97.9%	100.0%
	Loma Linda	Count	1	23	24	0	24	24
		% within PF	4.2%	95.8%	100.0%	.0%	100.0%	100.0%
	UCSD	Count	2	19	21	0	21	21
		% within PF	9.5%	90.5%	100.0%	.0%	100.0%	100.0%
Total		Count	38	548	586	5	575	580
		% within PF	6.5%	93.5%	100.0%	0.9%	99.1%	100.0%

US Schools of Pharmacy

	JPE pass fail status		Total
	F	P	
Auburn	0	2	2
U of AZ	0	4	4
UCSF	9	110	119
U of Pacific	12	150	162
USC	8	155	163
U of CO	0	3	3
U of Conn	1	1	2
Howard DC	1	3	4
FL A&M	1	1	2
U of FL	0	6	6
Mercer	0	2	2
U of GA	1	5	6
Idaho SU	3	3	6
U of IL Chi	1	8	9
Purdue	0	1	1
Drake	1	3	4
U of IA	0	4	4
U of KS	1	4	5
U of KY	0	1	1
NE LA U	1	0	1
Xavier	0	1	1
U of MD	2	6	8
MA Col Pharm	16	16	32
NE-MA	1	1	2
Ferris	0	2	2
U of MI	2	0	2
Wayne SU	2	2	4
U of MN	1	1	2
St. Louis Col of PH	3	0	3
UMKC	0	2	2
Creighton	10	13	23
U of NE	1	2	3
Rutgers	1	0	1
U of NM	4	3	7
Western	6	91	97
Midwestern U Chicago	0	2	2
A&M Schwartz	6	6	12
St. Johns	0	4	4
SUNY-Buff	0	1	1

	JPE pass fail status		Total
	F	P	
Union U	2	2	4
UNC	2	1	3
OH Northern U	1	2	3
OH State U	2	2	4
SW OK State	0	1	1
OR State U	1	5	6
Duquesne	1	0	1
Phl C of Pharm	3	4	7
Temple	2	6	8
U of Pitt	0	1	1
U of RI	0	1	1
Med U of SC	0	2	2
U of SC	1	1	2
U of TN	0	1	1
TX SO U	0	1	1
U of Hous	2	3	5
U of TX	1	2	3
Med C of VA	0	3	3
U of WA	1	8	9
WA State U	0	4	4
U of WI-Mad	0	2	2
Campbell U	0	1	1
Nova Southeastern	1	2	3
Texas Tech	0	2	2
Bernard J Dunn	0	1	1
Midwestern AZ	2	2	4
Nevada College of Pharmacy	15	23	38
Loma Linda University	1	23	24
UCSD	2	19	21
MA School of Pharmacy - Worcester	1	1	2
Palm Beach Atlantic University	1	1	2
Lake Erie Col	0	1	1
unclassified	1	0	1
Other/FG	58	49	107
	196	796	992

Graduating school location by country

	JPE pass fail status		Total
	F	P	
Armenia	0	1	1
Brazil	0	1	1
Canada	1	2	3
China	1	0	1
Egypt	3	8	11
France	1	0	1
United Kingdom	0	1	1
Israel/West Bank/Gaza Strip	0	1	1
India	22	10	32
Iran	1	1	2
Italy	2	0	2
Jordan	0	1	1
Korea (N&S)	3	5	8
Nigeria/New Guinea	3	0	3
Peru	0	1	1
Philippines	9	4	13
Paracel Is	0	1	1
Pakistan	2	1	3
Poland	1	0	1
USSR	1	0	1
Syria	0	1	1
Thailand	0	1	1
Taiwan	1	2	3
USA	139	749	888
Venezuela	2	0	2
Vietnam	1	0	1
Yugoslavia	0	1	1
South Africa	2	4	6
UK	1	0	1
Total	196	796	992

Licensing Statistics

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											267
Pharmacist (initial licensing applications)	5	405											410
Intern pharmacist	31	471											502
Pharmacy technician	450	574											1024
Pharmacy	18	46	44										108
Sterile Compounding	1	7	2										10
Clinics	2	8	13										23
Hospitals	2	2	2										6
Nonresident Pharmacy	3	4	0										7
Licensed Correctional Facility	0	0	0										0
Hypodermic Needle and Syringes	2	2	0										4
Nonresident Wholesalers	6	17	8										31
Wholesalers	5	4	3										12
Veterinary Food-Animal Drug Retailer	0	0	0										0
Designated Representatives	20	50	23										93
Issued													
Pharmacist	115	276	141										532
Intern pharmacist	36	245	243										524
Pharmacy technician	646	883	660										2189
Pharmacy	35	24	36										95
Sterile Compounding	5	4	9										18
Clinics	13	10	4										27
Hospitals	0	0	0										0
Nonresident Pharmacy	0	3	2										5
Licensed Correctional Facility	0	0	0										0
Hypodermic Needle and Syringes	0	0	0										0
Nonresident Wholesalers	5	3	1										9
Wholesalers	1	1	1										3
Veterinary Food-Animal Drug Retailer	0	0	0										0
Designated Representatives	17	1	24										42

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										
Intern pharmacist	u/a	u/a	371										
Pharmacy technician	974	845	878										
Pharmacy	39	55	49										49
Sterile Compounding	33	34	33										33
Clinics	57	56	52										52
Hospitals	7	8	8										8
Nonresident Pharmacy	51	53	52										52
Licensed Correctional Facility	0	0	0										0
Hypodermic Needle and Syringes	1	1	1										1
Nonresident Wholesalers	101	108	117										117
Wholesalers	47	50	52										52
Veterinary Food-Animal Drug Retailer	0	0	0										0
Designated Representatives													
Change of Pharmacist-in-Charge													
Received	72	168	113										353
Processed	86	86	75										247
Pending	62	144	182										182
Change of Exemptee-in-Charge													
Received	1	4	1										6
Processed	0	0	0										0
Pending	7	11	12										12
Change of Permits													
Received	33	59	20										112
Processed	33	18	25										76
Pending	150	191	186										186
Discontinuance of Business													
Received	17	24	13										54
Processed	41	0	0										41
Pending	26	50	63										63

Board of Pharmacy Licensing Statistics - Fiscal Year 2006/07

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Renewals Received													
Pharmacist	904	3466											4370
Pharmacy technician	1267	4488											5755
Pharmacy	603	696											1299
Sterile Compounding	16	53											69
Clinics	41	172											213
Nonresident Pharmacy	19	48											67
Hypodermic Needle and Syringes	16	43											59
Nonresident Wholesalers	22	68											90
Wholesalers	28	91											119
Veterinary Food-Animal Drug Retailer	2	5											7
Designated Representative	65	461											526

Board of Pharmacy Licensing Statistics - Fiscal Year 2005/06

	JUL	AUG	SEP	OCT	NOV**	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
APPLICATIONS													
Received													
Pharmacist (exam applications)	79	153	117	75	93	69	63	51	89	178	380	410	1757
Pharmacist (initial licensing applications)	32	439	149	13	202	75	94	16	105	63	48	9	1245
Intern pharmacist	35	234	232	255	53	53	68	57	48	102	98	95	1330
Pharmacy technician	369	558	609	556	484	447	450	490	593	570	742	797	6665
Pharmacy	39	36	30	18	30	30	18	20	30	33	536	19	839
Sterile Compounding	14	10	1	1	3	5	5	3	3	7	7	3	62
Clinics	5	5	1	10	4	2	7	7	6	6	8	4	65
Hospitals	1	2	0	4	4	2	0	0	0	0	0	0	13
Non-Resident Pharmacy	2	7	5	3	5	5	6	3	5	3	10	1	55
Licensed Correctional Facility	0	0	0	0	0	0	0	0	0	0	0	0	0
Hypodermic Needle and Syringes	0	1	0	2	0	0	3	3	0	1	1	3	14
Non-Resident Wholesalers	7	7	5	17	11	15	5	6	16	9	5	16	119
Wholesalers	2	19	2	9	5	2	5	3	5	6	15	8	81
Veterinary Food-Animal Drug Retailer	0	0	0	0	0	0	0	0	0	0	0	4	4
Designated Representatives	26	61	51	74	42	56	52	70	68	56	51	31	638
Issued													
Pharmacist	146	334	161	19	224	70	81	21	112	61	30	15	1274
Intern pharmacist	42	140	272	219	260	81	83	29	55	88	67	77	1413
Pharmacy technician	438	569	491	443	504	338	485	687	412	483	507	518	5875
Pharmacy	45	42	31	19	20	20	32	15	44	29	27	640	964
Sterile Compounding	5	5	12	5	4	4	5	5	4	3	5	0	57
Clinics	15	8	7	0	4	5	5	4	12	1	4	8	73
Hospitals	1	5	0	2	4	3	5	1	3	1	2	0	27
Non-Resident Pharmacy	9	3	7	2	3	4	4	3	1	0	2	3	41
Licensed Correctional Facility	0	0	0	0	0	0	0	0	1	0	0	0	1
Hypodermic Needle and Syringes	0	3	0	0	1	2	0	4	0	0	0	0	10
Non-Resident Wholesalers	10	13	5	3	5	2	23	5	4	6	7	0	83
Wholesalers	5	5	5	4	6	0	22	4	3	1	9	2	66
Veterinary Food-Animal Drug Retailer	0	0	0	0	0	0	0	0	0	0	0	0	0
Designated Representatives	42	47	33	59	31	31	82	83	90	46	40	20	604

*Denotes updated to include pending files to process and processed pending files.

**Denotes Pharmacist, Intern and Pharmacy Technician applications received updated to correct previous data inputting error.

Board of Pharmacy Licensing Statistics - Fiscal Year 2005/06

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Pending*													
Pharmacist Examination	u/a	u/a	u/a	u/a	u/a	139	u/a	u/a	57	u/a	u/a	173	u/a
Intern pharmacist	u/a	u/a	218	u/a	u/a	210	u/a	u/a	222	u/a	u/a	295	u/a
Pharmacy technician	906	668	727	730	964	844	812	863	1015	1222	1597	1926	u/a
Pharmacy	43	30	36	42	57	54	46	52	40	61	69	651	40
Sterile Compounding	38	40	33	32	29	32	34	30	29	27	34	30	29
Clinics	48	49	45	53	55	51	48	51	41	48	58	68	41
Hospitals	12	8	7	5	7	12	12	12	9	8	6	6	9
Non-Resident Pharmacy	19	20	14	15	12	11	14	20	20	21	29	50	20
Licensed Correctional Facility	0	0	0	0	0	0	1	1	0	0	0	0	0
Hypodermic Needle and Syringes	1	1	1	4	2	2	0	0	0	0	1	1	0
Non-Resident Wholesalers	54	53	50	49	63	54	55	59	67	67	78	92	67
Wholesalers	24	22	24	24	32	27	31	37	38	39	45	49	38
Veterinary Food-Animal Drug Retailer	0	0	0	0	0	0	0	0	0	0	0	4	0
Designated Representatives	116	130	148	163	174	201	103	124	102	112	123	134	102
Change of Pharmacist-in-Charge													
Received	72	128	128	110	89	99	94	82	153	134	137	226	1452
Processed	102	92	97	100	90	149	92	110	0	164	0	172	1168
Pending	209	245	276	286	285	197	199	171	324	294	431	485	485
Change of Exemptee-in-Charge													
Received	2	2	0	9	5	4	5	1	4	7	6	0	45
Processed	2	2	0	6	4	11	18	1	4	7	0	0	55
Pending	8	8	8	11	12	13	0	0	0	0	6	6	6
Change of Permits													
Received	33	73	39	69	58	50	36	29	44	73	57	45	606
Processed	21	50	48	69	56	21	31	37	58	19	25	29	464
Pending	171	194	184	184	186	215	220	212	198	252	284	300	300
Discontinuance of Business													
Received	17	17	9	7	8	12	16	18	24	23	16	17	184
Processed	30	1	0	0	0	0	61	0	0	59	0	0	151
Pending	39	55	64	71	79	91	46	64	88	52	68	85	85

*Denotes updated to include pending files to process and processed pending files.

**Denotes Pharmacist, Intern and Pharmacy Technician applications received updated to correct previous data inputting error.

Board of Pharmacy Licensing Statistics - Fiscal Year 2005/06

Renewals Received	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Pharmacist	1019	3078	1398	1362	1136	1245	1334	1181	1214	1323	608	283	15181
Pharmacy technician	1279	3553	1500	1503	1348	1380	1620	1494	1598	1647	906	576	18404
Pharmacy	591	592	903	493	242	310	407	602	1248	218	282	18	5906
Sterile Compounding	11	44	21	22	7	8	7	15	19	20	7	1	182
Clinics	60	126	64	79	59	44	80	62	78	67	56	13	788
Non-Resident Pharmacy	21	26	15	17	9	13	18	24	22	16	19	5	205
Hypodermic Needle and Syringes	20	35	19	24	39	25	21	23	17	19	12	9	263
Non-Resident Wholesalers	26	52	23	30	23	7	39	30	36	22	25	6	319
Wholesalers	25	97	35	33	17	12	56	27	35	35	26	10	408
Veterinary Food-Animal Drug Retailer	1	3	2	0	1	1	2	0	2	2	1	0	15
Designated Representatives	111	320	151	132	68	105	236	175	190	155	119	43	1805

*Denotes updated to include pending files to process and processed pending files.
**Denotes Pharmacist, Intern and Pharmacy Technician applications received updated to correct previous data inputting error.

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)	267*	N	N	N	9.27	N	N	N
Pharmacist (initial licensing)	410*	N	N	N	3.5	N	N	N
Pharmacy Intern	502*	N	N	N	30	N	N	N
Pharmacy Technician	1024*	N	N	N	16	N	N	N
Pharmacies	120	N	N	N	10	N	N	N
Non-Resident Pharmacy	7	N	N	N	30	N	N	N
Wholesaler	7	N	N	N	30	N	N	N
Veterinary Drug Retailers	0	N	N	N	0	N	N	N
Designated Representative	93	N	N	N	4	N	N	N
Out-of-state distributors	31	N	N	N	30	N	N	N
Clinics	23	N	N	N	15	N	N	N
Hypodermic Needle & Syringe Distributors	0	N	N	N	10	N	N	N
Sterile Compounding	10	N	N	N	4	N	N	N

*Denotes July and August 2006 information available at time of report development.

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	N	N	N
Pharmacist (initial licensing)	10	N	N	N
Pharmacy Intern	10	N	N	N
Pharmacy Technician	4	N	N	N
Pharmacies	15	N	N	N
Non-Resident Pharmacy	12	N	N	N
Wholesaler	11	N	N	N
Veterinary Drug Retailers	0	N	N	N
Designated Representative	10	N	N	N
Out-of-state distributors	10	N	N	N
Clinics	10	N	N	N
Hypodermic Needle & Syringe	0	N	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	N	N	N
Pharmacist (initial licensing)	1	N	N	N
Pharmacy Intern	1	N	N	N
Pharmacy Technician	3	N	N	N
Pharmacies	5	N	N	N
Non-Resident Pharmacy	3	N	N	N
Wholesaler	3	N	N	N
Veterinary Drug Retailers	0	N	N	N
Designated Representative	1	N	N	N
Out-of-state distributors	3	N	N	N
Clinics	1	N	N	N
Hypodermic Needle & Syringe	0	N	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*	N	N	N
Pharmacy Intern	524*	N	N	N
Pharmacy Technician	2189*	N	N	N
Pharmacies	95	N	N	N
Non-Resident Pharmacy	5	N	N	N
Wholesaler	3	N	N	N
Veterinary Drug Retailers	0	N	N	N
Designated Representative	42	N	N	N
Out-of-state distributors	9	N	N	N
Clinics	27	N	N	N
Hypodermic Needle & Syringe	0	N	N	N
Sterile Compounding	18	N	N	N

*Denotes July and August 2006 information available at time of report development.

5. Withdrawn licenses to applicants not meeting board requirements.

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacy Technician	0	N	N	N
Pharmacies	2	N	N	N
Non-Resident Pharmacy	2	N	N	N
Clinics	0	N	N	N
Sterile Compounding	0	N	N	N
Designated Representative	0	N	N	N
Hypodermic Needle & Syringe	0	N	N	N
Out-of-state distributors	0	N	N	N
Wholesaler	2	N	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.
2. Cashier renewal fees.
   1st 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:

1. Make address and name changes.
   1st Qtr 2006: Processed 1,832 address changes.
2. Process discontinuance of businesses forms and related components.
   1st Qtr 2006: Processed 41 discontinuance-of-business forms. Processing time is 46 days.
3. Process changes in pharmacist-in-charge and designated representative-in-charge.
   1st Qtr 2006: Processed 247 pharmacist-in-charge changes. Average processing time is 30 days. Processed 0 designated representative-in-charge changes.
4. Process off-site storage applications.
   1st Qtr 2006: Processed and approved 42 off-site storage applications. Average processing time is 30 days.
5. Transfer of intern hours to other states.
   1st Qtr 2006: Processed 76 applications. Average processing time is 30 days.

Objective 2.4	Implement at least 25 changes to improve licensing decisions by June 30, 2011.
Measure:	Number of implemented changes.
Tasks:	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. 2. Work with the University of California to evaluate the drug distribution system of its clinics and their appropriate licensure. 3. Work with the Department of Corrections on the licensure of pharmacies in prisons. 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. *Sept. 2006:* *Committee hears presentation by DHS on emergency preparedness.* *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.* 5. Evaluate the need to issue a provisional license to pharmacy technician trainees.