



California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

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

Licensing Committee Report

Members:

Stan Weisser, RPh, Chairperson
James Burgard, Public Member
Susan Ravnar, PharmD

LICENSING COMMITTEE REPORT AND ACTION

Report of the Licensing Committee Meeting of March 24, 2009

A. Meeting Summary of the Subcommittee to Evaluate Drug Distribution within Hospitals.

Attachment A-1

During the spring of last year, the board identified 94 hospital pharmacies with recalled heparin still within the facilities, two to three months following the last recall. The board cited and fined the hospital pharmacies and pharmacists-in-charge of these pharmacies. However, because many of these hospitals and PICs have appealed the citations and fines, board members cannot discuss the specific parameters of any of these cases without recusing themselves from voting on the specific case in the future should they be appealed to the Office of Administrative Hearings.

Nevertheless, the recall system is not working, and staff is pursuing identification of problems with the recall system with the California Department of Public Health, the California Society of Health-System Pharmacists, The California Hospital Association and the FDA. We are hoping to develop California-specific solutions.

To facilitate this process, the board contracted with a facilitator. President Schell established a two-board member task force to work with these agencies on ways to improve recalls, and other changes needed to provide for improved drug distribution and control within a hospital. The first meeting of this subcommittee was March 2, 2009, at the Crowne Plaza Hotel in Irvine, California and was well attended. During this first meeting, the FDA and Department of Public Health discussed recall requirements at both the state and federal level and participants discussed best practices related to drug recall process within hospitals. A summary of the meeting is provided in the attachments.

The next meeting is scheduled for June 2, 2009, at University of California San Francisco. Board staff will work with the hired facilitator to develop an agenda that will be more outcome oriented.

B. Report of the Licensing Committee Meeting Held March 24, 2000

1. INFORMATION ONLY - Emergency and Disaster Response Planning – EMS Authority Looking for Pharmacists and Other Health Care Volunteers.

Recently, the Emergency Medical Services Authority (EMSA) notified the board and other agencies that it is seeking service providers in three areas:

1. Maintenance of state-owned disaster readiness equipment and state-run warehouses
2. Management and deployment of licensed medical and support personnel for disaster response
3. Development and implementation of disaster response training program.

The EMSA has released a Request for Information for this project:

www.emsa.ca.gov/disaster/calmatrfi/CAL-MAT_RFI.doc

Comments were due March 17, 2009.

The EMSA has asked that we share this information to the "widest possible distribution" of potential service providers. This information was shared with the Licensing Committee, however because of the scheduling of the committee date; it was after the response date.

2. Review of the Professional Competency Statement for Pharmacy

Attachment A-2

For nearly 40 years, the board has had a competency statement for pharmacy. Since the early 1990s, it has been printed in the front of the board's lawbook, but does not appear anywhere else. A copy is provided.

Pharmacy historian and USCF Pharmacy School Dean Bob Day did know – he advises that it was created in 1971 when clinical pharmacy was under creation and there was no definition of what a pharmacist does. This statement was used by the board in part for what we use now CPJE content outline for: to develop test questions for the licensure examinations. The professional competency statement was used to construct exams prior to the advent of job analyses and content outlines which have been in use since the late 1980s at the board.

The committee discussed if the statement accurately reflects pharmacy practice today and whether such a statement is necessary. Based on discussion and advice from staff counsel, the board will no longer distribute this statement.

3. FOR INFORMATION – National Association of Boards of Pharmacy and Accreditation Council for Pharmacy Education's Confirmation of Appropriate Content for Continuing Education Provider Coursework

Attachment A-3

The ACPE advised all state board of pharmacies with independent approval authority for continuing education to ensure that pharmacists receive balanced and independent continuing education

This committee was that the Pharmacy Foundation of California, which is one of two approvers of pharmacist CE in California (the other is the ACPE) was provided with this information.

4. FOR ACTION – Request for Board Recognition of a School of Pharmacy with Precandidate Status with the Accreditation Council for Pharmacy Education Pursuant to 16 CCR § 1719 – Jefferson School of Pharmacy, Philadelphia PA

Attachment A-4

Committee Recommendation: Recognize Jefferson School of Pharmacy for purposes of issuing a California pharmacist intern license

Current regulation, Title 16 CCR 1719, states that a “recognized school of pharmacy” means a school accredited, or granted candidate status by the Accreditation Council for Pharmacy Education (ACPE).

Jefferson School of Pharmacy, Philadelphia, PA, was granted pre-candidate status by the ACPE during its January 2008 meeting and the first class of students was admitted in the Fall of 2008. Jefferson School of Pharmacy is undergoing review by the ACPE during 2008/09 Review Period for advancement to Candidate accreditation status.

Recently, the Jefferson School of Pharmacy requested board recognition of its program for purposes of issuing intern pharmacist licenses to students attending their program, but who may spend some time and work in CA. A copy of the letter from the school requesting recognition by the board is provided in the board materials..

Precandidate status is a provisional status awarded to a new school of pharmacy; however it is not “approved” status. Section 1719 provides that:

§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.

For purposes of issuing a California pharmacist intern license, the school needs to either be accredited by the ACPE or recognized by the board.

5. FOR INFORMATION – Assembly Bill 418 (Emmerson): Pharmacy Technician Qualifications

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

Thereafter, CSHP sponsored stakeholder meetings with the California Pharmacists Association (CPhA) in 2008 as well as other stakeholders to elicit recommendations and comments to refine the proposal for 2009.

On December 4, 2008, CSHP sponsored another stakeholder meeting. Discussion at this meeting revealed that there is still disagreement within industry about what and if there is a

problem with the current existing pharmacy technician qualifications requirements as well as whether the draft legislative proposal correctly addresses the minimum qualifications. At that time, CSHP indicated that they may move forward with their legislative proposal, but scale back the requirements to apply to only pharmacy technicians working in the inpatient setting.

More recently, AB 418 (Emmerson) was introduced. This legislation will change the minimum qualifications for licensure as a pharmacy technician as well as require 20 hours of continuing education each renewal cycle.

However, the bill was amended after the Licensing Committee Meeting. This bill was discussed during the board's Legislation and Regulation Committee Meeting on April 15; that committee is recommending a support position on the bill.

6. FOR INFORMATION – ExCPT Examination for Pharmacy Technicians

Attachment A-5

Business and Professions Code Section 4202 specifies the requirements for licensure as a pharmacist technician in California. Specifically, an applicant must either be a high school graduate or possess a general education certificate equivalent as well as satisfy one of four qualification methods:

1. Possess an associate's degree in pharmacy technology.
2. Complete a course of training specified by the board in regulation.
3. Graduate from a school of pharmacy recognized by the board.
4. Be certified by the Pharmacy Technician Certification Board (PTCB).

In September 2006, this committee discussed another pharmacy technician examination, the Exam for the Certification of Pharmacy Technicians (ExCPT) and the board directed a review of this exam to determine if it is job-related. The ExCPT exam is a computer-based test used to assess the knowledge of pharmacist technicians and is accredited by the National Commission for Certifying Agencies. The examination is accepted by several states as a qualifying method for licensure. The exam is being offered in all 50 states and there are currently 42 test sites available in California. Because of staffing changes with the Department's Office of Examination Resources and legislative proposals to alter the licensing requirements for pharmacy technicians, additional review of the ExCPT was tabled.

Recently board staff met with the Chief Executive Officer at her request to discuss the exam. Board staff provided technical input on the process for California law to allow use of this exam as one of the qualification methods for licensure, which would require an assessment of the exam for job-relatedness as well as a statutory change to B&PC 4202(a)(4).

AB 418 (Emmerson) would alter the requirements for licensure. In its current form, this bill would make the necessary statutory changes to allow the use of the ExCPT in addition to any other exam that is accredited as specified. If this bill is not enacted, if the board so chooses, the board will need to sponsor legislation will be needed to allow for the use of this exam.

Should the board decide to pursue use of this examination, an assessment of the examination also will need to be conducted for compliance with Section 139 of the Business and Professions Code. Board staff would recommend that a similar assessment be conducted on the PTCB.

A copy of the ExCPT content outline as well as a printout of the requirements to take the examination is provided.

7. FOR INFORMATION – Update on the Coalition on Shortages of Pharmacists in Hospitals

Attachment A-6

In mid-2008, the California Hospital Association established a coalition to develop and implement strategic solutions to the shortage of non-nursing allied health professionals. This coalition was comprised of workforce committees, an advisory council and four workgroups. Board executive staff was invited to participate on the pharmacy services workgroup. The focus was on pharmacists and pharmacy technicians in the hospital setting.

This workgroup, comprised of staff and members of the California Hospital Association, the California Society of Health-Systems Pharmacists, a representative from academia, representatives from various hospitals and health systems as well as board staff, met on at least three occasions.

A copy of this report is provided. The report concludes that although there has been an increase in the number of pharmacists educated within California over the prior few years, there continues to be a gap in the number of pharmacists that California will need. The CHA Workforce Committee plans to work on strategic options to resolve these issues during 2009.

Some of the data presented in the report includes:

- There will be a 22 percent growth in the number of pharmacists from 2006 to 2016 (Table 1, page 3)
- In 2005, there were between 21,000 to 25,700 pharmacist jobs in California, (9.3 to 11 percent of the pharmacist positions in the US) (Table 2, page 3).
- The EDD predicts 1,030 annual openings for pharmacists for each year between 2006 – 2016 (Table 3, page 3)

The report concludes (page 4):

In California, there are currently eight schools of pharmacy (based on eligibility for membership in the American Association of Colleges of Pharmacy). (Table 4) One of these schools is not scheduled to graduate its first class until spring 2009 (Touro) and another one even later (California North State). In 2006-07, California schools of pharmacy conferred the degree of Pharm.D. to approximately 758 graduates. (Table 5) Assuming projections are correct, California will need to produce 272 additional graduates each year (2006)-2016) just to fill anticipated openings due to growth and separation. That is approximately a 36 percent increase in the number of graduates needed each year and does not take into consideration that California is already experiencing a shortage. The public schools of pharmacy do not have capacity (adequate number of slots) at this time to match this need. Although Touro University will have an impact – graduating an estimated 100 students in spring 2009 – these graduates will be needed to mitigate current shortages in the field.

To generate these conclusions, the CHA use somewhat dated data regarding the number of pharmacists graduated. As referenced in a footnote to the report, on 2007-08 board statistics show that 2061 applicants took the board's examination; 890 of those applicants were graduates of California Schools of Pharmacy. A total of 1,385 pharmacists were licensed during 2007-08, which exceeds the openings due to growth and separate noted in the report of 1,030 (Table 3, page 3).

8. **FOR INFORMATION – US Department of Health and Human Services, Health Resources and Services Administration's Report: The Adequacy of Pharmacist Supply: 2004-2030**

Attachment A-7

Very recently the board was provided with a copy of a Health and Human Services Agency report titled: *The Adequacy of Pharmacist Supply 2004-2030*. This report presents a slightly less dire picture of the supply of future pharmacists than the California Hospital Association's Report also scheduled for discussion at this meeting; however, both predict continued shortages of needed pharmacists.

The conclusions of this report are:

- The supply of pharmacists is growing significantly faster than was previously projected.
- The demand for pharmacists continues to grow.
- There is currently a moderate shortfall of pharmacists.
- The future supply of pharmacists is projected to grow at a rate similar to the projected growth in demand from changing demographics.
- Supply and demand are projected with a level of uncertainty. Only under an optimistic supply projection combined with a conservative demand projection is future supply adequate to meet demand.

9. **FOR INFORMATION – Experiences of an Employer Recruiting Foreign-Trained Pharmacists for Work in the United States**

Attachment A-8

Documentation of workforce shortages continues to emerge. With a limited number of pharmacy schools in the US and a rising demand for pharmacist services, one potential recruitment source are foreign-trained pharmacists. As recently as the November 2008 Pact Summit, the Department of Consumer Affairs encouraged all attendees to consider foreign-trained professionals to address shortages.

To be eligible for licensure as either an intern or pharmacist, such individuals must be certified by the Foreign Pharmacy Graduate Examination Committee (FPGEC) before applying for a license in California. The certification process through the FPGEC includes:

- a. Passing the Foreign Pharmacy Graduate Equivalency Examination (FPGEE).
- b. Passing the Test of Spoken English (TSE) and Test of English as a Foreign Language (TOEFL) or iBT TOEFL.
- c. Evaluation by the FPGEC of educational curriculum and foreign licensure requirements of each applicant.

In addition, the board is required by law to collect a social security number prior to the issuance of any license.

While our law establishes the requirements for licensure of a pharmacist intern and pharmacist there are several other steps outside of the board's purview that must also be fulfilled. Alan Pope, Safeway, presented during the committee meeting and discussed both the process and lessons learned when recruiting foreign-trained pharmacists. These comments are in the meeting's minutes.

On a separate but related note, the committee was also provided information from the NABP regarding the launch of a new computerized FPGEE to replace the paper-and-pencil examination. A copy of this advisement is provided.

10. FOR INFORMATION – Pharmacy Access Partnership's Request to Establish a Hormonal Contraception Pilot in Pharmacies

Attachment A-9

The Pharmacy Access Partnership is seeking to provide patients with greater pharmacy access to hormonal contraception. To establish support for this practice, they propose a study under the aegis of the board. Documents relating to this request are provided.

The committee heard a presentation from Sharon Cohen Landau and Belle Taylor-McGhee

Specifically, The Pharmacy Access Partnership proposed a pilot to establish practice protocols where physicians and pharmacists would collaborate in writing protocols to allow pharmacists in a community pharmacy to provide limited supplies (up to one year) of oral contraceptives, contraceptive patches and vaginal rings, to women who come into the pharmacy and meet the screening criteria. If the pilot is successful, they proposed seeking statutory authority to allow such programs permanently.

The request is based on regulation section 1705.6:

§1706.5 Experimental Programs.

In order to enable any accredited school of pharmacy recognized by the Board to experiment with new and innovative methods for drug handling, teaching, research, or to develop new and better methods or concepts involving the ethical practice of pharmacy, the Board enacts the following:

- (a) The application of particular provisions of the Pharmacy Rules and Regulations contained in Title 16, California Administrative Code, Chapter 17, may be waived as to an accredited school of pharmacy recognized by the Board if the Dean of said school has filed with the Board an experimental plan or program which specifies the particular provisions to be waived, and which has been approved by the Board.
- (b) Any plan or program approved by the Board shall have: definite time limitations; progress reports which shall be filed as required by the Board.
- (c) The Board may rescind approval and terminate said plan or program at its discretion, at any time it may deem the public interest is not fully protected; nor shall any such plan or program be approved by the Board if such proposal might jeopardize public health or welfare or conflict with provisions of Chapter 9, Div. 2, Business and Professions Code.

This section allows the board to waive a regulation section for purposes of a pilot study, but it does not allow the board to waive statutory law (laws enacted by the Legislature). Based on discussion during the meeting and input from staff counsel, the committee advised Dr. Landau and Dr. Taylor-McGhee that the board does not have the statutory authority to approve their request. These individuals will consider sponsoring future legislation.

11. **FOR INFORMATION** – Competency Committee Report

Each Competency Committee workgroup met earlier this year and focused on examination development and item writing. Additional workgroup meetings are scheduled throughout the year.

The committee will also begin to develop a job analysis survey to be used to complete an occupational analysis with the board's contracted psychometric firm. Pursuant to Business and Professions Code section 139, the board is required to complete an occupational analysis periodically which serves as the basis for the examination. We anticipate releasing this survey to a random sample of pharmacists before the end of year. The information learned from this survey will determine if changes are necessary to the content outline of the CPJE.

Statistics for the CPJE and NAPLEX Exams are not yet available, but will be provided during the board meeting, if possible.

12. **FOR INFORMATION** – Summary of the Licensing Committee Meeting Held on March 24, 2009.

Attachment A-10

Attachment 10 contains the meeting summary of the Licensing Committee Meeting of March 24, 2009.

C. THIRD QUARTERLY REPORT ON LICENSING COMMITTEE GOALS FOR 2008/09

Attachment A-11

Attachment 11 contains the third quarter's report of the Licensing Committee for 2008/09.

Attachment A-1

Meeting Summary of the Subcommittee to Evaluate Drug Distribution with Hospitals

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
SUBCOMMITTEE TO EVALUATE DRUG DISTRIBUTION WITHIN HOSPITALS
MINUTES**

DATE: March 2, 2009

LOCATION: Crowne Plaza Hotel – Irvine
17941 Von Karman Ave.
Irvine, CA 92614
(949) 863-1999

BOARD MEMBERS PRESENT: Kenneth Schell, Pharmacist Member, President
Robert Gaul, Pharmacist Member

STAFF PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Caroline Kline, Legislation and Regulation Coordinator
Kristy Schieldje, Senior Staff Council
Tessa Fraga, Administrative Analyst

CONSULTANTS PRESENT: Val Sheehan, Meeting Facilitator
Carmen Fraser, Senior Associate

The meeting was called to order at 9:30 a.m.

1. Welcome, Agenda Overview, Introductions

Val Sheehan, Meeting Facilitator, introduced herself and Senior Associate, Carmen Fraser and welcomed the group to the subcommittee meeting. Ms. Sheehan then introduced Board of Pharmacy staff and board members who were in attendance. Board President Ken Schell gave opening remarks and noted the importance of the meeting as a vehicle for professionals to review the rules, regulations and practices pertaining to the practice of pharmacy in hospital settings with the ultimate purpose of improving patient care and safety. Ms. Herold also gave opening remarks echoing Dr. Schell's comments and cautioned pharmacists with pending citation and fine appeals not to discuss their situation in detail in order to preserve the integrity of the appeals process. She urged those individuals to keep their comments more general in nature.

Ms. Sheehan reminded audience members to sign in, in order to receive more information on future meetings and to sign in if they wanted to receive continuing education credits for the meeting. Ms. Sheehan emphasized that people were not required to sign in if they preferred to remain anonymous. Ms. Sheehan then asked everyone in the audience to introduce themselves, again with the understanding that if an individual did not want to identify him/herself, then he/she was under no obligation to do so. Ms. Sheehan reviewed the agenda, meeting values, and meeting courtesies and noted that a section of the agenda towards the end of the meeting had been set aside for public comment. Ms. Sheehan added that audience members could also comment at the end of each agenda item as well. Ms. Sheehan concluded by asking for any questions. One question arose about whether or not the meeting was being recorded. Ms. Sheehan confirmed that the meeting was being recorded and announced that

minutes from the meeting would be available on the Board of Pharmacy's web site as part of the April Board Meeting materials.

2. Overview of Federal and State Regulatory Agencies Involved in Product Recalls

Alonsa Cruse, District Director for the U.S. Food and Drug Administration (FDA) gave a presentation on product recalls. Major points from Mr. Cruse's presentation included:

- The three main stages of a product recall are:
 - First Alert – FDA hears about problems through adverse event reporting. Alerts can come from patients, pharmacies, hospitals, manufacturers and even the CDC.
 - Alert the Public – FDA posts regular updates about recalls to its website and all recalls appear in the agency's weekly enforcement reports. Not every recall gets reported; it depends on the severity.
 - Effectiveness Checks – FDA reviews all of a company's corrective actions to determine when a recall is complete.
- All product recalls are classified as I, II or III relative to the degree of health hazard presented by the product being recalled. The FDA uses a Health Hazard Evaluation to determine the classification.
 - Class I – A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse consequences or death.
 - Class II – A situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
 - Class III – A situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.
- A recall is a voluntary action by a firm although the FDA has the authority to take to court manufacturers who do not order recalls on their own. He added that it is important for supply chain members to act immediately. The FDA can take legal action (seize a product) or issue press if a firm is not complying. As a matter of practice, it is important for firms to have a recall strategy as part of a business plan, no matter what size the organization/business is.
- The FDA or firm will eventually issue a press release for almost all Class I recalls where a product is likely to be in the hands of the consumer. The FDA can seize a product or issue a press release if the firm is not complying. FDA alerts are listed on their website: www.fda.gov/opacom/7alerts.html.
- If an organization is held accountable to pull the product, the organization must follow directions on the recall notice. Each recall is handled uniquely. If there is confusion, entities can check the FDA web site or contact their local FDA district office with questions.

Daniel Seid, Chief, Drug Safety Unit, Food and Drug Branch at the California Department of Public Health (CDPH) gave a brief presentation on his agency's role in product recalls. Major points from Mr. Seid's presentation included:

- The CA Food and Drug Branch is the enforcement arm of the CDPH. The Food and Drug Branch is similar to the FDA, but its jurisdiction is limited to California. They have the authority to investigate issues that affect the efficacy, quality or safety of a drug product in CA to determine the risk to the public.
- The Food and Drug Branch licenses manufacturers in the state and has statutory and regulatory authority over those entities. If a product is contaminated, it is considered adulterated and comes under jurisdiction of the Food and Drug Branch. Suspicion of an adulterated product is enough for the Food and Drug Branch to enter facilities and conduct investigations. They have embargo authority and can immediately tie up a product that

is just suspected of being adulterated. The Food and Drug Branch can investigate and file cases. Anyone found to be holding, selling, manufacturing, distributing or giving away adulterated or falsely advertised product can be subject to civil, administrative and criminal action.

- A question arose about how regulatory agencies were addressing the “gray market” or the sale of goods through means other than what was intended or approved by the original maker. Mr. Cruse emphasized that the closed system in the US, where a drug goes from manufacturer to wholesaler or pharmacy to patient should minimize the introduction of counterfeit product. Mr. Cruse added that drugs purchased outside the closed system (e.g., from internet pharmacies) can be called the same name, but the quality of the drug or its ingredients may be very different. Federal and state laws provide that drugs be purchased from an approved source or licensed facility. Any concerns regarding counterfeit drugs should be directed to the FDA (or under California law, to the California State Board of Pharmacy).
- Ms. Herold concurred with Mr. Cruse’s comments and added that if a wholesaler is not licensed with the Board of Pharmacy, the company is operating illegally. Legitimate businesses will not sell to such firms, and any entity buying from an unlicensed source is not only violating the law, but dealing with suspect products. Ms. Herold emphasized the importance of instituting a drug tracking program such as “e-pedigree” to minimize the circulation of counterfeit drugs.
- Dr. Schell posed a question about the level of due diligence for pharmacists when they are obtaining a product or what pharmacists can do to ensure the pedigree of a product that they are receiving. The consensus was that purchasing from approved sources, providing appropriate management oversight, and possibly in large settings, assaying products are important steps to take. In addition, hospital staff must pay close attention to adverse events and report them through the MedWatch system.
- A comment was made that recall notices often do not have clear instructions about what to do with a recalled product. Mr. Cruse agreed to work with his staff to more carefully examine how closely firms are following the model recall notices. Mr. Cruse and his staff will follow up with entities as needed. He confirmed that having clear directions about whether to return, hold or destroy a product is imperative.
- A comment was made that the combination of drug shortage and the recall have created a public health crisis. The audience member noted that developing a set of best practices related to recalls may take stages or drafts before an ideal is reached. In the interim, examining templates that help hospital-based pharmacists more effectively comply with a recall will be helpful. She added that all the entities – suppliers, wholesalers, hospitals, etc. need to be involved. A lot of time and energy were lost due to confusion, and everyone would prefer to avoid a similar situation in the future. A good first step would be to develop an agreement around due diligence.

3. Examination of Hospital/Health System-based Drug Recall Processes – Case Study: Heparin

Loriann DeMartini, Chief Pharmaceutical Consultant, California Department of Public Health (CDPH), Center for Healthcare Quality (licensing and certification), gave an overview of what occurred in California during the recent heparin drug recall. Her presentation covered the FDA recall process, state and federal regulatory requirements, a chronology of recall-related events, and information uncovered by the CDPH during the recall. Main points from Dr. DeMartini’s presentation included:

- Based on what was learned during the recent heparin recall, California has an incredible opportunity to lead the nation in addressing the gaps in the efficient and effective execution of drug recalls in hospitals.
- The Center for Healthcare Quality’s responsibility is to enforce all state and federal laws and regulations pertaining to the provision of health care in licensed institutions. Hospitals are only one of 30 entities that they license and certify. Licensing relates to the California code of regulations, and certification relates to

federal regulations. Hospitals need to be in compliance with all applicable codes regardless of whether or not they are accredited by the Joint Commission.

- The FDA has the responsibility for securing the drug system as codified in 21 Code of Federal Regulations (CFR). Their recall policy is “to remove a product that is in violation of laws administered by the FDA.” [21CFR 7:40] The FDA also ensures that the recalled product is removed from the system.
- The FDA conducts a Health Hazard Evaluation (HHE) to determine the classification of a recall. The HHE has six components:
 1. Whether any disease/injuries have already occurred.
 2. Whether any existing conditions could contribute to a clinical situation that could expose humans to a health hazard.
 3. Assessment of the hazard to various segments of the population.
 4. Assessment of the degree of seriousness of the health hazard.
 5. Assessment of the likelihood of the occurrence.
 6. Assessment of the consequences of the hazard.
- Based on results of the HHE, the FDA classifies each recall as I, II or III. In the absence of product seizures, all recalls are voluntary and they usually are effective. Elements of a recall strategy include the depth of the recall, public warning and effectiveness checks.
- Recalling firms are responsible for promptly informing each of their affected direct accounts that further distribution is prohibited. A consignee who receives a recall notification, such as a hospital, must immediately act upon and carry out instructions set forth in recall notice.
- Relevant state and federal regulatory requirements include:
 1. It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated. [HSC 111295]. A recalled medication is an adulterated drug [HSC 111285]
 2. It is unlawful for any person to receive in commerce any drug or device that is adulterated or to deliver or proffer for delivery any drug or device. [HSC 111305]
 3. No contaminated or deteriorated drugs shall be available for use. [CCR Title22 § 70263(q)(9)]
 4. The P&T committee shall develop written policies and procedures for establishment of safe and effective use of medications [CCR Title 22 § 70263(c)(1)].
 5. Entities must take all reasonable steps to conform to all applicable federal, state and local laws and regulations including those relating to...safety measures. [CCR Title 22 §70701(a)(5)]
 6. Outdated, mislabeled, or otherwise unusable drugs must not be available for patient use. [42CFR § 482.25(b)(3)]
 7. Drugs maintained on the nursing unit shall be inspected at least monthly by a pharmacist. [CCR Title 22 § 70263(q)(10)]
 8. In order to provide patient safety, drugs must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law [42 CFR § 482.25(b)]
 - Guidelines state: “Medications dispensed by the hospitals are retrieved when recalled.” Survey procedures; “Does the hospital retrieve and remove medications available for patient use when the hospital has been informed of a drug recall? Does the recall include notification of patients that have been impacted and those that would order, dispense or administer the medication?”
 9. The recipient of a recall notification “should immediately carry out the instructions set forth by the recalling firm.” [21 CFR § 7.49(d)]

- Dr. DeMartini summarized the events of the heparin recall notification and added that the heparin recall was unusual because the Board of Pharmacy and the CDPH were very involved. Both entities became involved because heparin continued to be found in hospital facilities even after five recalls. Dr. DeMartini added that California wasn't the only state that had difficulties removing the recalled drug. She stressed the importance of learning from what happened from this event in order to prevent future occurrences.
- The Board of Pharmacy conducted an initial inspection and found that 40% of California hospitals had heparin products available even after receiving recall notices. The Board ultimately found heparin in 94 of 533 hospitals. Based on information provided by the Board of Pharmacy, the CDPH then conducted 87 of its own inspections.
- The results were that nearly 20% of hospitals were identified with recalled medications available for patient use. The total potential patient exposure from recall to removal of medication(s) numbered in the thousands.
- Dr. DeMartini stated that the findings revealed systemic deficits in hospital recall processes and drug distribution systems. She stated that the failures came down to a few issues: communication, education, and getting other disciplines involved. She reiterated that this was an important opportunity for improvement and prevention of a recurrence.
- A comment was raised about the discrepancy in the recall process between what wholesalers considered immediate as opposed to hospitals. For example, once a drug is sent back, there is an expectation that a drug won't be sent out again by a wholesaler. Ms. Herold commented that there needs to be a better partnership among entities in the drug supply chain to avoid this type of scenario in the future.
- One audience member commented that having more specific language about the definition of immediate (e.g., "within 24 hours") would be helpful. The consensus was that "immediate" needs to be taken seriously and adhered to as much as possible.
- Another comment was made that it can be challenging to communicate with administrators, CFOs, etc. about the importance of using staff to comply with a recall. The group agreed that communicating effectively with different entities can be challenging and that it may mean quantifying the cost of failure to comply with a recall as the cost of negative press, the price of a lawsuit or even the value of one human life.
- One audience member asked about the regulation requiring notification to all patients and what is expected to be in compliance with that regulation. Dr. DeMartini said that the expectation of the CDPH is that each hospital knows where medications are so they can be removed and that they are notifying patients who may have received recalled medications. If a hospital is not tracking what brand of medication is going to each patient, then that hospital needs to notify all patients.
- One participant asked if the recalled heparin that was found during the investigations was outside the usual drug storage areas. Dr. DeMartini reminded participants that drugs, no matter where they are in a hospital, are the responsibility of the pharmacist. Dr. DeMartini elaborated that wherever they touched heparin was where a pharmacist could touch it (it wasn't in lab coats or lockers).

4. Discussion of Best Practices Related to Drug Recall Processes in Hospitals/Health Systems

Ms. Sheehan asked participants to form ten small groups and discuss the following questions:

- What's working well in relation to drug recall in CA hospitals/health systems?

- What's not working as well in relation to drug recall in CA hospitals/health systems?
 - i. How could these be improved?
 - ii. Are there any other state or national practices, policies or laws that are needed in CA to help improve the drug recall process?

Each group shared two to three best practices and two to three suggestions for improvement.

Group	Best Practices	Suggestions for Improvement
1	<ul style="list-style-type: none"> ▪ Maintain all stock in cabinets in order to easily and quickly do an electronic lockout in the event of a recall. ▪ Implement an Adverse Drug Reaction (ADR) system that allows you to go back and track what occurred in relation to a recalled drug. This would allow a hospital to capture the data in order to better communicate with patients. ▪ Create a duties list or detailed list with all the steps needed during a recall so that any staff member can effectively carry out the steps. 	<ul style="list-style-type: none"> ▪ Have a more effective notification system that should come from one source listing what the issue is, what should be done, what steps should be taken, etc. Having one notice from one source with all the relevant information would minimize confusion. ▪ Institute bar coding to better track drugs.
2	<ul style="list-style-type: none"> ▪ Have someone who is employed by the wholesaler be dedicated to a particular group or hospital. That person is better able to quickly run reports and identify which hospitals received recalled drugs. ▪ Require individual departments to verify that they looked for the recalled product. ▪ As a result of the heparin recall, there are more avenues for notification. 	<ul style="list-style-type: none"> ▪ Messages are not always clear. Improve and simplify messages regarding recalls. ▪ One department has to take responsibility for something that is the responsibility of the whole hospital. If the emphasis was placed on the CEO or president instead of the PIC, a lot more action might have been taken. ▪ Hospitals need to prioritize bar coding technology.
3	<ul style="list-style-type: none"> ▪ Limit the number of people pulling the product during a recall for better accountability and control. ▪ Set up an organized storage facility for drugs – just one place to go. ▪ Establish a dedicated and trained “recall team” who knows all the policies, procedures and pertinent regulations. 	<ul style="list-style-type: none"> ▪ Electronic tracing or notification (e.g., secure email) of recall would be helpful.
4	<ul style="list-style-type: none"> ▪ Minimize the number of and maximize the quality and authority of the individuals carrying out the immediate and monthly inspections. Someone who's authorized to do what's necessary is ideal. ▪ Establish a method to close the loop and perform an audit. For example, recall notices were faxed 	<ul style="list-style-type: none"> ▪ Institute RFID or bar codes and advocate to have standardized methodology in the way the information is sequenced. This should apply to the entire lifecycle of the product. ▪ Require that drugs be stored in a specific location and institute consequences when

	to all pharmacies, and responses confirming that all drugs were removed were expected within 72 hours. After the faxes were received, an individual conducted site visits to double-check.	drugs are stored out of the area.
5	<ul style="list-style-type: none"> Continue to collaborate and communicate effectively with wholesaler. 	<ul style="list-style-type: none"> Establish a centralized method to interpret and disseminate information about recalls.
6	<ul style="list-style-type: none"> Have a centralized method to receive and interpret and disseminate information about recalls, especially Class I recalls. <p>(Other best practices have been stated by other groups.)</p>	<ul style="list-style-type: none"> Have a better system to identify outpatient clinics that are on the facility's license. This would help clarify what a PIC is responsible for. Improve coordination of recall notices, especially for ubiquitous products. Expand policies to increase responsibility of other department heads during a recall.
7	(Felt that they didn't have a good demonstrated best practice.)	<ul style="list-style-type: none"> Have a centralized system or body in a hospital that would disseminate recall information through email. This would hopefully create better accountability and better response time. Increase authority of PIC to better control where and how drugs are stored.
8	(Didn't feel that there were any best practices.)	<ul style="list-style-type: none"> Recall notices should state whether this is a Class I, II or III recall. Also, notices should have clear instructions about what actions to take. Establish radio frequency identifiers (RFID) as a way to track drugs (a non line-of-sight read). This would be one way to carry e-pedigree. E-pedigree would be a way to better execute a recall.
9	<ul style="list-style-type: none"> Electronic receipt of recall. 	<ul style="list-style-type: none"> To avoid confusion, create recall notices with more uniform language or have notice come from one source. Establish an authorized storage area. If something is not in an authorized storage area, then it is stored unlawfully. Increase accountability. All health care providers that are touching the drug are accountable. Outside medications from vendors or contractors should not be allowed in the hospital.

		<ul style="list-style-type: none"> ▪ At the site level, involve nurses, physicians, dialysis techs, therapists, administrators in discussion about accountability. Pharmacists need more authority if held accountable. ▪ Bring together management, California Hospital Association, Medical Board, Nursing Board. Others should be willing to accept citations and fines.
10	<ul style="list-style-type: none"> ▪ Post flyers. For example, one facility posted flyers saying “bad heparin” with the lot numbers. This information was communicated to all of the nursing units. ▪ Offer a reward. One facility offered a reward of \$10 per vial of recalled heparin. The CEO got involved and upped amount to \$100 per vial. 	<ul style="list-style-type: none"> ▪ Encourage wholesalers to take more responsibility in terms of communicating recalled lot numbers. ▪ Increase accountability and collaboration among members of the health care team. There is a lack of consequences for other health care professionals.

5. Brainstorming Session: Future Topics for the Subcommittee to Improve the Drug Delivery Systems

Ms. Sheehan asked participants to form small groups to brainstorm topics for future meetings. Before the brainstorming session began, Ms. Sheehan asked Ms. Herold to address the group regarding parameters for the discussion. Ms. Herold shared that the goal of these meetings is to examine possible changes in pharmacy law or in practice settings that the Board of Pharmacy can influence or assist with in providing better care to patients. She added that some topics may be not as useful to include. For example, the California Department of Public Health has communicated that changing Title 22 is not a high priority at this time, so any discussion regarding changing Title 22 would not be useful. Ms. Herold encouraged the group to explore what they need for effective patient care. She urged them to consider questions such as, what is impeding your ability to provide quality care to patients? What’s keeping you as a pharmacist from exercising control over drug distribution in hospitals? She added that in the coming year, the Board of Pharmacy will pursue some means to authorize satellite pharmacies. The law currently does not recognize satellite pharmacies, yet many hospitals have them. She added that this session was their opportunity to come forward with ideas.

Dr. DeMartini added that while today’s discussion is focused on the heparin recall, the bigger issue is about the drug distribution system and whether or not it supports effective patient care in the hospital setting. She encouraged participants to consider whether or not other aspects of the drug distribution system prevent the pharmacist from being an effective patient advocate. She encouraged participants to think beyond an effective recall.

A comment was made by an audience member that the things that get people’s attention around quality and safety are those things that are fiscal or regulatory mandates. She added that it would be in the best interest of pharmacists to bring other boards together to discuss shared accountability. A key stakeholder is the California Hospital Association although no representative was at the meeting.

Another audience member wanted to know about the likelihood of creating interpretive guidelines for Title 22. Dr. DeMartini confirmed that they are prohibited from creating interpretive guidelines. She added that furnishing specific language from Title 22 that clarifies certain sections would also not be helpful because each facility is unique and one size does not fit all.

After brainstorming and sharing potential ideas and topics, the group voted on the most desired topics. The following is a list of all the suggestions ranked by the number of votes that each one received (similar topics were consolidated to minimize redundancy).

Topic	Number of Votes
Pharmacy Technicians – licensing, training program, “intern” hours, practical experience	25
Registered Pharmacist/Patient Ratio by “X” Date – by level of service	18
Pharmacy Director Role – including reporting to CEO, give pharmacist authority and accountability	17
Automation – rules and regulations, scope of use	15
Separating Rules and Regulations Between Hospitals, Retail Pharmacies and Correctional Facilities	12
Effective Patient Care – legal requirements of number of RPhs staffing, alternatives to recalled drugs (who makes decision), refocus on patient care including process vs. taking care, mandate percentage of time in clinical role, minimum pharmaceutical care standards [added from discussion following the voting]	11
Healthcare Information Technology – guidance, QA, distribution, impact of automation (ADL, BPOC)	10
E-pedigree – gray market (ethics/contamination of source), market manipulation, monopoly	9
Pharmaceutical Care Standards – board certification	8
Provision of Pharmaceutical Care – quality and safety of drug distribution and clinical services, role of satellite pharmacies	8
Electronic Record Retention – purity of the order, controlled substance records (1 year on-site)	7
Authority vs. Accountability - recognition by other disciplines (e.g., nursing, respiratory, medical)	7
Hospital vs. Retail Health Safety Codes	6
PIC’s Responsibilities for Outpatient Hospital-based Clinics	5
Compounding – manufacturing?	3
Summit with Other Boards and Organizations (e.g., CHA, ONA (?) ?	3
Infusion Center Licensing	2
Hospital Administration Involvement – increase awareness/importance of issue	2
Professional Guidelines	1
Clinical Pharmacy Services – required clinical services	1
Licensing of a Hospital Administrator	1
Limit Number of Orders Reviewed by Registered Pharmacist Per Shift or Per Hour	1
Organize Communication Process – identify roles in recall process, standardize recall process	1
Unit Inspections – content of inspection, inspecting individuals	0
Authority of Pharmacy	0
Conflicting/Unclear Language Between Title 22 and Board of Pharmacy Regulations	0
Requirement of Chief Pharmacy Officer vs. PIC Definitions – PIC accountability for more than one physical location	0
Clarification Regarding Laws and Applicability to Different Pharmacy Practice Sites (inpatient, retail, manufacturer, SNF)	0
Compensation for Certifications	0
Increase Wholesaler Requirements for Recall Notifications	0
Medical Storage Areas – licensing and regulation, penalties not to pharmacists, but to hospital administrators	0

A comment was made acknowledging the Board of Pharmacy’s history of and leadership role in promptly addressing clinical pharmacy services in California. The participant added that going forward, she wanted to

preserve that focus on the pharmacist's role in clinical care. Another participant added that there was a need to be cognizant of pharmacist/patient ratios in order to be able to provide high quality patient care. Ms. Sheehan concluded the session by thanking everyone for their time and input to the Board of Pharmacy for their further consideration.

6. Additional Public Comment

Ms. Sheehan asked if there were any public comments before the meeting was officially adjourned. A participant raised the issue of collaboration and what it means in the context of these meetings. He added that one way to look at collaboration would be to emphasize the role of regulation and enforcement to keep patients safe while another model of collaboration would focus more on open dialogue and developing a common purpose between regulators and pharmacists in order to make patient care safer. Creating a mutual understanding of what's trying to be accomplished is ultimately what's important. Another comment underscored the need to collaborate with other disciplines because decision-making around patient care involves more than just the pharmacist. The person added that continued enforcement with just pharmacists may not necessarily bring about the desired change that everyone would like to see.

7. Closing, Evaluation, Adjournment

Ms. Sheehan closed the meeting and thanked the speakers and the Board of Pharmacy for hosting the meeting. Dr. Schell added his appreciation on the behalf of the Board of Pharmacy for everyone's time and commitment to improving patient care and safety.

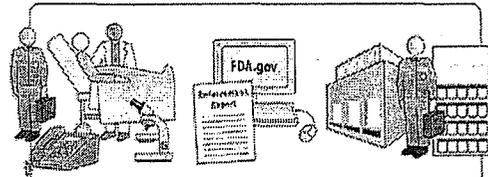
The meeting was adjourned at 3:00pm

Introduction to FDA Recalls

Abrisa Cross District Director
Los Angeles District Office
Abrisa.cross@fda.hhs.gov

FDA-Los Angeles District Recall Team
Tamara Boggs
949-606-3004/949-323-4120
LARRY HOWELL
949-606-4405/949-322-8784

FDA 101: Product Recalls From First Alert to Effectiveness Checks



First Alert

FDA hears about product problems through company notification, agency inspections and adverse event reports, and through CDC.

Alerting the Public

FDA posts regular updates about recalls to its Web site, and all recalls appear in the agency's weekly Enforcement Report.

Effectiveness Checks

FDA reviews all of a company's corrective actions to determine when a recall is complete.

Definitions 21CFR7.3

- Recall
- Product
- Correction
- Market Withdrawal
- Stock Recovery
- Classification

Recall

- A firm's removal or correction of a marketed product(s) that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure.

Product

- An article subject to the jurisdiction of the Food and Drug Administration, including any food...intended for human or animal use...

Correction

- Repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location.

Market withdrawal

- A firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the FDA or which involves no violation (normal stock rotation, routine equipment adjustments, etc.)

Stock recovery

- A firm's removal or correction of a product that has not been marketed or that has not left the direct control of the firm, i.e. the product is located on premises owned by, or under the control of, the firm and no portion of the lot has been released for sale or use.

Name This Action

Stock Recovery - Market Withdrawal - Recall

- | | |
|--|-------------------|
| Product implicated in an outbreak of E. coli O157: H7. | Recall |
| Product does not declare a net weight, but is still in the firm's warehouse. | Stock Recovery |
| Label does not list mfg city and has been shipped to retail stores. | Market Withdrawal |
| ■ Positive Shigella sample, with no reported illnesses. | Recall |

Classification

- Numerical designation, i.e., I, II, or III, assigned by the Food and Drug Administration to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled.

Health Hazard Evaluation

- Diseases or injuries which have already occurred
- Existing conditions that can contribute to a clinical condition
- Population
- Seriousness of hazard
- Likelihood of occurrence of hazard
- Immediate and long term consequences

Classification

- **Class I** is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause **serious adverse health consequences or death.**

Class I Examples

- *Listeria monocytogenes*, *Salmonella*, *E. coli* O157:H7 in RTE food
- Dietary supp. products containing aristolochic acid, a potent carcinogen and nephrotoxin
- Dietary supp. products containing a prescription drug that could have serious, life-threatening consequences in some people. (Liqiang Dietary Supp. containing glyburide)

Classification

- **Class II** is a situation in which use of, or exposure to, a violative product may cause **temporary or medically reversible adverse health consequences** or where the **probability of serious adverse health consequences is remote.**

Class II examples

- Hard/sharp foreign objects 7 – 25 mm
- Undeclared yellow 5 & 6
- Unapproved/uncertified colors
- Cosmetic products found to be contaminated with bacteria

Classification

- **Class III** is a situation in which use of, or exposure to, a violative product is **not likely to cause adverse health consequences.**

Class III examples

- Mold, yeast, lactobacillus
- Hard/sharp foreign objects less than 7 mm
- Off odor/off taste from contaminant at levels not likely to pose a hazard to health
- Misbranded products (The label states zero mg potassium per serving; the product actually contains 370mg potassium per serving)

What Recall Classification?

- Class II
 - Chicken and beef burritos contain a very small amount of undeclared soy ingredients
 - Egg product associated with a Salmonella outbreak
- Class I
 - Weight of Sliced-Smoked Ham is under the declared net weight.

Recall Terminology

- Class III
 - Pathogen recently involved in recalled spinach and ground beef.
- Recall
 - A firm's voluntary removal of distributed product that is adulterated or misbranded.
- E. coli 0157: H7
 - This is a class of recall where the use of the product will not cause adverse health consequences.

Code of Federal Regulations

- 21 CFR Part 7, Subpart C: Recalls (Including Product Corrections) – Guidelines on Policy, Procedures, and Industry Responsibility
http://www.access.gpo.gov/nara/cfr/waisidx_04/21cfr7_04.html
- Recall is a voluntary action by a firm
- Guidance on development of recall strategy (depth, public warning, effectiveness checks)
- Guidance on recall communications with consignees
- Who to contact at FDA and what information to provide

Code of Federal Regulations

- 21 CFR Part 107, Subpart E – Infant Formula Recalls (Gives FDA authority to require recalls of adulterated or misbranded infant formula that presents a risk to human health)
- 21 CFR Part 806-Medical Device Firm must report the recall to FDA and conduct the recall in the manner specified in this part (21 CFR Part 810-Procedures for FDA recall authority)
- 21 CFR Part 1271.440-Includes provisions for FDA to order retention, recall and/or destruction of Human Cell, Tissue and Cellular & Tissue-based products.

Press releases

- Issued by FDA or firm for almost all Class I recalls where the product is likely to be in the hands of the consumer
- May be issued by FDA or firm for some class II recalls
- Models for most class I recalls posted on FDA website
- Follow FDA models as closely as possible – "fill in the blanks"

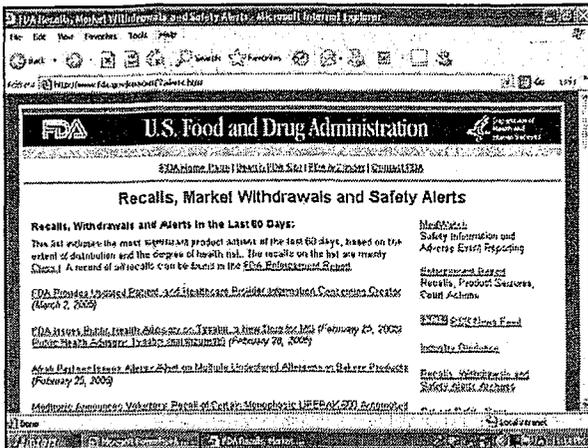
Press releases (cont.)

- Do not change hazard statement – don't take out "life threatening"
- Issue press release to Associated Press
- Provide FDA with confirmation that press release was sent to AP
- FDA will issue if firm will not or if firm's is inadequate

The screenshot shows the FDA website interface. At the top, it says "U.S. Food and Drug Administration". Below that, there's a search bar and navigation links. The main content area is titled "FDA NEWS" and features several news items:

- Marketing of MS Drug Tysabri Suspended
- Health Study of Peanut Butter Supplements Sealed
- New Product Approved to Treat Smokers' Nicotine Cravings
- New Substances in FDA's Drug Safety Program Announced
- Cellular, Tissue and Gene Therapies Advisory Committee to Meet March 24
- Health Product Safety

On the right side, there are links for "Food Industry" (Biologicals, Cellular, Etoposide, M309015) and "FDA Activities" (About FDA).



Recent Recall Issues Involving Imports

- Melamine contaminated pet food (China)
- Ethylene glycol in toothpaste
- Heparin recall
 - Heparin sourced from pig intestine
 - Reports of anaphylactoid reactions after bolus administration
- Hypothesis: low level contaminant
- API manufactured in facility in China

Los Angeles Districts Recalls for FY08

	Class I	Class II	Class III	Safety Alert
CBER	0	17	5	
ODER	3	4	0	
CDRH	3	73	10	2
CESAN	16	8	5	
CVM	1	1	0	
TOTAL	23	103	20	2

Determining the scope of a recall

- When did the problem start/end
- Can additional lots/products be affected other than the lot/product analyzed and found adulterated
- How many sizes/labels for the product
- Is the product coded with a lot number

Responsibilities of Recalling Firm

Preparing for a Recall

- Review available recall guidance
- Develop a recall plan
- Maintain manufacturing and distribution records in a manner to facilitate a timely and effective recall
- Identify finished products with a lot number/code

Responsibilities of Recalling Firm

Communicating with FDA

- Notify FDA and provide information in a timely manner (A current list of FDA recall coordinators can be found on FDA's website at: http://www.fda.gov/ora/inspect_ref/ior/ioradmir_monitors.html#recall)
- Info needed by FDA includes: product (identity, size and type of containers, brand names, lot numbers, whether refrigerated/frozen/shelf stable), codes, amount manufactured and amount distributed, number of and types of consignees, area of distribution, reason for recall

Responsibilities of Recalling Firm

Communicating with FDA

- Discuss recall strategy with FDA (including disposition of recalled product)
- Let FDA review text of phone notifications, written recall notifications, press releases (follow models provided in FDA guidance)
- Provide FDA with consignee list
- Provide actual labels or clear photos of labels

Responsibilities of Recalling Firm

Communicating with Consignees

- The timely dissemination of communications about recalls of FDA-regulated products, important drug safety information, and other important product safety information is essential for the protection of the public health.

Responsibilities of Recalling Firm

Communicating with Consignees

- The FDA's current thinking interprets the provisions of 21 CFR 7.49 and 200.5 to allow the use of e-mail and other electronic communication methods, such as fax or text messaging, to accomplish any recall notification or distribution of important safety information.

Responsibilities of Recalling Firm

Communicating with Consignees

- Be brief and to the point
- Identify clearly the product, size, lot number(s), code(s) or serial number(s) and any other pertinent descriptive information to enable accurate and immediate identification of the product
- Explain concisely the reason for the recall and the hazard involved, if any

Responsibilities of Recalling Firm

Communicating with Consignees

- Provide specific instructions on what should be done with respect to the recalled products
- Provide a ready means for the recipient of the communication to report to the recalling firm whether it has any of the product
- Provide sub-recall instructions (if necessary)

Responsibilities of Recalling Firm

Recall Monitoring/Closure

- Maintain record of responses and re-contact non-responders
- Maintain record of units
 - returned/reconditioned/destroyed
- Maintain returned product under quarantine
- Destroy/recondition product under FDA supervision
- Make corrections to minimize probability that problem will repeat

Responsibilities of the FDA DISTRICTS

- Submit a 24 hour alert of the recall to the affected FDA centers
- Collect information on the recall
- Offer guidance on recall (recall strategy & communications)
- Submit a recall recommendation to the affected FDA Center
- Monitor the recall

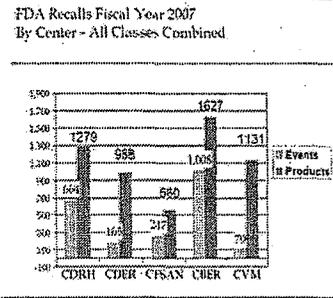
Responsibilities of the FDA DISTRICTS

- Witness product destruction or monitor the completion of an FDA approved reconditioning plan
- Initiate & monitor recall audit checks
- Notify the firm of recall classification and termination
- Terminate Class II and III recalls

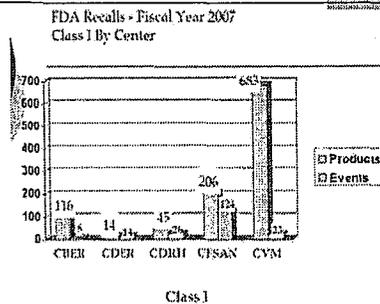
Responsibilities of the FDA Centers

- Receive & review recall recommendations
- Initiate Health Hazard Evaluations (HHE)
- Review and evaluate the firm's recall strategy
- Update FDA's recall database with recall classification, strategy and recommendations.
- Place recall information on the FDA Enforcement Report (weekly notice of recalls)
- Terminate Class I recalls

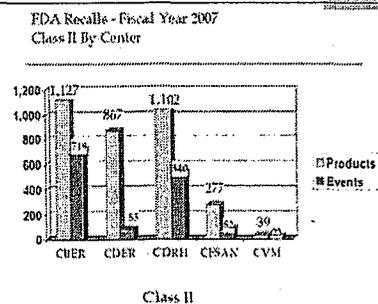
Recalls By FDA Center-FY2007



Class I Recalls By FDA Center-FY2007

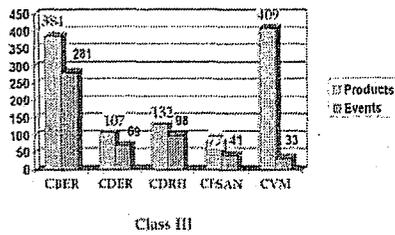


Class II Recalls By FDA Center-FY2007



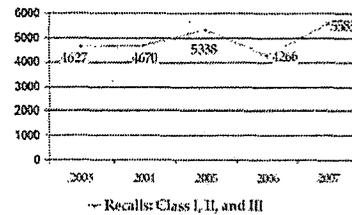
Class III Recalls By FDA Center- FY2007

FDA Recalls - Fiscal Year 2007
Class III By Center



FDA Five-Year Recall Activity For All Centers

Recalled Products - All Centers
Fiscal Years 2003 - 2007



~ Recalls: Class I, II, and III

RESOURCES

- ❖ [WWW.FDA.GOV](http://www.fda.gov)
- ❖ 21 C.F.R. PART 7
- ❖ FDA REGULATORY PROCEDURES MANUAL, CHAPTER 7, "RECALL PROCEDURES" (MARCH 2006)
- ❖ FDA GUIDANCE FOR INDUSTRY, "PRODUCT RECALLS, INCLUDING REMOVAL AND CORRECTION" (NOVEMBER 2003)
- ❖ FDA INVESTIGATIONS OPERATIONS MANUAL, SUBCHAPTER 800, "RECALLS" (2008)

Recall Contacts

- ❖ CDR Larry Howell
(949)808-4440
Larry.howell@fda.hhs.gov
- ❖ Tamala Bogan
(949)808-3504
Tamala.bogan@fda.hhs.gov
Food and Drug Administration
19701 Fairchild
Irvine, CA 92612
- ❖ A current list of FDA recall coordinators can be found on FDA's website at:
http://www.fda.gov/ora/inspect_ref/om/iomradir_monitors.html#recall

California Department of
Public Health
Heparin Recall Inspection
Findings

Loriann De Martini Pharm.D.
Chief Pharmaceutical Consultant
Center for Health Care Quality

Presentation Outline

- Overview of FDA Recall Process
- Regulatory Requirements – State /Federal
- Heparin Recall Notification Chronology
- CDPH Findings

FDA Recall Process

- "FDA has the responsibility for assuring the safety and efficacy of all regulated marketed medical products."
- Regulatory authority 21 Code of Federal Regulations (CFR) §§ 7.40 – 7.59
- Recall Policy
To remove a product that is in violation of laws administered by FDA. [21CFR § 7.40]

FDA Recall Process: Health hazard evaluation and recall classification

- An evaluation of the health hazard will be conducted and will evaluate minimally the following factors:
- (1) Whether any disease/injuries have already occurred
- (2) Whether any existing conditions could contribute to a clinical situation that could expose humans to a health hazard.
- (3) Assessment of hazard to various segments of the population

21CFR § 7.41

FDA Recall Process: Health hazard evaluation and recall classification

- (4) Assessment of the degree of seriousness of the health hazard
- (5) Assessment of the likelihood of occurrence of the hazard.
- (6) Assessment of the consequences of the hazard.

21CFR § 7.41

FDA Recall Process: Health Hazard Evaluation and Recall Classification

- Based on the health hazard evaluation the FDA will assign the recall a classification (Class I, II or III)
- Class 1: A situation in which there is a reasonable probability that the use of or exposure will cause serious adverse health consequences or death.
- Class II: A situation in which use may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- Class III: "A situation in which use is not likely to cause adverse health consequences."

FDA Recall Process: Recall Strategy

- FDA will review the adequacy of a proposed recall strategy developed by a recalling firm and recommend changes as appropriate.
- Elements of a recall strategy includes:
 - (1) Depth of recall.
 - (2) Public warning.
 - (3) Effectiveness checks.

21 CFR § 7.42

FDA Recall Process: Recall Communication

- A recalling firm is responsible for promptly notifying each of its affected direct accounts about the recall. The recall notices informs that the further distribution or use of any remaining product should cease immediately.
- Responsibility of recipient: Consignees that receive a recall communication should immediately carry out the instructions set forth by the recalling firm.

21 CFR § 7.49

Regulatory Requirements - Drug Recalls

1. Unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated. [HSC 111295] A recalled medication is an adulterated drug [HSC 111285]
2. It is unlawful for any person to receive in commerce any drug or device that is adulterated or to deliver or proffer for delivery any drug or device. [HSC 111305]
3. No contaminated or deteriorated drugs shall be available for use. [CCR Title 22 § 70263(q)(9)]
4. The P&T committee shall develop written policies and procedures for establishment of safe and effective use of medications [CCR Title 22 § 70263(c)(1)].

Regulatory Requirements - Drug Recalls

5. Take all reasonable steps to conform to all applicable federal, state and local laws and regulations including those relating to... safety measures. [CCR Title 22 §70701(a)(5)]
6. Outdated, mislabeled, or otherwise unusable drugs must not be available for patient use. [42CFR § 482.25(b)(3)]
7. Drugs maintained on the nursing unit shall be inspected at least monthly by a pharmacist. [CCR Title 22 § 70263(q)(10)]

Regulatory Requirements - Drug Recalls

9. In order to provide patient safety, drugs must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law [42 CFR § 482.25(b)]
 - Guidelines state: "Medications dispensed by the hospitals are retrieved when recalled." Survey procedures: "Does the hospital retrieve and remove medications available for patient use when the hospital has been informed of a drug recall? Does the recall include notification of patients that have been impacted and those that would order, dispense or administer the medication?"

Regulatory Requirements - Drug Recalls

10. The recipient of a recall notification "should immediately carry out the instructions set forth by the recalling firm." [21 CFR § 7.49(d)]

Heparin Recall Notification Chronology

- **Jan 25- Mar 28**
 - Baxter
 - American Health Packaging (AHP)
 - B.Braun
 - Covidien - "Formerly of Tyco"
- **May 2** CDPH issues an All Facilities Letter
- **May 5** CSHP posts AFL 08-14 to it's website
- **May 9** FDA issues an e-alert.
- **May 9** CMS issues an e-alert to all provider types
- **May 9** ASHP issues a "Special ASHP NewsLink"
- **May 12** Baxter issues an "important recall reminder"
- **May 12** CSHP issues an e-alert.
- **May 16** CPhA CEO Message

Heparin Recall Notification Chronology

- **May 2** CDPH issues an All Facilities Letter (AFL 08-14). "requesting that you immediately review all of your drug storage areas, including emergency kits, dialysis units and automated drug storage cabinets to ensure that all of the recalled heparin has been removed."

Heparin Recall Notification Chronology

- **May 9** FDA issues an e-alert. "Help FDA spread the word about recalls of heparin. Affected heparin products have been found in medical care facilities in one state. Although product recall instructions were widely distributed they may not have been fully acted upon. There have been many reports of deaths associated after heparin administration. We ask that health professionals and facilities please review and examine all drug/device storage areas, including emergency kits, dialysis units and automated drug storage cabinets to ensure that all of the recalled heparin products have been removed are no longer available for patient use."

Heparin Recall Notification Chronology

- **May 9** CMS issues an e-alert to all provider types mirroring the FDA e-alert. "Ensure that all of the recalled heparin products are removed and no longer available for patients."
- **May 9** ASHP issues a "Special ASHP NewsLink" "FDA today asked health professionals and facilities to examine all drug and device storage areas. We're asking folks to rethink about all the places where heparin is placed," said Jason Woo, an associate director in the Office of Compliance at FDA's Center for Drug Evaluation and Research. Woo said follow-up work by an FDA field office revealed recalled heparin products in "more than a handful" of California hospitals. The products were found in crash carts, surgical units, cardiac catheterization laboratories, and automated drug dispensing cabinets and on pharmacy shelves, he said."

Heparin Recall Notification Chronology

- **May 12** Baxter issues an "important recall reminder" sent to all hospitals and clinics nationwide. "Baxter has been alerted by the FDA that on-site effectiveness checks by state regulatory agencies have revealed certain hospitals and other health care facilities have failed to remove all previously recalled Baxter heparin products from potential use in their facilities. As indicated in previous communications sent to Baxter customers on February 29, 2008 due to an increase in reports of adverse patient reactions, Baxter performed a recall. There should be no Baxter heparin products remaining in your facility. To ensure patient safety, you must immediately locate and discontinue use of these heparin products."

Heparin Recall Notification Chronology

- **May 12** CSHP issues an e-alert. "Executive Officer Virginia Herold of the California Board of Pharmacy met with the CSHP Board of Directors at its recent board meeting. She reported that the Board of Pharmacy would be conducting inspections for recalled heparin. Recently, members have stated that they have also been surveyed by the California Department of Public Health (CDPH) for heparin-related issues."

Professional Competency Statement for Pharmacy

PROFESSIONAL COMPETENCY IN PHARMACY

INTRODUCTION

The Professional Competency in Pharmacy Statement, first written in 1971 and revised several times since, is a statement which serves two purposes. First, it outlines the level of professional competencies which the State Board of Pharmacy tests for in its professional licensure examination; second, it provides goals and lends support for the direction in which the practice of pharmacy is developing in California. The statement is not to be construed as a standard of practice for the profession of pharmacy.

A pharmacist is a professional whose overall function should contribute to better patient care through the promotion of appropriate therapy. The pharmacist should be able to recognize the significance of clinical diagnoses for commonly encountered medical conditions, comprehend the medical management of the patient and be capable of conferring with both the patient and the patient's physician regarding drug therapy.

The pharmacist should have knowledge of prescription and nonprescription drugs and drug products, including indications, efficacy and dosage; their mechanism(s) of action; their fates and dispositions (if known); their major contraindications and potential side effects; and the influence which the patient's age, sex, concomitant disease states, concurrent drug therapy, foods and diagnostic procedures may have on their activities and dispositions. With the use of appropriate reference materials, a pharmacist should be able to compare and contrast the drugs commonly used to treat a specific medical condition and be able to recommend to another health professional a specific drug product and dose which will be the most beneficial and produce the fewest adverse effects for a particular therapeutic need.

When patients present themselves to the pharmacist with symptoms or a self-diagnosed condition, the pharmacist should be able to form a tentative assessment of the severity of the problem. The pharmacist should then be able to assist the patient to determine whether nonprescription medications or referral to another health professional or agency is indicated. If the patient elects to self-medicate with nonprescription medications, the pharmacist should be able to evaluate the drug products available to treat that condition and assist the patient in the selection of a safe and beneficial mode of therapy, taking into consideration any concurrent medical problems and medications. The pharmacist should be able to advise the patient when additional medical attention is indicated if the patient's condition worsens or fails to improve within a reasonable time period.

A pharmacist having access to pertinent objective and subjective medical information should be able to monitor and evaluate the response of the patient and recognize the common side effects and toxicities attributable to the drug therapy. In the absence of the desired therapeutic response or the presence of a drug side effect, the pharmacist should be able to recommend appropriate changes in the drug therapy plan to the physician, other health professional or patient which would result in the desired therapeutic response and/or alleviate the side effect.

From a complete medical profile and medical history, if available, a pharmacist should be able to deduce the nature of the patient's medical problems. Using an available medication

PROFESSIONAL COMPETENCY IN PHARMACY

profile and medical history containing the patient's medical problems and medications, the pharmacist should be able to identify potential drug/drug, drug/laboratory test, drug/diet or drug/disease interactions as well as problems related to noncompliance.

A pharmacist should be able to effectively communicate with a patient (orally and/or in writing) the proper instructions for use and storage of drugs as well as appropriate precautions and common side effects. The pharmacist should be able to provide patient-specific drug information to other health professionals and also provide drug education to the public.

A pharmacist should be able to utilize major reference sources to answer basic drug information and drug ingestion questions. In cases of drug ingestion, the pharmacist should be able to assess the severity of the situation in order to determine whether to recommend immediate therapy or to refer the patient to the nearest poison control center or emergency room.

A pharmacist should be able to evaluate the validity of the conclusions reached by the authors of a literature report of a clinical trial and summarize the practical implications of the findings as they relate to the clinical use of drugs. The pharmacist should be able to appraise advertising claims for drug products objectively.

A pharmacist, using appropriate reference materials, should be able to determine the stability characteristics and storage requirements of drugs and drug products; the factors that influence the bioavailability of various dosage forms; how the route of administration may influence the absorption of a specific drug form, its dosage form; and how these factors may interact to influence the onset, peak activity or duration of the activity of the drug.

A pharmacist should be aware of the current legal limitations on procurement, storage, distribution and sale of drugs. The pharmacist should also be aware of current FDA-approved indications for drugs, acceptable medical practice and the ethical and legal responsibilities to the patient to whom drugs are dispensed.

A pharmacist should be capable of compounding drugs or drug combinations in acceptable dosage forms.

A pharmacist, using appropriate reference materials, should be capable of identifying a drug based on its unique description and its proposed use.

A pharmacist is a professional who should identify, achieve and maintain those competencies directly relevant to his or her specific area of practice.

A pharmacist shall be responsible for assuring, whenever possible, that the safety of a patient and/or the integrity of a patient's pharmaceutical care is not jeopardized by a pharmacist who is cognitively impaired, whether due to a mental disease or state, or substance abuse. A pharmacist, therefore, shall be able to recognize the common symptoms of such impairments and shall be capable of initiating appropriate actions.

CONCLUSION

The Board of Pharmacy is aware that the education of a pharmacist in the state of California has changed extensively over the past few years in that there has been an increased emphasis placed upon the biological sciences, pathophysiology, biopharmaceutics and pharmacokinetics, therapeutics and clinical clerkships. As a result of both this education and legislation which permits better use of the pharmacist as a health professional, a growing number of clinically trained pharmacists are providing direct patient care management either as part of a medical team or under the supervision of a physician. Examples of such pa-

PROFESSIONAL COMPETENCY IN PHARMACY

patient care management functions include: triage; medication refills; management of post-diagnosed, stabilized patients with medical conditions which are primarily controlled through chronic drug therapy (e.g., hypertension, diabetes, conditions requiring anticoagulation therapy); diagnosis and management of acute, self-limited disease under protocol; preparation, administration and monitoring of parenteral medications requiring close therapeutic monitoring (e.g., cancer chemotherapeutic agents, heparin, antiarrhythmic agents, hyperalimentation); and establishment of specific dosing regimens for selected drugs based upon patient specific pharmacokinetic parameters.

The Board encourages pharmacists with appropriate clinical training to pursue lawfully expanded roles as health professionals. Furthermore, the Board encourages every pharmacist to utilize his or her knowledge and expertise in drug therapy to promote better patient care.

PROF. COMPETENCY

ACPE – Definition of Continuing Education for the Pharmacy Profession



Accreditation Council for Pharmacy Education
20 North Clark Street, Suite 2500 Chicago, IL 60602
Phone: 312/664-3575
Fax: 312/664-1652
info @ acpe-accredit.org



National Association of Boards of Pharmacy
1600 Feehanville Drive, Mount Prospect, IL, 60056
Phone: 847/391-4406
Fax: 847/391-4502
custserv@nabp.net

March 12, 2009

Dear State Pharmacy Board Executive,

It has come to the attention of the Accreditation Council for Pharmacy Education (ACPE) and the National Association of Boards of Pharmacy (NABP) that some of the individual state-based continuing pharmacy education (CPE) approval processes of non-ACPE CPE that awards credit towards pharmacist relicensure has occurred for content that was commercial in nature (e.g. promotional talks, advisory board slides, pharmaceutical company speakers, etc.)

Over the past fifteen years, various organizations and agencies have released guidance documents for interactions with pharmaceutical and device manufacturers (see Attachment). The two most notable relative to continuing education (CE) are the Office of Inspector General (OIG) Compliance Program Guidance for Pharmaceutical Manufacturers (2003) and the Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support (SCS, 2004). In particular, the OIG's emphasis is the concern under the anti-kickback statute where educational grants for activities are used improperly to induce or reward product purchases or if the manufacturer influences the substance of the educational program for inappropriate marketing purposes.

The updated SCS were released by ACCME in 2004; adopted by ACPE in November 2007 and implemented for ACPE CPE providers on January 1, 2008. The SCS call for independence and balance in accredited CE activities through specific requirements. State Boards of Pharmacy should be aware of the issues and approval requirements for accredited CE activities. Providers offering accredited CE (ACPE, ACCME and the American Nurses Credentialing Center – ANCC) must comply with the SCS and therefore include an additional level of review and scrutiny to ensure independence, conflict resolution and appropriate disclosure to participants.

ACPE advises that non-accredited CPE activities should be screened to ensure the aspects of the OIG and SCS guidance are maintained. Without the appropriate screening, State Board approval processes could mistakenly allow credit for promotional materials and undermine the

accreditation process as well impact the pharmacist who received relicensure credit for those activities. ACPE and NABP acknowledge the need for independent State Board approval processes to permit pharmacists to meet their individual continuing education and learning needs. However, during these times of heightened investigation and evaluation of educational influence for commercial gain, it is paramount that the State Boards with independent approval processes implement safeguards to ensure their pharmacists receive balanced and independent education that is applied towards relicensure requirements. Whereas some of these promotional venues may look like valid continuing education when presented to a State Board, careful investigation is warranted to discern promotion from education, as defined by the OIG and ACPE.

Please see the resources on the attached page for additional information regarding independent continuing education, industry guidelines and differentiation of continuing education and promotion. The list includes links to pages on the ACPE Web site. Due to the transmission method, these links may or may not be operational. Please see the ACPE Web site for the documents referenced.

For further information regarding ACPE standards for CPE including the Standards for Commercial Support, please contact ceinfo@acpe-accredit.org | 312/664-3575.

Sincerely,

Peter H. Vlases, Pharm. D.

Peter H. Vlases, PharmD, BCPS, FCCP
Executive Director
Accreditation Council for Pharmacy Education (ACPE)
20 North Clark St., Suite 2500
Chicago, IL 60602-5109

Carmen A. Catizone

Carmen A. Catizone, MS, RPh, DPh
Executive Director/Secretary
National Association of Boards of Pharmacy (NABP)
1600 Feehanville Drive
Mount Prospect, IL 60056

cc: NABP Executive Committee
Peter H. Vlases, ACPE executive director

Attachment

ACPE Standards for Continuing Pharmacy Education

ACPE Standards for Commercial Support

Cover Memo

View Standard - Adobe Acrobat File

Commercial Interest Definition - Updated 01/08

View Guidelines for Standards for Commercial Support - Updated 08/08 - Adobe Acrobat File

Guidance Documents

- Pharmaceutical Research and Manufacturers Association (PhRMA): Code on Interactions with Healthcare Professionals (2008)
- Office of Inspector General (OIG): Compliance Program Guidance for Pharmaceutical Manufacturers (2003)
- American College of Clinical Pharmacy (ACCP): Position Paper Pharmacists and Industry: Guidelines for Ethical Interactions

National Faculty Education Initiative



ACCREDITATION COUNCIL FOR PHARMACY EDUCATION

20 North Clark Street, Suite 2500 • Chicago, Illinois 60602-5109 • www.acpe-accredit.org
312/664-3575 • FAX 312/664-4652 • E-mail: dtravlos@acpe-accredit.org



Dimitra Vrahnos Travlos, Pharm.D., BCPS
Assistant Executive Director and
Director, Continuing Pharmacy Education Provider Accreditation

TO: ACPE-accredited Continuing Pharmacy Education (CPE) Providers

CC: ACPE constituents (e.g. pharmacy organizations, state boards of pharmacy, colleges and schools of pharmacy)

FROM: Dimitra V. Travlos, PharmD, BCPS
Assistant Executive Director and Director, CE Provider Accreditation Program

RE: ACPE Definition of Continuing Education for the Profession of Pharmacy

At its October 2006 Board of Director's Meeting, ACPE approved a revised *Definition of Continuing Education for the Profession of Pharmacy*. This definition better describes the quality of continuing pharmacy education required by ACPE and will assist providers of CPE in planning activities that will be applicable to the professional development of pharmacists and pharmacy technicians.

Changes from the 2003 ACPE Definition of Continuing Education for the Profession of Pharmacy are as follows:

1. Inclusion of:
 - a. Institute of Medicine's five core areas all health care professionals should develop and maintain proficiency;
 - b. American Association of Colleges of Pharmacy's (AACCP) Center for the Advancement of Pharmaceutical Education (CAPE) contemporary educational outcomes needed to prepare pharmacists for their evolving role in meeting patient and public health needs;
 - c. National Association of Boards of Pharmacy redefined Blueprint for the pharmacist licensing exam;
 - d. Future Vision of Pharmacy Practice by the Joint Commission of Pharmacy Practitioners (JCPP, executive directors of eleven professional pharmacy organizations).
2. Differentiation of CPE activities designed for pharmacists from CPE activities designed for pharmacy technicians that includes:
 - a. Pharmacy Technician Certification Board's Practice Analysis of pharmacy technicians.
 - b. A "P" designation in the Universal Program Number that is assigned to each CE activity targeted for pharmacists. Specific performance objectives for each CE activity targeted for pharmacists.
 - c. A "T" designation in the Universal Program Number that is assigned to each CE activity targeted for pharmacy technicians. Specific performance objectives for each CE activity targeted for pharmacy technicians.
3. Addition of a topic designator Patient Safety (05)

Implementation Timeline:

This definition will be implemented August 1, 2007. A transition period will occur August 1, 2007 to December 31, 2007. Providers will be first evaluated by this definition and its contents beginning January 1, 2008.

Summary of the Revision Process:

The draft of the revised *ACPE Definition of Continuing Education for the Profession of Pharmacy* was distributed profession-wide for comment during the period October 11, 2005 to December 8, 2005. The definition was also presented and discussed at ACPE's 11th Conference on Continuing Education in Chicago, NABP's Fall Education Meeting in Miami, and the ASHP Midyear Meeting in Las Vegas. Fifty written responses were also received directly to the ACPE office.

The original timeline indicated that the comments would be reviewed, discussed, and a new *Definition* would be approved by the Board of Directors at the January 2006 Board meeting. However, due to the number of varied concerns, ACPE reviewed and discussed the comments with its CE Provider Advisory Committee and its stakeholders from January to September 2006. ACPE, along with input from NABP and PTCB, drafted a second version. This version was presented and approved by the ACPE Board of Directors at its Strategic Planning Meeting October 2006.

If you have any questions regarding the content of the documents or what constitutes CE activities conducted by ACPE-accredited providers for pharmacists and/or pharmacy technicians, please contact the ACPE staff.

Attached:

1. Definition of Continuing Education for the Profession of Pharmacy
2. Guidelines Associated with the ACPE Definition of Continuing Education



**Accreditation Council for Pharmacy Education
Definition of Continuing Education for the Profession of Pharmacy**

What is the definition of continuing education?

Continuing education for the profession of pharmacy is a structured educational activity designed or intended to support the continuing development of pharmacists and/or pharmacy technicians to maintain and enhance their competence. Continuing pharmacy education (CPE) should promote problem-solving and critical thinking and be applicable to the practice of pharmacy.

What does 'applicable to the practice of pharmacy' mean?

In general, for guidance in organizing and developing CPE activity content, providers should ensure that, as for all health care professionals, pharmacists should develop and maintain proficiency in five core areas*:

- delivering patient-centered care,
- working as part of interdisciplinary teams,
- practicing evidence-based medicine,
- focusing on quality improvement and
- using information technology.

*Adapted from Institute of Medicine's Health Professions Education: A Bridge to Quality, April 2003.

Pharmacist competencies. Pharmacists should always strive to achieve the *Future Vision of Pharmacy Practice* (see Appendix A). Specific competency statements have been developed by the American Association Colleges of Pharmacy and are expected to be achieved upon graduation from an ACPE-accredited professional degree program in pharmacy (see Appendix B: Center for the Advancement of Pharmaceutical Education, Educational Outcomes 2004). Post graduation, pharmacy graduates need to take and pass the pharmacy licensure exam, NAPLEX[®], in order to practice pharmacy. NABP has developed the NAPLEX[®] Blueprint (see Appendix C: The NAPLEX[®] Competency Statements) as the competencies needed to pass the exam. These documents are synergistic in establishing the competencies required of pharmacists to enter practice and to continue as a "student of pharmacy for a lifetime."

Pharmacy Technician Competencies. The Pharmacy Technician Certification Board (PTCB) has developed the Pharmacy Technician Certification Exam (PTCE) Blueprint as the competencies needed to pass the exam (see Appendix D: PTCB Exam Content Outline).

Note: The appendices should be utilized by ACPE-accredited providers as guides in developing CE activity content appropriate for pharmacists and/or pharmacy technicians.

How will CPE activities for pharmacists and pharmacy technicians be designated?

Promotional materials (e.g., brochures, advertisements, memoranda, letters of invitation, or other announcements) should clearly and explicitly identify the target audience that will benefit from the content of the CPE activity. If a CPE activity includes pharmacists and pharmacy technicians in the same CPE activity specific and separate learning objectives should be described for each, pharmacists and pharmacy technicians.

In addition, a Universal Program Number is an identification number that is assigned to each CPE activity developed and sponsored, or cosponsored, by an ACPE-accredited provider. This number is developed by appending to the ACPE provider identification number (e.g. 197), the cosponsor designation number (000 for no cosponsor, 999 for all non-ACPE-accredited cosponsors, or the ACPE identification number for ACPE-accredited cosponsors), the year of CE activity development (e.g., 06), the sequential number of the CPE activity from among the new CPE activities developed during that year (e.g., 001), and the topic and format designators (see below).

Cosponsor Designators:

- 000 - no cosponsoring organization
- 999 - cosponsoring with a non-ACPE-accredited organization
- 001 - 998 - the ACPE provider identification number of the cosponsoring provider

Format Designators:

- L - Live activities
- H - Home study and other mediated activities
- C - Activities that contain both live and home study or mediated components

Topic Designators – activities are related to:

- 01 - Disease State Management/Drug therapy
- 02 - AIDS therapy
- 03 - Law (related to pharmacy practice)
- 04 - General Pharmacy

In order to identify the target audience, **new topic designators** are being proposed as follows:

If a CPE activity's target audience is exclusively for *pharmacists* the designation "P" will be used as follows:

- 01-P Disease State Management/Drug therapy
- 02-P AIDS therapy
- 03-P Law (related to pharmacy practice)
- 04-P General Pharmacy
- 05-P Patient Safety: The prevention of healthcare errors, and the elimination or mitigation of patient injury caused by healthcare errors (An unintended healthcare outcome caused by a defect in the delivery of care to a patient.) Healthcare errors may be errors of commission (doing the wrong thing), omission (not doing the right thing), or execution (doing the right thing incorrectly). Errors may be made by any member of the healthcare team in any healthcare setting. (definitions approved by the National Patient Safety Foundation® Board July 2003)

If a CPE activity's target audience is exclusively for *pharmacy technicians* the designation "T" will be used as follows:

- 01-T Disease State Management/Drug therapy
- 02-T AIDS therapy
- 03-T Law (related to pharmacy practice)
- 04-T General Pharmacy
- 05-T Patient Safety: The prevention of healthcare errors, and the elimination or mitigation of patient injury caused by healthcare errors (An unintended healthcare outcome caused by a

defect in the delivery of care to a patient). Healthcare errors may be errors of commission (doing the wrong thing), omission (not doing the right thing), or execution (doing the right thing incorrectly). Errors may be made by any member of the healthcare team in any healthcare setting. (definitions approved by the National Patient Safety Foundation® Board July 2003)

Note: If the CPE activity is intended for both pharmacists and pharmacy technicians, that activity will have the same Universal Program Number with respect to the provider identification number, cosponsor designation, year of release, sequence number and format; however, the topic designator in the number will be specific to each audience, either a “P” or “T.” For example:

197-000-06-001-L05-P (program number to be used for pharmacists)

197-000-06-001-L05-T (program number to be used for pharmacy technicians)

What are the responsibilities of an ACPE-accredited provider?

It is the responsibility of the provider to assure that each activity complies with the Definition of Continuing Education, be applicable to the practice of pharmacy, identifies the appropriate target audience as it relates to the content, and adheres to *ACPE Criteria for Quality and Interpretive Guidelines*.

As outlined in the *ACPE Criteria for Quality and Interpretive Guidelines*, every ACPE-accredited provider is ultimately responsible for CPE activity planning, faculty selection, content of the activity, site selection, method of delivery, marketing to the appropriate target audience and assurance that the activity is fair, balanced and free from bias and/or promotion. In addition, the provider is responsible for explaining and guiding the faculty in its expectations regarding development of learning objectives and instructional materials and incorporation of active learning and learning assessment mechanisms within the activities. The provider should also ensure that the statements of credit include the appropriate designation as well as the other required elements noted in the *ACPE Criteria for Quality*, Guideline 8.1 Statements of Credit.

Have questions?

If you have any questions as to what constitutes continuing education for the profession of pharmacy, please contact the ACPE staff at ceinfo@acpe-accredit.org or phone 312-664-3575.



**Accreditation Council for Pharmacy Education
Guidelines Associated with the ACPE Definition of
Continuing Education for the Profession of Pharmacy**

In October 2006, the ACPE Board of Directors adopted a revised Definition of Continuing Education for the Profession of Pharmacy. This definition better defines continuing pharmacy education (CPE), includes pharmacy technicians, describes the professional competencies identified for pharmacists and pharmacy technicians, and explains the responsibilities of a provider of continuing pharmacy education.

A multitude of educational CPE activities exist in various formats and venues. Some of these activities benefit pharmacists and pharmacy technicians in their lifelong learning process but do not necessarily constitute CPE as defined by the ACPE *Definition of Continuing Education for the Profession of Pharmacy* and the ACPE *Criteria for Quality and Interpretive Guidelines*. As a result, such CE activities should not have continuing pharmacy education credit provided. At the same time, some of these formats and venues may be restructured to meet the requirements for CPE. The following document includes commonly asked questions to further guide the CPE provider as to what constitutes CPE and how some of these venues may be reformatted so they may be offered for CPE credit. The questions are provided in sections, alphabetically, by venue.

If you have any questions or need further clarification, please contact the ACPE staff.

Association membership or leadership activities

- What leadership activities are considered CPE?
Leadership activities that may be considered as CPE are activities that include the development of supervision and management skills of the pharmacist and/or pharmacy technician as it relates to their pharmacy practice.
- Can an association offer CPE activities in conjunction with a membership rally?
Yes, however the hours awarded for credit should be only for the CPE component and not the membership rally.

Committee meetings

- Can committee meetings award CPE credit?
A committee, such as a Board of Directors, association committees, hospital committees, etc. consists of a group of individuals delegated to consider, investigate, take action on, or report on some matter. If the committee's agenda includes a formal, structured, and specific educational component that is conducted by an ACPE-accredited provider, a minimum of 60 minutes (equal to one contact hour) and the participants can be engaged in the activity, participants may receive credit only for the educational component. The committee members may not receive credit for the time spent on the work of the committee.

Location of the continuing pharmacy education activity

- Can CPE be offered during a cruise or at a resort?

The facilities utilized should be appropriate and adequate to the content and method of delivery of the CPE activity and be appropriately equipped. In addition, the educational delivery should be separate from any promotional, extracurricular or leisure activity. Credit should only be awarded for the time the pharmacist participates in the educational activity.

News briefs and/or news updates

- Are newsletters that cover a variety of brief unrelated subjects considered CPE?

No. Although this type of newsletter may be worthwhile and quick to read, it is mostly informational and does not constitute CPE. This content defies Criterion 19 of ACPE's *Criteria for Quality* that states, "Each CE activity shall be designed to explore one subject or a group of closely related subjects." Instead, providers may use this venue as an educational needs assessment whereby, a pharmacist informs the provider of areas within the newsletter for which he or she would like further education; or providers may alter the format and content of this type of newsletter to have a common theme, relate content to the contemporary practice of pharmacy, and incorporate relevant active learning or learning assessments so then it may be considered for CPE credit.

Participation on clinical rounds

- Can pharmacists receive CPE credit for participation on clinical rounds?

Clinical rounds can be an invaluable learning experience; the exposure to real patients, multidisciplinary discussion, and active participation provide a great opportunity for learning. However, in order to offer CPE credit, the experience needs to be formal and structured. It can:

- i. be organized as part of a larger organized CPE series,
- ii. be part of a certificate program that meets Standards No. 3 Instructional Design (*Standards and Quality Assurance Procedures for ACPE-Accredited Providers of Continuing Pharmacy Education Offering Certificate Programs in Pharmacy*) or
- iii. held in conjunction with other related and integrated instructional experiences such as didactic components, reflection exercises, etc.

- Can teaching, precepting or mentoring of pharmacy students be considered for CPE credit?

No. Teaching as part of one's work responsibilities cannot be considered as CPE. A pharmacist may receive CPE credit as the faculty member for an activity that is providing CPE credit, but only on the first occasion of the activity, and only for the amount of credit being awarded to participants.

Participation and/or presentation in journal clubs

- Can journal clubs be offered for CPE?

A journal club can be offered for CPE credit if it is formal, structured, has a specific focus or theme, includes measurable learning objectives and an instructional design where assessment of learning can take place. The provider should notify participants of the requirements for credit if various formats are used (e.g. pre-reading of the article, live discussion directed by the journal club leader, etc.)

- How are hours assigned to a journal club?

As indicated in the *Criteria for Quality*, Criterion 6, an educationally sound and defensible process must be employed and documented. Acceptable procedures include, but are not limited to:

- Pilot testing the activity with a group of pharmacists and/or pharmacy technicians who are representative of the target audience and ascertaining the average length of time for completion for only those participants who successfully complete the CPE activity.
- Rendering a determination by an advisory panel, consisting of individuals qualified by experience and training in the development and administration of CPE.

Participation and/or presentation of poster sessions

- Are poster sessions considered CPE?

A poster session can be offered as CPE credit if it is formal, structured, has a specific focus or theme, includes measurable learning objectives and an instructional design in which assessment of learning can take place. The provider must ensure that the posters include appropriate content. For example, research-based poster sessions on a variety of topics that do not focus on a specific focus or theme would not be considered CPE. In addition, the setting must be in an environment conducive for learning and discussion. For example, exhibit halls are not considered a setting conducive for CPE poster sessions. A poster session that has a limited number of posters with a specific theme, appropriate learning objectives, includes active learning and learning assessment components, and the provider is able to verify the pharmacists' and/or pharmacy technicians' participation may be considered for CPE credit.
- How are hours assigned to a poster session?

As indicated in the *Criteria for Quality*, Criterion 6, an educationally sound and defensible process must be employed and documented. Acceptable procedures include, but are not limited to:

 - Pilot testing the activity with a group of pharmacists and/or pharmacy technicians who are representative of the target audience and ascertaining the average length of time for completion for only those participants who successfully complete the CPE activity; or,
 - Rendering a determination by an advisory panel, consisting of individuals qualified by experience and training in the development and administration of CPE.

Patient Safety

- What topic areas would be assigned the topic designator "05" for patient safety?

The prevention of healthcare errors, and the elimination or mitigation of patient injury caused by healthcare errors (defined as an unintended healthcare outcome caused by a defect in the delivery of care to a patient). Healthcare errors may be errors of:

 - i. commission (doing the wrong thing),
 - ii. omission (not doing the right thing), or
 - iii. execution (doing the right thing incorrectly).

Errors may be made by any member of the healthcare team in any healthcare setting. (definitions approved by the National Patient Safety Foundation® Board July 2003)

Personal development, i.e. financial seminars, etc.

- Can personal financial seminars be considered CPE?

No. Educational sessions that pertain solely to personal issues, such as financial seminars that discuss individual retirement accounts, investments, etc. are not considered CPE. However, financial management courses that pertain to managing pharmacy practice can be considered for continuing education credit if the activity is applicable to the practice of pharmacy.
- Can a pharmacist and/or pharmacy technician receive credit for a session regarding time management or burn out prevention?

If the session includes content relating to the practice of pharmacy, it can be considered for CPE credit.

Universal Program Number (UPN)

- How will the UPN be depicted if a CPE activity is designed only for pharmacists?
If the CPE activity is intended for pharmacists only, that activity will have the same UPN with respect to the provider identification number, cosponsor designation, year of release, sequence number and format; however, the topic designator in the number will be specific to each audience. For example: 197-000-06-001-L05-P (program number to be used for pharmacists).
- How will the UPN be depicted if a CPE activity is designed only for pharmacy technicians?
If the CPE activity is intended for pharmacy technicians, that activity will have the same UPN with respect to the provider identification number, cosponsor designation, year of release, sequence number and format; however, the topic designator in the number will be specific to each audience. For example: 197-000-06-001-L05-T (program number to be used for pharmacy technicians).
- How will the UPN be depicted if a CPE activity is designed for pharmacists and pharmacy technicians?
If the CE activity is intended for both pharmacists and pharmacy technicians, providers must be able to demonstrate needs assessments, performance objectives, and learning assessments for the pharmacists and pharmacy technicians, respectively. The CPE activity will be assigned two UPNs specific to each audience. For example:
197-000-06-001-L05-P (program number to be used for pharmacists)
197-000-06-001-L05-T (program number to be used for pharmacy technicians)
- How will the UPN be depicted if a CPE activity is also designed for physicians and/or nurses?
If the physician or nurse participated in a CPE activity and request an ACPE statement of credit, the UPN would be depicted as it is for pharmacists. For example: 197-000-06-001-L05-P (program number to be used for pharmacists).
- What happens if pharmacy technicians attend and participate in a CPE activity designed for pharmacists (“P” designation)?
The UPN designation is based upon the content and the intended audience. If the content is geared for pharmacists, the UPN should have a “P” designation and the statements of credit should contain a UPN with the “P” designation. The pharmacy technician would receive a “P” designated statement of credit that should not be acceptable to the pharmacy technicians’ regulatory body.
- What happens if pharmacists attend and participate in a CPE activity designed for pharmacy technicians (“T” designation)?
The UPN designation is based upon the content and the intended audience. If the content is geared for pharmacy technicians, the UPN should have a “T” designation and the statements of credit should contain a UPN with the “T” designation. The pharmacist would receive a “T” designated statement of credit that should not be acceptable for credit for relicensure.

Work experience

- Is on the job training considered CPE?
In general, on-the-job training/work experience would not be considered for CPE credit. However, if the training/work experience is formal, structured, involves knowledge and skills that can be applied to any pharmacy setting, and is conducted by an ACPE-accredited provider then the training/work experience may be offered for CPE credit. For example, if the employee were to observe other employees for a certain time period, this would not be considered for CPE credit. However if the training/work experience includes a

didactic/classroom component, viewing a videotape, etc. this may be considered for CPE credit. In addition, if the training/work experience is specific to that setting, CPE credit cannot be offered, e.g. reading the company's policies and procedures, attending a training session for the hospital or chain computer system, etc.

- Can a pharmacist and/or pharmacy technician who is conducting a session that awards CPE credit also receive the CPE credit?

Yes. The pharmacist and/or pharmacy technician may receive CPE credit for the time assigned to the activity and only on the first occasion of the activity. The pharmacist and/or pharmacy technician cannot receive CPE credit for the time spent in the preparation of the material.

Heparin Recall Notification Chronology

- **May 16** CPhA CEO Message: "Earlier this month, both the California Department of Public Health and the Board of Pharmacy issued provider notices indicating that certain lots of Heparin have been recalled because of contamination of the raw material used to produce the products. However, state surveyors are still finding the recalled Heparin in nursing facility emergency kits. Please read the CDPH letter (attached) and act according to its instructions—be sure to pull all of the recalled Heparin from the emergency supply kits and any automated drug delivery systems."

CDPH Inspections

- **Purpose:** Ensure Patient Safety – recalled medications are not available for patient use.
 - Assess facility's recall process
 - Determine potential clinical impact on patients.
 - Ascertain if recalled medications are available for patient use.
- **Facility Type Investigations**
 - End Stage Renal Dialysis (ESRDs)
 - Hospitals
- Activities coordinated with CDPH Food and Drug Branch

CDPH Findings - Hospitals

- 87 inspections were conducted
 - 84 - BOP referrals
 - 3 - CDPH identified
- Assessment for presence of available recalled medications included heparin, Digitek and Procrit
- Inspection dates May 1 through August 12th
- Average length of inspection visit – one day
- 30% of hospitals were identified with recalled medications available for patient use

CDPH Findings - Hospitals

- More than one in four hospitals were identified with recalled medications available for patient use after the BOP inspection.
- Total potential patient exposures from recall to removal of medication(s): Thousands
- Average lag time following BOP visit – 13 days
 - Range: 1 to 32 days

CDPH Findings - Hospitals

- Majority of recalled medications found available for patient use was heparin and principally Baxter
- Location of found heparin was primarily in patient care areas and at dosage formulations greater than 100 units/ml
- On average Baxter heparin was found 67.5 days after February recall notice

Summary

- Findings reveal systemic deficits in hospital's recall process and drug distribution system.
- Patient impact
- Costly
- Opportunity for Improvement
 - Identify root causes of these deficits
 - Develop plans of action aimed at system deficits
 - Goal: prevent a reoccurrence

Request from Jefferson School of Pharmacy



JeffersonTM
College of Health Professions

RECEIVED BY STATE
BOARD OF PHARMACY

2009 FEB -3 AM 10:54

Licensing
Jefferson School of Pharmacy.

Rebecca S. Finley, PharmD, MS
Dean

T 215.503.9000 F 215.503.9052

rebecca.finley@jefferson.edu

January 28, 2009

Virginia Herold
Executive Officer
California State Board of Pharmacy
1625 N. Market Boulevard, Suite N219
Sacramento, CA 95834

Subject: Recognition of the Jefferson School of Pharmacy, Thomas Jefferson University

Dear Ms. Herold:

The Jefferson School of Pharmacy (JSP) is an academic unit within Thomas Jefferson University (TJU), a private, nonprofit health sciences University and Academic Health Center located in Philadelphia, Pennsylvania. TJU is dedicated to furthering humanitarian principles of health preservation and the advancement of the art and science of health care. In addition to JSP, TJU also includes schools of medicine, nursing, graduate studies, population health and health professions (physical therapy, occupational therapy, bioscience technology, and radiologic sciences).

The Doctor of Pharmacy (PharmD) degree at JSP requires completion of a 4 year program of study (see attachment). The first three years of the PharmD program are comprised of two 15-week semesters and year 4 includes six 6-week advanced pharmacy practice experiences as well as approximately 4 weeks on campus for capstone seminar coursework and law review. The Experiential Education portion of the curriculum includes both Introductory Pharmacy Practice Experiences (IPPEs) and Advanced Pharmacy Practice Experiences (APPEs).

During years 1 and 2 of the program, students are enrolled in an IPPE each semester. IPPEs I-IV include 3 hours weekly (for the 15 week semester) in each of the following: Healthcare Related Service Learning, Community Pharmacy, Hospital or Health System Pharmacy, and Ambulatory Care. IPPE V is a 6 hour per week (15 weeks) Acute/Direct Patient Care Experience and IPPE VI is a 6 hour per week Elective IPPE. In addition, all JSP PharmD students are required to participate in the Jefferson Health Mentors program throughout their first two years. During the Health Mentors program students are assigned to interdisciplinary teams (eg, medicine, nursing, pharmacy and physical or occupational therapy) which meet approximately 4 times a year with an individual with one or more chronic diseases. During these visits the students learn about how the health conditions impact the patient's life and the challenges associated with negotiating through the health care system. The interdisciplinary team of students regularly meeting with faculty facilitators to discussion their interactions and write reflective papers.

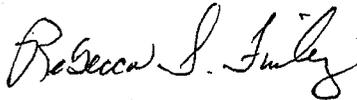
Collectively, the 300 contact hours of IPPEs are designed to allow students to observe and then apply didactic information and skills obtained throughout the PharmD program ultimately preparing students to effectively advance to the APPEs.

The APPEs include required Community Pharmacy, Hospital or Health System Pharmacy, Ambulatory Care and Acute / Direct Patient Care Rotations. In addition, all students are required to complete a minimum of two 6-week elective rotations, one of which must be in a Direct Patient Care environment (either inpatient or ambulatory). In total students complete a minimum of 300 contact hours of IPPEs and 1440 contact hours of APPEs. All IPPEs and APPEs are precepted by licensed pharmacists.

JSP respectfully requests recognition by the California State Board of Pharmacy. JSP was granted Precandidate accreditation status by the Accreditation Council on Pharmacy Education (ACPE) at their January 2008 meeting and we enrolled our first class of 73 students in September of 2008. We are proud to have several California residents in our inaugural class. Our next on site evaluation from ACPE is scheduled in late March of 2009 to consider JSP for Candidate status. Further information regarding JSP maybe found on our website: <http://www.jefferson.edu/jchp/pharmacy/index.cfm> or by contacting my office at 215-503-9000.

Thank you very much for your consideration of our request to be recognized by the California State Board of Pharmacy.

Sincerely,



Rebecca S. Finley, PharmD, MS, FASHP
Dean

Jefferson School of Pharmacy – Doctor of Pharmacy Curriculum

First Year – P1

Fall	Credits	Spring	Credits
Biochemistry	3	Biostatistics	3
Immunology	3	IPPE II – Community pharmacy	*1
IPPE I - Healthcare related service learning	*1	Medicinal Chemistry	2
Healthcare Communications and Patient Counseling	2	Molecular and Cell Biologies	3
Healthcare Delivery Systems	2	Pathophysiology II	3
Pathophysiology I	3	Pharmacy Practice II	1
Pharmacy Practice I	1	Physical Assessment and Clinical Skills	3
Preventive Healthcare and Self-Care Issues	2		
Total Credits	17		16

Second Year – P2

Fall	Credits	Spring	Credits
Drug Information and Literature Evaluation	3	Clinical Diagnosis / Pharmacotherapy I	4
IPPE III - Hospital/Institutional Pharmacy	*1	Biopharmaceutics and Principles of Clinical Pharmacokinetics	3
Medication Safety	2	IPPE IV – Outpatient/Ambulatory Care Clinic	*1
Pharmaceutics and Drug Delivery Systems	3	Pharmacology II	3
Pharmaceutics Lab	1	Pharmacy Practice IV	1
Pharmacology I	3	Pharmacy Practice Lab I	1
Pharmacy Management: Theory and Applications	3	Professional Elective(s)	3
Pharmacy Practice III	1		
Total Credits	17		16

Third Year – P3

Fall	Credits	Spring	Credits
Clinical Diagnosis / Pharmacotherapy II and III	6	Clinical Diagnosis / Pharmacotherapy IV and V	6
IPPE V - Inpatient, Direct Patient Care	*2	Milestone Assessment	1
Pharmacology III	3	IPPE VI – ‘Elective’	*2
Pharmacy Grand Rounds	2	Pharmacoeconomics and Health Outcomes	3
Pharmacy Practice Lab II	1	Pharmacy Practice Lab III	1
Professional Elective(s)	3	Professional Seminar I	2
		Professional Elective(s)	3
Total Credits	17		18

Fourth Year – P4

APPEs

4 Core (Community Pharmacy, Hospital/Health System Pharmacy, Ambulatory Care, Inpatient/Acute Care)

2 Open – 1 direct patient care, 1 free (6 X 6 weeks each x 40 hours/week = 1440 hours)

36 credits

Pharmacy Law

1 credit

Professional Seminar II

2 credits

Total Credits**39****Total Curriculum Credits = 140**

* = Without regard to semester

IPPE = Introductory Pharmacy Practice Experience

APPE = Advanced Pharmacy Practice Experience



California State Board of Pharmacy

1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

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

February 4, 2009

Rebecca S. Finley, PharmD, MS, FASHP
Dean
Jefferson College of Health Professions
130 South 9th Street, Suite 1520
Philadelphia, PA 19107

Dear Dr. Finley:

Congratulations on attaining precandidate accreditation from ACPE for your new pharmacy school.

I have received your request seeking board recognition of your program so that students in your program from California may work as interns here. I have also received your brochure describing the program.

The process for board recognition typically requires review by the board's Licensing Committee, and then action by the Board of Pharmacy itself.

The likely timing of this process for the Jefferson School of Pharmacy would be for the Licensing Committee to review your request at its March 24 meeting, and then have the board take action on the request at the Board Meeting scheduled for April 30. I will notify you following this meeting of the board's decision (or you can contact me if you wish the information sooner).

Again, congratulations on attaining a major step in your accreditation. If you have questions, please do not hesitate to contact me at (916) 574-7911.

Sincerely,

A handwritten signature in cursive script, appearing to read "Virginia Herold".

VIRGINIA HEROLD
Executive Officer



Jefferson School of
Pharmacy



THOMAS JEFFERSON UNIVERSITY



The Jefferson Difference

THOMAS JEFFERSON UNIVERSITY REDEFINES HEALTHCARE EDUCATION BY PREPARING STUDENTS TO BE MEMBERS OF TOMORROW'S INTEGRATED HEALTHCARE TEAM. JEFFERSON GRADUATES ARE RECOGNIZED THROUGHOUT THE COUNTRY AS LEADERS IN EDUCATION, RESEARCH, HEALTHCARE DELIVERY, AND COMMUNITY SERVICE.

CONTENTS

- 1 THE JEFFERSON DIFFERENCE
- 2 EDUCATING COLLABORATORS
- 4 CAREERS IN PHARMACY
- 6 CURRICULUM OVERVIEW & PREREQUISITES
- 10 EXPERIENTIAL LEARNING & LICENSURE
- 12 STUDENT LIFE
- 14 APPLYING TO JEFFERSON
- 16 TUITION & FINANCIAL AID



A Community of Learners

Jefferson College of Health Professions (JCHP) is an integral part of one of the nation's first academic health centers, Thomas Jefferson University, which also includes Jefferson Medical College and Jefferson College of Graduate Studies. JCHP has three schools: a School of Health Professions (consisting of Departments of Bioscience Technologies, Couple and Family Therapy, General Studies, Occupational Therapy, Physical Therapy, and Radiologic Sciences), a School of Nursing, and a School of Pharmacy.

Interprofessional Focus

Jefferson's model for healthcare education depends on a true community of professionals and scholars whose members learn with and from one another, embrace each other's contributions, and collaborate to provide the finest care possible.

The newly opened Dorrance H. Hamilton Building brings future nurses, pharmacists, physicians, therapists, and technologists into the same classrooms and simulated clinical settings. Training together using the latest technologies in realistic environments gives students the knowledge, experience, and mindset to be successful members — and leaders — of the integrated healthcare team.

Real World Experience

JCHP students attend more than a university — they are a part of one of the nation's few academic health centers with access to a variety of research and clinical training opportunities through the Jefferson Health System and more than 1,800 sites locally and across the nation.

To learn more about the Jefferson Difference, visit www.jefferson.edu/jchp.

Educating Collaborators

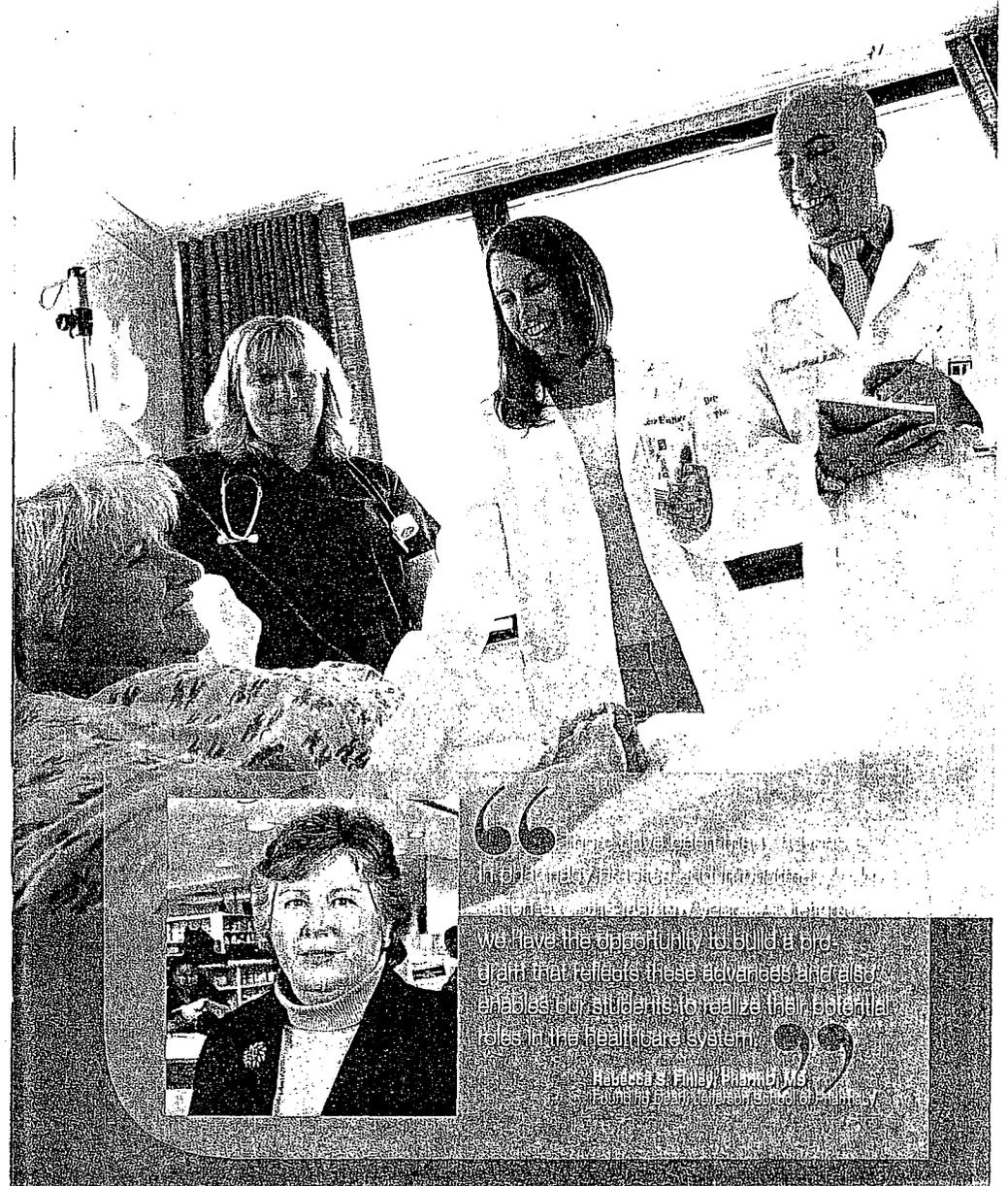


Pharmacists are the most accessible healthcare professionals. They are face to face with patients who need prescriptions filled and request medical advice. They interact with physicians and the rest of the healthcare team about medicine interactions and treatment options. They conduct research to develop the latest drug therapies. Collaboration is an important skill for pharmacists today, and Jefferson students learn that skill by interacting regularly with peers from other disciplines, including medicine, nursing and other healthcare professions. By learning to problem solve together, students develop a strong, positive understanding of each other's roles and are prepared to work as a team.

The Jefferson School of Pharmacy

- offers students opportunities to learn side-by-side with medical, nursing, and other healthcare students and to regularly work with pharmacists in real-life patient-care settings
- is closely affiliated with Thomas Jefferson University Hospital which, for more than 40 years, has been widely regarded as having one of the most outstanding hospital pharmacies in the country.

Jefferson School of Pharmacy students engage in classroom discussion and learn through integration and application of the basic, clinical, and administrative sciences. The curriculum is designed to help students effectively collaborate with other healthcare professionals to ensure that all patients receive safe and effective drug therapy and to understand how pharmacists can influence the healthcare system and positively impact public health.



“We have the opportunity to build a program that reflects these advantages and also enables our students to realize their potential roles in the healthcare system.”
HARVEY S. FINLEY, PHARM.D., M.S.
FOUNDING DEAN, JEFFERSON SCHOOL OF PHARMACY

A Career for You in Pharmacy



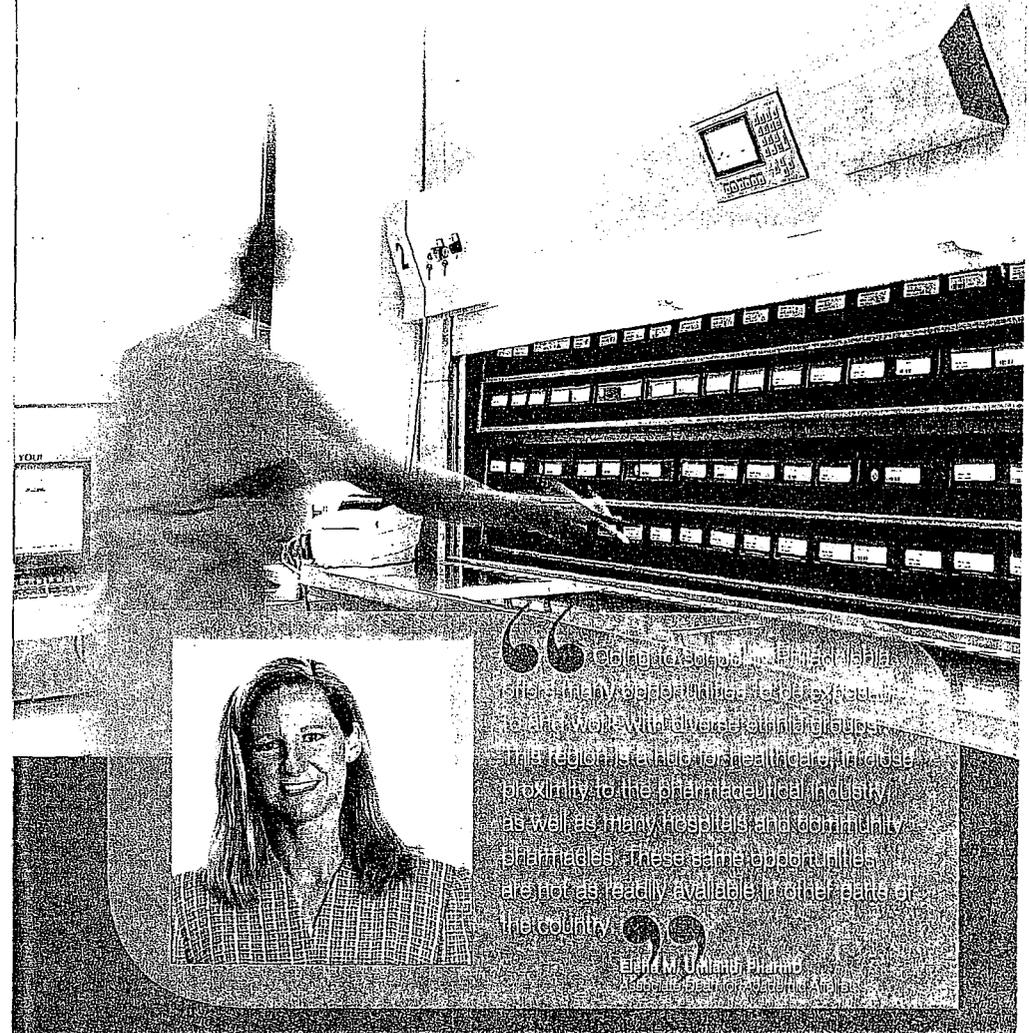
Due to rapid growth in the healthcare and pharmaceutical industries, as well as an increase in the elderly population, the need for well-trained pharmacists continues. Estimates show a predicted shortfall of more than 150,000 pharmacists by the year 2020.

Practice in a Variety of Settings

Students in the Jefferson School of Pharmacy will develop the knowledge and expertise to practice in a wide range of pharmacy settings such as:

- community or retail settings
- hospitals
- clinics
- long-term care facilities
- pharmaceutical industry
- pharmaceutical advertising
- pharmaceutical publishing companies

Post-graduate training is widely available for pharmacists who aspire to leadership positions such as managers or directors of pharmacies, and for those who want to specialize in caring for patients with specific healthcare needs such as children, the elderly, or individuals with heart disease, cancer, or other critical illnesses.



...the region is a leader in healthcare, it also
proximity to the pharmaceutical industry,
as well as many hospitals and community
pharmacies. These same opportunities
are not as readily available in other parts of
the country.

Jefferson University Pharmacy
1335 Locust Street, Philadelphia, PA 19107
215-955-1000

The Doctor of Pharmacy Program



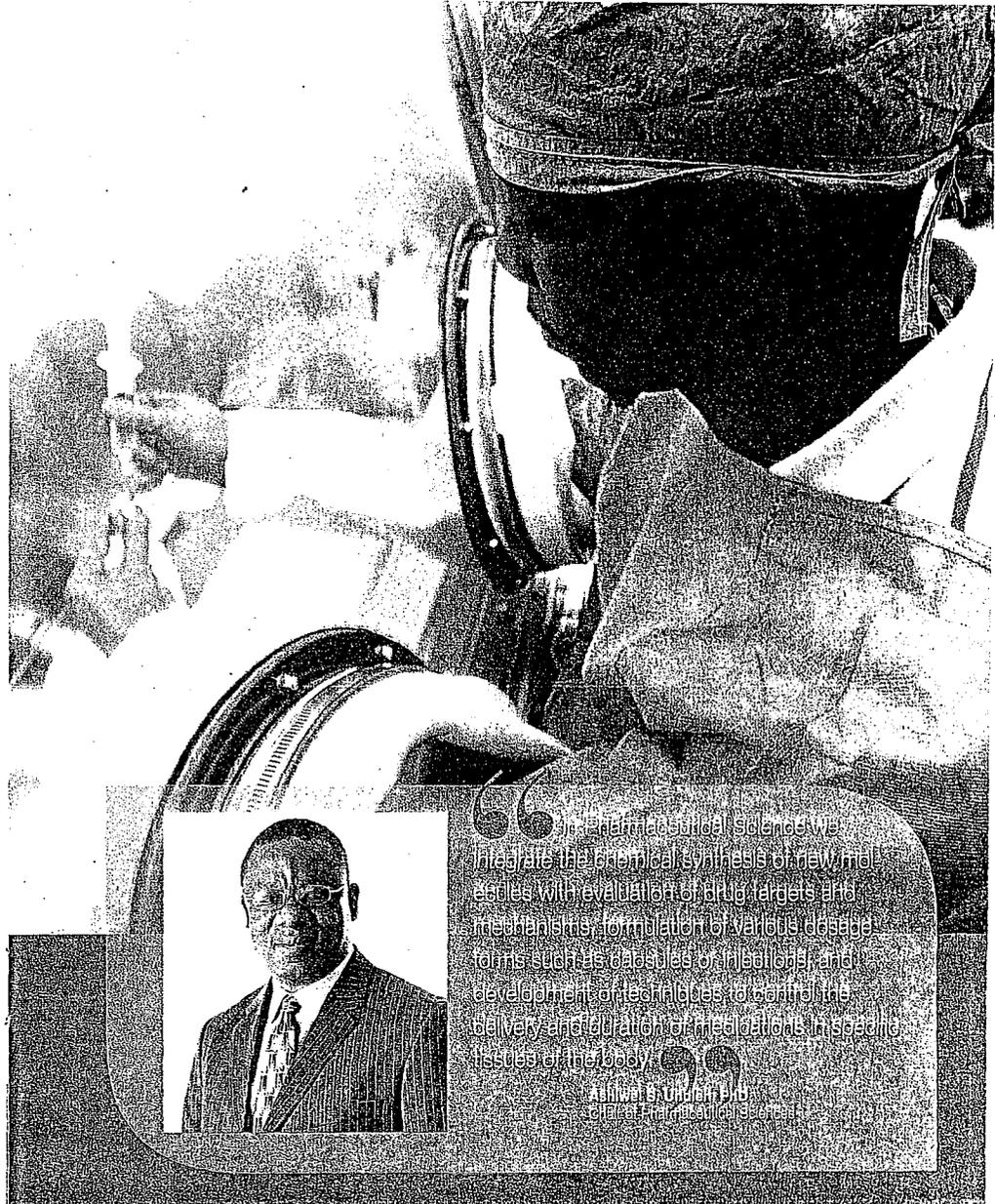
The 4-year PharmD program requires a minimum of 140 credits including classroom instruction and hands-on experiential learning (approximately 30% of the program).

Curriculum Overview

The Doctor of Pharmacy curriculum is modeled on the core curriculum developed by the Accreditation Council for Pharmaceutical Education (ACPE). It encourages collaborative learning among its own students as well as interaction with students enrolled in other disciplines at Thomas Jefferson University, including nursing, medicine, physical therapy, and occupational therapy. In developing students into professionals and creating the foundation for their life-long learning, the didactic component of the Doctor of Pharmacy curriculum includes active learning techniques, simulated patient care environments, online learning, and problem-based learning.

PREREQUISITES		SEMESTER HOURS	
Anatomy & Physiology I*	4 credits	Organic Chemistry I*	4 credits
Anatomy & Physiology II*	4 credits	Organic Chemistry II*	4 credits
Biology I*	4 credits	Physics I*	4 credits
Biology II*	4 credits	Physics II*	4 credits
General Chemistry I*	4 credits	Microbiology [†]	4 credits
General Chemistry II*	4 credits	English Composition	3 credits
Calculus [‡]	3 credits	Social Sciences	9 credits
		Humanities	9 credits
		TOTAL CREDITS	68

* Prerequisite for PharmD program.
[†] Prerequisite for PharmD program.
[‡] Prerequisite for PharmD program.



The pharmaceutical sciences will integrate the chemical synthesis of new molecules with evaluation of drug targets and mechanisms, formulation of various dosage forms such as capsules or injections, and development of techniques to control the delivery and duration of medications in specific tissues of the body.

Adrian Williams, PhD
 CHIEF OF PHARMACEUTICAL SCIENCES



The didactic component of our curriculum includes active learning techniques, simulated patient care environments, online learning, and problem-based learning.

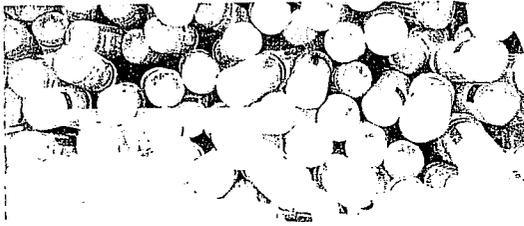
WITH OUR REGARD TO SEMESTER
 IPPE = INTRODUCTORY PHARMACY
 PRACTICE EXPERIENCE
 APPE = ADVANCED PHARMACY
 PRACTICE EXPERIENCE

Doctor of Pharmacy Degree Program

CURRICULUM

FIRST YEAR	CREDITS		
Fall semester		IPPE IV: Outpatient/ Ambulatory Care Clinic*	1
Biochemistry	5	Pharmacology II	3
Immunology	3	Pharmacy Practice IV	1
IPPE: Healthcare Related Service Learning*	1	Pharmacy Practice Lab I	1
Healthcare Communications and Patient Counseling	2	Professional Elective(s)	3
Healthcare Delivery Systems	2	TOTAL	16
Pathophysiology I	3	THIRD YEAR	CREDITS
Pharmacy Practice I	1	Fall semester	
Preventive Healthcare and Self-Care Issues	2	Clinical Diagnosis/ Pharmacotherapy II and III	6
TOTAL	17	IPPE V: Inpatient, Direct Patient Care*	2
Spring semester		Pharmacology III	3
Biostatistics	3	Pharmacy Grand Rounds	2
IPPE II: Community Pharmacy*	1	Pharmacy Practice Lab II	1
Medicinal Chemistry	2	Professional Elective(s)	3
Molecular and Cell Biology	3	TOTAL	17
Pathophysiology II	3	Spring semester	
Pharmacy Practice II	1	Clinical Diagnosis/ Pharmacotherapy IV and V	6
Physical Assessment and Clinical Skills	3	Milestone Assessment	1
TOTAL	16	IPPE VI: Elective*	2
SECOND YEAR	CREDITS	Pharmacoeconomics & Health Outcomes	3
Fall semester		Pharmacy Practice Lab III	1
Drug Information and Literature Evaluation	3	Professional Seminar I	2
IPPE III: Hospital/ Institutional Pharmacy*	1	Professional Elective(s)	3
Medication Safety	2	TOTAL	18
Pharmaceutics and Drug Delivery Systems	3	FOURTH YEAR	CREDITS
Pharmaceutics Lab	1	APPEs*	
Pharmacology I	3	4 Core:	
Pharmacy Management: Theory and Applications	3	Community Pharmacy, Hospital/Health System Pharmacy, Ambulatory Care, Inpatient/Acute Care	24
Pharmacy Practice III	1	2 Open: 1 direct patient care, 1 free (6 x 6 weeks each x 40 hours/week = 1440 hours)	12
TOTAL	17	Pharmacy Law	1
Spring semester		Professional Seminar II	2
Clinical Diagnosis/ Pharmacotherapy I	4	TOTAL	39
Biopharmaceutics and Principles of Clinical Pharmacokinetics	3	TOTAL CURRICULUM CREDITS	140

Experiential Learning



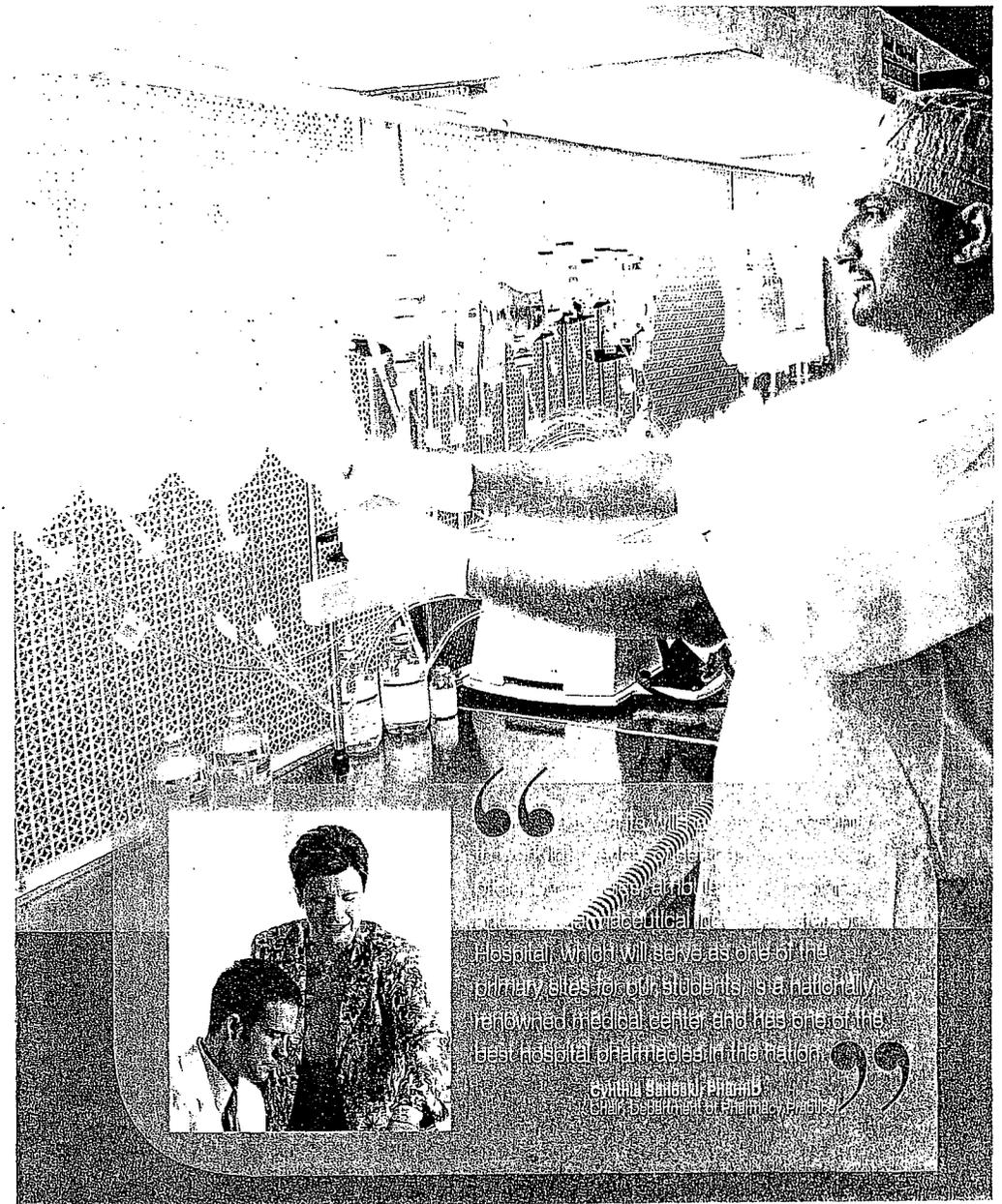
Experiential Learning is a key component of the Jefferson School of Pharmacy curriculum. Students will participate in the Introductory Pharmacy Practice Experience (IPPE) for approximately 3 hours a week each semester during the first 2 years of the program (IPPE I-IV). They will spend approximately 6 hours per week participating in IPPEs V and VI during the third year of the program.

Year 4: Full-Time Practice

During the final year, students participate in 6 full-time Advanced Pharmacy Practice Experiences (APPEs), approximately 40 hours a week, in a variety of pharmacy settings (APPEs I-VI as defined on page 9). Four of these experiences must be completed in the required fields of Community Pharmacy, Hospital/Health System Pharmacy, Ambulatory Care, and Inpatient/Acute Care. The remaining two APPEs are elective experiences which students can choose according to their interests.

Licensure/Certification

After earning the Doctor of Pharmacy degree, graduates will be eligible to take state licensure examinations. Following licensure, pharmacists may choose to practice in a wide range of patient care settings or to pursue post-graduate training programs.



“Hospital, which will serve as one of the primary sites for our students, is a nationally renowned medical center and has one of the best hospital pharmacies in the nation.”

William G. Gorman, Pharm.D.
Chair, Department of Pharmacy Practice

Student Life

Whether on campus or the bustling streets of Center City, there is always something happening at Jefferson.



On Campus

Housing

The Department of Housing and Residence Life provides a "home away from home." First-year students are guaranteed on campus housing. Take a virtual tour at www.jefferson.edu/housing.

Student Perks

Jefferson Medical and Health Science Bookstore and Commuter Services

Receive a 10% discount on textbooks as well as discounts on public transit.

Jefferson/Independence Blue Cross Wellness Center

Dip your toes in the pool, enjoy state-of-the-art cardio and weight training rooms or join an intramural sports team. Membership is free for full-time students. Take dance classes, learn scuba, get a massage, and more for small fees.

Library and Learning Resources Center

- 220,000 volumes in the life sciences, clinical medicine, and patient education and inter-library loan
- specialized databases, more than 4,000 electronic journals in the sciences and 300 electronic books
- 24-hour access to the Library Café, with comfortable seating, computers, and wireless network access
- access to videos, models, and other non-print materials.

Activities Office

- social, cultural and recreational programs on campus
- discounts to professional sporting events, amusement parks, museums, performing arts and cultural attractions
- more than 100 student organizations, from the African-American Student Society to the Water Polo Club. Check out www.jefferson.edu/activities/activities_guide.

Community Service

Make a difference with one of Jefferson's community service organizations. Some students earn work study dollars while serving their community.



Philadelphia: America's Next Great City

Culture

JCHP is within walking distance of the city's historical sites, world renowned museums, theater, and athletic events. Highlights include Independence Hall and the Liberty Bell, Philadelphia Museum of Art, and the National Constitution Center.

Cuisine

With its diverse flavors and renowned five-star restaurants, Philadelphia boasts a thriving dining scene. Zagat recently named it one of the most exciting and diverse dining cities in the country.

Applying to Jefferson

When to Apply

Admission to the School is on a rolling basis. All application materials must be received by PharmCAS and the Jefferson Supplemental Online Application must be completed prior to March 2, 2009.

Admission to the Pharmacy program is available for the Fall semester.

Preference is given to complete applications that meet the deadline; however, we will accept applications as long as space is available. JCHP will begin notifying applicants of admission decisions after October 31, 2008.

You need not complete all prerequisites before you apply, but they must be completed before you enter the program. You may also earn credits through standardized tests, including CLEP. Admission is competitive, as there are a limited number of seats in each class.

Apply Online

Step 1: Visit www.pharmcas.org to complete an online application for admission through PharmCAS.

Step 2: Visit www.jefferson.edu/jchp/pharmacy and click the link that reads Application Instructions.

Application Requirements for Admission

- Completed PharmCAS and Jefferson applications
- PharmCAS application fee; \$25 supplemental Jefferson application fee
- PCAT scores (sent to PharmCAS)
- Official transcripts from all education institutions attended (sent to PharmCAS)
- 2 letters of recommendation (sent to PharmCAS)
- Demonstration of English Language Proficiency (sent to PharmCAS)
- Essay/personal statement (included in PharmCAS application)
- 68 prerequisite credits (see page 9)
- An interview is required for all academically eligible applicants

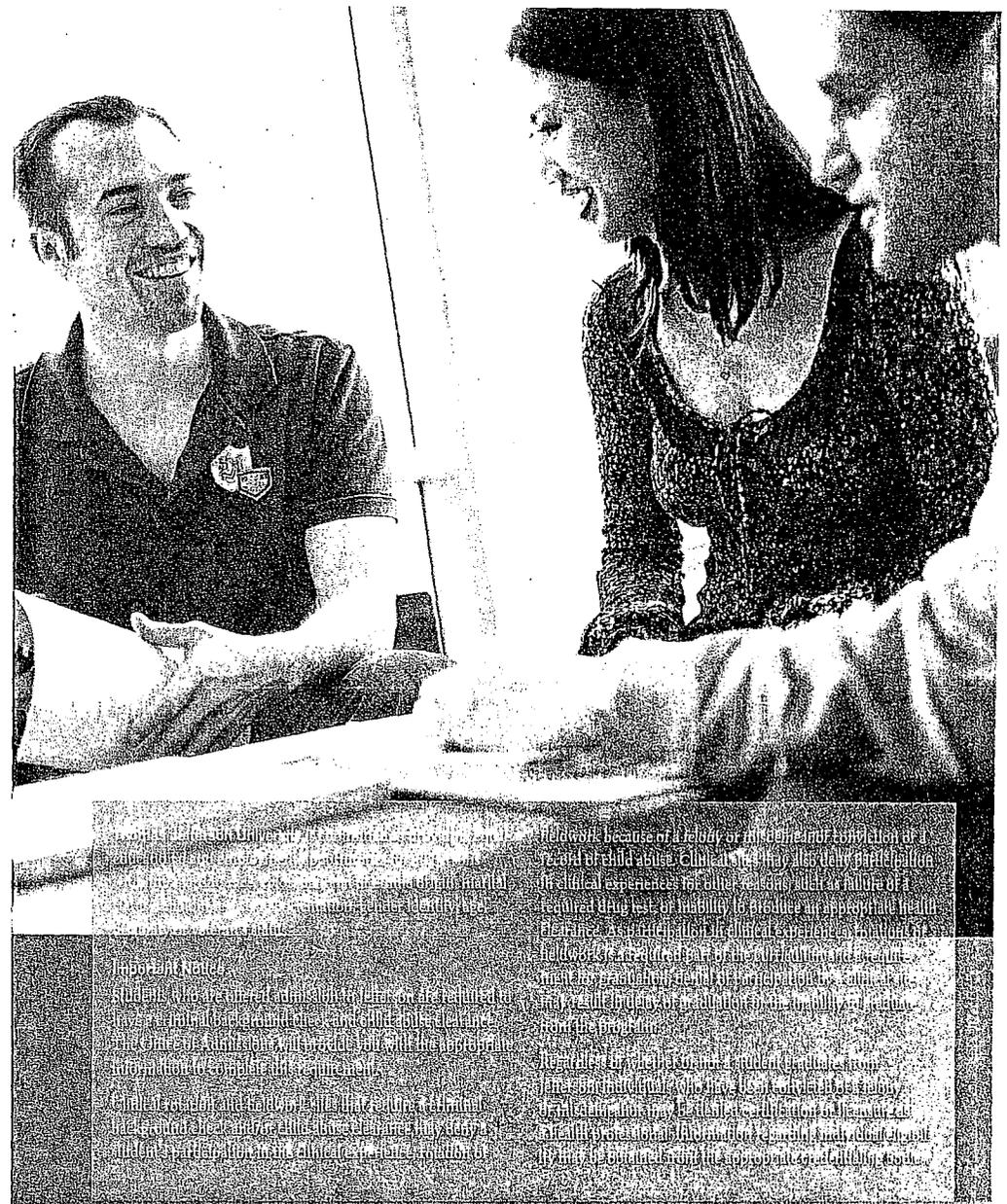
In addition to meeting all academic requirements, students must meet all performance standards for the program. Refer to the online JCHP Catalog for details, www.jefferson.edu/jchp/studentlife/cal.cfm.

Criminal background check and child abuse clearance required for accepted students; see notice on the inside back cover.

Admissions Questions?

Call toll-free 877-JEFF-CHP (533-3247) or email jchp@jefferson.edu.

For up to date information on the admissions process please visit www.jefferson.edu/jchp/pharmacy.



Tuition & Fees

Please review our TOEFL statement at
<http://www.jefferson.edu/jchp/admissions/TOEFL.cfm>

2008-2009 Academic Year

Full-time comprehensive fee: \$27,627
Information technology fee: \$300
Library fee: \$200
Pharmacy fee: \$200

Financial Aid

Jefferson College of Health Professions is committed to providing a high-quality education at an affordable price. More than three-quarters of our students receive some form of financial assistance through a combination of federal, state, institutional and private loans; scholarships; grants; and work-study programs.

The University Office of Financial Aid works closely with students to identify resources to help meet educational costs. To ensure that your financial aid funds are received by the tuition due date, financial aid applications should be completed by May 1 for fall-term students and August 1 for spring-term students.

If you have questions about financial aid opportunities or the application process, please contact the University Office of Student Financial Aid:

215-955-2867

financial.aid@jefferson.edu

www.jefferson.edu/financialaid

Accreditation Disclosure Statement

Thomas Jefferson University is fully accredited by the Middle States Association of Colleges and Schools.

The Accreditation Council for Pharmacy Education (ACPE; <http://www.acpe-accredit.org>) accredits Doctor of Pharmacy programs offered by Colleges and Schools of Pharmacy in the United States and selected non-US sites for a Doctor of Pharmacy program offered by a new College or School of Pharmacy. ACPE accreditation involves three steps: pre-candidate status, candidate status, and full accreditation. Pre-candidate accreditation status requires a developmental program, which is expected to mature in accord with stated plans and within a defined time period. Pre-candidate status is awarded to a new program of a College or School of Pharmacy that has not yet enrolled students in the professional program, and authorizes the college or school to admit its first class. Candidate accreditation status is awarded to a Doctor of Pharmacy program that has students enrolled, but has not yet had a graduating class. Full accreditation is awarded to a program that has met all ACPE standards for accreditation and has graduated its first class. Graduates of these programs designated as having candidate status have the same rights and privileges of those graduates from a fully accredited program. ACPE conveys its decision to the various boards of pharmacy and makes recommendations in accord with its decisions. It should be noted, however, that decisions concerning eligibility for licensure, by examination or reciprocity, reside with the respective boards of pharmacy in accordance with the statutes and administrative rules.

The Doctor of Pharmacy program of the Thomas Jefferson University, Jefferson College of Health Professions, Jefferson School of Pharmacy was awarded pre-candidate accreditation status during the January 9-13, 2008 meeting of the ACPE Board of Directors, based upon an on-site evaluation conducted November 6-8, 2007, and discussions with institution and school officials. Following the enrollment of the inaugural class of students in Fall 2008, an on-site evaluation will be scheduled during the academic year 2008-2009 for purposes of gathering additional information to be considered in the Board's consideration of advancement to Candidate accreditation status. Based upon this evaluation, should the Board feel that candidate status cannot be conferred, the school could respond to the Board's concerns and reapply prior to the graduation of the first class. If candidate status is not granted, even after reapplication, graduates may not be eligible for licensure as pharmacists. If candidate status is granted and the program continues to develop as planned, full accreditation of the Doctor of Pharmacy program would be considered by the Board following the graduation of students from the program.



Office of Admissions

130 South 9th St., Suite 100

Philadelphia, PA 19107

877-JEFF-CHP

215-503-8890

www.jefferson.edu/jchp



JG 09-0129

ExCPT Information

ExCPT Content

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

1.1 Overview of technician duties and general information

- 1.1.1 The role of pharmacists and pharmacy technicians
- 1.1.2 Functions that a technician may and may not perform
- 1.1.3 Prescription department layout and workflow
- 1.1.4 Pharmacy security
- 1.1.5 Inventory control
- 1.1.6 Stocking medications
- 1.1.7 Identifying expired products

1.2 Controlled substances

- 1.2.1 Difference among the controlled substances schedules
- 1.2.2 Refills, partial refills, filing, and prescription transfers
- 1.2.3 Correct procedures for handling Schedule V sales
- 1.2.4 Controlled Substance Act
- 1.2.5 DEA numbers

1.3 Other laws and regulations

- 1.3.1 Federal privacy act
- 1.3.2 Generic substitution (incl. brand vs. generic products)
- 1.3.3 Professionals with prescribing authority (and acronyms)
- 1.3.4 Child-resistant packaging
- 1.3.5 Role of government agencies (Board of Pharmacy, DEA, FDA, etc.)
- 1.3.6 Manufacturer drug package labeling
- 1.3.7 OTC package labeling

2. Drugs and drug therapy (~23% of exam)

2.1 Drug Classification

- 2.1.1 Major drug classes (e.g., analgesics, anesthetics, antibiotics, etc.)
- 2.1.2 Dosage forms (types, characteristics and uses)
- 2.1.3 Over-the-counter products
- 2.1.4 NDC number

2.2 Most frequently prescribed medications

- 2.2.1 Brand and generic names
- 2.2.2 Basic mechanism of action (pharmacology) and drug classification
- 2.2.3 Primary indications
- 2.2.4 Common adverse drug reactions, interactions, & contraindications

(over)

3. Dispensing Process (~52% of Exam)

3.1 Prescription information

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

3.2 Preparing/dispensing prescriptions

- 3.2.1 Avoiding errors (such as sound-alike/look-alike names)
- 3.2.2 Systems for checking prescriptions
- 3.2.3 Automated dispensing systems (including quality control)
- 3.2.4 Procedures for preparing prescriptions and data entry
- 3.2.5 Labeling prescriptions properly
- 3.2.6 The purpose and use of patient records
- 3.2.7 Proper packaging and storage
- 3.2.8 Managed care prescriptions

3.3 Calculations

- 3.3.1 Conversions / Systems of measurement used in pharmacy
- 3.3.2 Calculating the amounts of prescription ingredients
- 3.3.3 Calculating quantity or days supply to be dispensed
- 3.3.4 Calculating individual and daily doses
- 3.3.5 Calculations used in compounding
- 3.3.6 Calculating dosages and administration rates for IVs
- 3.3.7 Business calculations (pricing, markup, inventory control)

3.4 Sterile products, unit dose and repackaging

- 3.4.1 Drug distribution systems used in hospitals and nursing homes
- 3.4.2 Procedures for repackaging medications
- 3.4.3 Prescription compliance aids
- 3.4.4 Aseptic technique and the use of laminar flow hoods
- 3.4.5 Special procedures for chemotherapy
- 3.4.6 Routes of administration for parenteral products
- 3.4.7 Types of sterile products
- 3.4.8 Correct procedures for maintaining the sterile product environment
- 3.4.9 Accurate compounding and labeling of sterile product prescriptions

ExCPT Exam - Eligibility Rules

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 not been convicted of or pled guilty to a felony. Candidates who have been convicted of or pled guilty to a drug-related felony are not eligible for certification. Candidates who were convicted of a nondrug-related felony occurring more than 7 years prior may petition to apply for the ExCPT. ICPT will review and make decisions on their status on a case-by-case basis. ICPT reserves the right to deny certification to any convicted felon.

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 government-issued photo identification at the time of the exam to verify identity.

Healthcare Workforce Coalition – Issue Statement

HEALTHCARE WORKFORCE COALITION

PHARMACY
WORKFORCE SHORTAGE

ISSUE STATEMENT

SUBMITTED BY THE
PHARMACIST SHORTAGE WORKGROUP

TO THE
CALIFORNIA HOSPITAL ASSOCIATION
WORKFORCE COMMITTEE

DECEMBER 1, 2008

PURPOSE OF ISSUE STATEMENT

The primary purpose of this issue statement is to communicate to the California Hospital Association (CHA) Workforce Committee the major barriers linked to an insufficient supply of pharmacists in California. This document stops short of making specific recommendations (although some may be implied), but is instead designed to provide the committee with background information and data on the pharmacist workforce shortage.

The CHA Workforce Committee will work closely with the Pharmacist Shortage Workgroup and the Allied Healthcare Workforce Advisory Council as it develops recommendations in 2009.

DEFINING THE ISSUE

Currently, many parts of the U.S. are experiencing a shortage of pharmacists. The shortage has the potential to worsen if not addressed soon. Nationally, job growth for pharmacists is expected to increase much faster than average through 2016 as a result of rapid population growth and the need to replace workers who leave the occupation. This job growth is estimated to be 21.72 percent from 2006–2016.¹ (Table 1)

Anecdotal reports regarding pharmacist workforce shortages in California are abundant. Hospitals and health systems, as well as retail pharmacies, report difficulties in recruiting and retaining pharmacists. According to the California State Board of Pharmacy, there are 32,938 pharmacists licensed in California. However, only 27,835 have California addresses. This current supply of licensed pharmacists is not sufficient to meet demand, as documented in a December 2007 CHA survey in which 179 respondents reported a total of 164 vacancies.

In addition, according to the Pharmacy Manpower Project, California received an Aggregate Demand Index (ADI) score of 4.20 in September 2008.² The Pharmacy Manpower Project collects, analyzes and disseminates data on the supply of licensed pharmacists in the United States. A score of 4.20, according to the project website, corresponds to “moderate demand: some difficulty filling open positions.” Thirty-eight states also fell into the “moderate” category, while one, Wisconsin, was rated a 5.0 (high demand) and 12 other states were rated as “balanced demand.”

Demand for pharmacists will be exacerbated in the coming decade not only due to a projected increase in the overall population, but also by the fact that California’s population is growing older. According to a recent study conducted by the California Budget Project³, by the year 2020, California’s population is expected to increase by 10 million people, with more than 6 million residents projected to be 65 years of age or older. This increase in the 65 and over population represents a 75.4 percent increase since 2000. As California’s population ages, older people will be retiring and leaving the workforce, while at the same time creating an increased demand for health care services.

In recent years, pharmacist salaries have increased dramatically due to the shortage. According to a 2008 survey by *Drug Topics* magazine, the median annual earning of pharmacists was \$107,403 in 2007, as compared to \$78,624 in 2000, an increase of 36.6 percent. By comparison, between 2000 and 2007, U.S. median earnings in general increased from \$22,346 to \$26,905, an increase of only approximately 20 percent.⁴

In addition, California's pharmacist ratio in 2005 per 100,000 population was smaller compared to the nation as a whole, yet wages were much higher.⁵ (Table 2)

The California Employment Development Department (EDD), Labor Market Information Division, projects the total annual openings of pharmacists in California due to growth and separation to be 1,030 for projected years 2006–2016⁶ (Table 3), representing a 3.7 percent increase in the number of practicing licensed pharmacists needed in California to meet growth and separation demands alone.

TABLE 1: U.S. Projected Growth for Pharmacists, 2006–2016

Occupational title	SOC Code	Employment, 2006	Projected Employment 2016	Change in Number	Change in %
Pharmacists	29-1051	243,000	296,000	53,000	21.72%

TABLE 2: 2005 Employment for Pharmacists, U.S. vs. California

Description	California	United States
Number of Jobs (2005)	21,000–25,700	226,000–233,400
Employment per 100,000 Population (2005)	58–71	76–9
Annual Median Wage (2005)	\$102,000–\$106,000	\$89,000–\$90,000

TABLE 3: California Estimated Annual Openings for Pharmacists, 2006–2016

Area	Code	Occupation	Estimated Yr – Projected Yr	Total Annual Openings Due to Growth and Separation
California	291051	Pharmacists	2006–2016	1,030

TABLE 4: Education, Enrollment and Pharm. D. Degrees Conferred in California, 2007⁷

Number of pharmacy schools in California (includes California North State):	8
Enrolled in all programs:	3,440
Graduate annually all programs 2006–2007:	758
Per EDD Labor Market Information Division: Estimated annual openings for pharmacists in California due to growth and separation 2006–2016:	1,030

PHARMACY TECHNICIANS:

Pharmacist Shortage Workgroup members recognize that pharmacy technicians can become *part* of the solution to the pharmacist shortage. However, the pharmacist shortage should take priority. The pharmacist technician classification is an understudied category with little reliable data. Workgroup members came to a consensus that for the purposes of this project, the focus would be on the pharmacist shortage specifically, reserving consideration of pharmacy technician issues for discussions related to increasing *qualified and skilled* technicians. The workgroup recognized that qualified technicians can support pharmacists, allowing them to fulfill their most important role of utilization of drugs and clinical pharmacy.

PHARMACIST CAREER PATHWAY: EDUCATION, TRAINING AND LICENSING

To graduate with a Pharm. D. degree and practice as a pharmacist, one must:

- Complete four-year undergraduate degree.
- Complete +/- four more years of pharmacy school.
- Successfully pass the national pharmacy licensing exam (NAPLEX).
- Successfully pass the state board licensing exam to practice in California.

PHARMACIST WORKFORCE SUPPLY ISSUES AND BARRIERS

Current systemic deficiencies in the education and training infrastructure for pharmacy severely limit the number of pharmacists who can be educated and trained each year in California. These deficiencies include a limited number of pharmacy school “slots” for students, a short supply of faculty to support the expansion of pharmacy schools, and an insufficient number of experiential training sites.

In California, there are currently eight schools of pharmacy (based on eligibility for membership in the American Association of Colleges of Pharmacy). (Table 4) One of these schools is not scheduled to graduate its first class until spring 2009 (Touro) and another one even later (California North State). In 2006-07, California schools of pharmacy conferred the degree of Pharm. D. to approximately 758 graduates.⁷ (Table 5) Assuming projections are correct, California will need to produce 272 additional graduates each year (2006-2016) just to fill anticipated openings due to growth and separation. That is approximately a 36 percent increase in the number of graduates needed each year, and does not take into consideration that California is already experiencing a shortage. The public schools of pharmacy do not have capacity (adequate number of slots) at this time to match this need. Although Touro University will have an impact — graduating an estimated 100 students in spring 2009 — these graduates will be needed to mitigate current shortages in the field.

Table 5: Pharm. D. Graduates by School in California, 2006-07*

California School of Pharmacy	Graduates 2006-07
Loma Linda University	39
Touro University-California	0
University of California, San Diego	23
University of California, San Francisco	147
University of the Pacific	210
University of Southern California	221
Western University	118
Total 2006-07 Graduates:	758
Touro University Class of Spring 2009	100
California North State School of Pharmacy (2012?)	+/- 80
Samuel Merritt College	unknown

*Please note: 2007-08 graduate data per the California State Board of Pharmacy states that there were 890 graduates in California. It appears that with the increase over 2006-07 we are getting closer to meeting demand; however, it is important to note that this increase in graduates is fulfilling an immediate demand. If California is going to meet the demand of pharmacists due to growth and separation over the next 10 years, this number must continue to climb. It should also be noted that the graduate data does not necessarily translate into the number of pharmacists practicing in California. It is possible that some may not go into the profession or they may leave the state.

Exacerbating the issue of limited "slots" is the need for school of pharmacy faculty. "The shortage of pharmacy faculty, now and in the future, represents a serious public health threat in the face of the rapidly growing consumer demand for prescription drugs," says Lucinda Maine, executive vice president of the American Association of Colleges of Pharmacy. One of the challenges in recruiting faculty is that there is a considerable difference in the salary of a practicing pharmacist versus non-tenured faculty. There is little financial incentive to teach, especially when many students graduate from pharmacy school with high student debt loans.

The two aforementioned issues must be addressed concurrently and are related to a third barrier, which is an insufficient number of experiential training opportunities. Experiential training of 1,500 hours is necessary for students to complete their education and training, and graduate with a Pharm. D. However, currently there are an inadequate number of experiential training opportunities. This issue is critical because if there were a sufficient number of pharmacy school slots, and faculty supply increased, there still would not be enough experiential sites to accommodate students. Reasons for a limited number of training opportunities include the time commitment required to offer experiential training, and a lack of trained preceptors. (Preceptors must be trained per school of pharmacy accreditation requirements.)

The overall capacity of the education and training infrastructure for pharmacy must be addressed in its entirety in order to allow for an optimum number of Pharm. D. graduates.

Other barriers and issues:

In recent years, gender trends in pharmacy have shifted. Historically, men dominated this field. However, in recent years the gender balance has equalized.⁸ Pharmacy can be a very attractive career for many women because of the potential for part-time positions. While this has the potential to bring more people to the field, it also would result in the need for more pharmacists because it can take up to 1.5 pharmacists to make up 1.0 full-time equivalent.

Another additional issue is that there is little elasticity in the field to allow for transition among types of practice. Practice in a hospital pharmacy setting is complex, making it difficult for hospitals to identify and recruit pharmacists from outside of the hospital setting.

Lastly, estimates of the racial and ethnic composition of California's current pharmacist workforce illustrate the predominance of Asian and white practitioners. Collectively, Asian and white pharmacists represent more than 90 percent of the workforce. However, it appears that certain Asian sub-populations, as well as African Americans, are under-represented by comparison with their presence in California's general labor force and population.⁸ According to a study published by the California Budget Project, California has the most ethnically diverse population in the nation, with future projections indicating it will become even more diverse in the next 12 years. For example, the Latino population is projected to rise from 32.4 percent in 2000 to 41.4 percent in 2020. These statistics underscore the need to develop a culturally competent health care workforce, including pharmacists, that represents California's ethnically diverse population.

CONCLUSION

Specific recommendations to address the pharmacist shortage in California, as well as to address workforce shortages in imaging and laboratory service, are needed now if we are to avoid serious breaches in access to care. The CHA Workforce Committee, in coordination with the Pharmacist Shortage Workgroup and the Allied Healthcare Workforce Advisory Council, will develop short- and long-term recommendations in 2009.

For more information, please contact Cathy Martin, Project Director for the California Hospital Association at (916) 552-7511 or camartin@calhospital.org.

ACKNOWLEDGEMENTS

The Healthcare Workforce Coalition and the California Hospital Association would like to thank the following individuals for their participation in the Pharmacist Shortage Workgroup. We are grateful for their time and commitment to this project and recognize that this issue statement would not be possible without their valuable knowledge and expertise.

PHARMACIST SHORTAGE WORKGROUP PARTICIPANTS

ANIECE AMOS, PHARM. D.

Interim Director of Pharmacy Services
Sutter Medical Center of Santa Rosa

MARY ANNE KODA-KIMBLE, PHARM. D.

Dean
UCSF, School of Pharmacy

DAWN BENTON, M.B.A.

Executive Vice President, CEO
California Society of Health-System
Pharmacists

ELAINE LEVY

System Director of Pharmacy
Sharp HealthCare

ALLAN COHEN, PHARM. D., M.B.A.

Director of Pharmacy
Goleta Valley Cottage Hospital

**MARIANN NOVARINA, PHARM. B.S.,
M.P.A./H.S.A.**

Director of Pharmacy
Community Hospital of Monterey Peninsula

JAMES COLBERT, PHARM. D.

Associate Clinical Professor of Pharmacy
Assistant Dean for Experiential Education
Skaggs School of Pharmacy, UCSD

LORIE RICE, M.P.H.

Associate Dean of External Affairs
UCSF, School of Pharmacy

BARRY DYKES, PHARM. D.

Assistant Pharmacy Operations Leader
Northern California Kaiser Permanente

GLORIA ROBERTSON

OSHPD, Healthcare Workforce
Development Division

BLAIR E. FRATER

Pharmacy Manager
Sharp Mary Birch Hospital for Women

KENNY SCOTT, R.PH.

*NCal Regional Pharmacy Operations
Leader*
Kaiser Permanente

VIRGINIA HEROLD

Executive Officer
California State Board of Pharmacy

MARIA D. SERPA, PHARM. D., FCSHP

Senior Pharmacist, System Support
Sutter Medical Center, Sacramento

KATHERINE KNAPP, PHARM. D.

Dean & Professor
College of Pharmacy Touro University

ANNE SODERGREN

Assistant Executive Officer
California State Board of Pharmacy

JUDITH YATES

Regional Vice President
HASD&IC

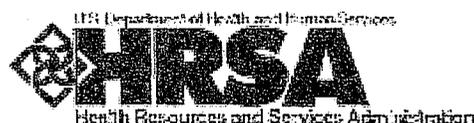
References

1. *Occupational Outlook Handbook, 2008-09 Edition*, U.S. Department of Labor, Bureau of Labor Statistics. www.bls.gov/oco/ocos079.htm
2. Pharmacy Manpower Project: www.pharmacymanpower.com/state.html
3. *Budget Backgrounder, Making Dollars Make Sense*, California Budget Project Report, August 2008. www.cbp.org/pdfs/2008/0808_bb_demographics.pdf
4. U.S. Census Bureau, Current Population Survey, Annual Social and Economic Supplements. www.census.gov/hhes/www/income/histinc/p01AR.html
5. *Tracking the Supply of Health Professions Educations Programs*, Timothy Bates, M.P.P., and Susan A. Chapman, Ph.D., R.N., April 2007. www.futurehealth.ucsf.edu/publications/index.html
6. State of California, Employment Development Department, Labor Market Information Division, www.labormarketinfo.edd.ca.gov/cgi/databrowsing/occExplorerQSDetails.asp?searchCriteria=Pharmacist&careerID=&menuChoice=occExplorer&geogArea=0601000000&socode=291051&search=Explore+Occupation
7. American Association of Colleges of Pharmacy, www.aacp.org/site/page.asp?TRACKID=&VID=1&CID=1500&DID=8838
8. *Diversity in California's Health Professions: Pharmacy*, UCSF, Center for the Health Professions Report, 2008. http://futurehealth.ucsf.edu/pdf_files/Pharmacy%20brief_final.pdf

US Department of Health and Human Services Report: The Adequacy of Pharmacist Supply:
2004-2030

The Adequacy of Pharmacist Supply: 2004 to 2030

Department of Health and Human Services
Health Resources and Services Administration
Bureau of Health Professions
December 2008



Acronyms Used in Report

AACP	American Association of Colleges of Pharmacy
ASHP	American Society of Health-System Pharmacists
BHPr	Bureau of Health Professions
BLS	Bureau of Labor Statistics
B.Pharm	Bachelors of pharmacy degree
FTE	Full time equivalent
HRSA	Health Resources and Services Administration
NABP	National Association of Boards of Pharmacy
NACDS	National Association of Chain Drug Stores
NAMCS	National Ambulatory Medical Care Survey
NHAMCS	National Hospital Ambulatory Medical Care Survey
NCPA	National Community Pharmacists Association
NPWS	National Pharmacist Workforce Survey
Pharm.D	Doctorate of pharmacy degree
PhSRM	BHPr's Pharmacist Supply and Requirements Model

Table of Contents

EXECUTIVE SUMMARY	iii
I. BACKGROUND	1
II. PHARMACIST SUPPLY	2
A. Current Supply	2
B. Trends in Supply Determinants	5
1. <i>New Graduates and Training Capacity</i>	6
2. <i>Distance and Distributive Learning Models</i>	8
3. <i>Increasing Number of Women in Pharmacy</i>	10
4. <i>Pharmacist Hours Worked</i>	11
5. <i>Attrition from the Pharmacist Workforce</i>	12
C. The Future Pharmacist Supply	13
1. <i>Modeling Future Supply</i>	13
2. <i>Baseline Supply Projections</i>	14
3. <i>Alternate Supply Projections</i>	17
4. <i>Comparison to Previous Supply Projections</i>	23
III. PHARMACIST REQUIREMENTS	24
A. Current Demand	24
B. Trends in Demand for Pharmaceuticals	25
1. <i>Population Growth and Aging</i>	25
2. <i>Trends in per Capita Use of Pharmaceuticals</i>	28
3. <i>Medicare Part D</i>	32
C. Trends in Dispensing Setting, Practices and Efficiency.....	33
1. <i>Trends in Dispensing Location</i>	34
2. <i>Role of the Pharmacist and Productivity Trends</i>	36
3. <i>Technological Advances</i>	38
D. Future Pharmacist Requirements.....	41
IV. CURRENT AND FUTURE ADEQUACY OF PHARMACIST SUPPLY	48
V. CONCLUSIONS	51
A. Summary of Key Findings and Implications.....	51
B. Study Strengths, Limitations, and Areas for Future Research	52

EXECUTIVE SUMMARY

The U.S. Department of Health and Human Services, Health Resources and Services Administration's (HRSA's) 2000 report on the pharmacist workforce documented the current and growing shortfall of pharmacists. Health care providers and professional organizations have continued to report signs of a moderate current shortage of pharmacists, as indicated by persistent vacancy rates, difficulty recruiting and retaining pharmacists, growing dissatisfaction by pharmacists with long hours worked, and rising costs to employ pharmacists.

Since the 2000 report, the U.S. Bureau of the Census has revised upward its projections of population growth, the Federal Government enacted the Medicare Part D program which expands prescription drug coverage to more elderly; technology continues to advance, minimum credentials for entry into the workforce for new pharmacists changed from baccalaureate to doctorate degrees, the Nation's educational capacity to train new pharmacists and pharmacy technicians continues to expand and enrollment in schools of pharmacy is at an all time high. The role of pharmacists in providing care to patients continues to evolve as well.

Acknowledging the Federal government's role and interest in ensuring an adequate supply of pharmacists, Congress issued in Senate Report 108-345 a directive to

...encourage the Department [HHS] to begin a study on comprehensive pharmacy services in light of changes in technology, distance and distributive learning models, the aging of the population and the Department's study on the severe pharmacist shortage in order to analyze how they may influence the nature of pharmaceutical education and interventions in healthcare.

In response to this directive, HRSA's Bureau of Health Professions developed the Pharmacist Supply and Requirements Model (PhSRM) to examine the current and projected future adequacy of pharmacist supply in the United States. The PhSRM was used to generate a best-estimate baseline forecast of the future balance between supply and demand, as well as to provide a range of projections based on possible alternate scenarios that use different assumptions about factors affecting pharmacist education and productivity, and demand for pharmaceuticals. This work also reflects findings from a literature review, original empirical analysis, and discussions with representatives from pharmaceutical associations and subject matter experts to develop supply and demand scenarios.

Key findings from this study include the following:

- **The supply of pharmacists is growing significantly faster than was previously projected.** The total active pharmacist supply is projected to grow from 226,000 in 2004 (the base year for the projection model) to 305,000 by 2020 and 368,000 by 2030. The number of full time equivalent (FTE) pharmacists is projected to grow from 191,200 in 2004 to 260,000 by 2020 and 319,000 by 2030. These projections are higher than those in the HRSA 2000 report and primarily result from updated retirement patterns, the opening of new pharmacy programs, and increased enrollment at existing programs.
 - The number of colleges and schools of pharmacy with accredited professional degree programs rose from 82 in 2000 to 92 by 2005. The American Association of Colleges of Pharmacy predicts that 103 programs will be open by Fall 2007 and 110 by Fall 2010.

- The number of entry-level degree graduates from schools of pharmacy has increased from 7,300 in 2000 to 9,100 in 2005. This number will likely continue to increase to about 12,000 graduates per year by 2030.
- The use of distance learning models in pharmacy education has expanded since the 2000 report, and has contributed to the growth in existing training programs.
- Raising the minimum education level (to a Pharm.D) for new pharmacists does not appear to have reduced the desirability of pharmacy as a career. Applications to pharmacy programs are at an all time high.
- **The demand for pharmacists continues to grow.** Changing population demographics are expected to increase demand to 256,000 pharmacists by 2020 and 295,000 by 2030 if per capita consumption of pharmaceuticals were to remain unchanged; supply and demand would remain roughly in balance. Per capita consumption will likely increase, however, as new drugs become available. Under a scenario with moderate growth in per capita consumption of pharmaceuticals, demand would likely reach 289,000 by 2020 and 357,000 by 2030. The major demand determinants are:
 - Population growth—especially growth of the elderly population.
 - Rising per capita consumption of pharmaceuticals (controlling for changing demographics).
 - Increased need for pharmacists to counsel and educate patients as drugs become more complex and a growing portion of the population receives care for chronic conditions.
 - Increased use of pharmacy technicians and technology that can improve productivity, dampening the growth in demand for pharmacists.
- **There is currently a moderate shortfall of pharmacists.** Vacancy rates of 8 percent and higher that were common in the early 2000s have moderated. In 2004 the overall vacancy rate was approximately 5 percent, which is equivalent to a shortfall of approximately 10,400 pharmacists. Factors that contributed to this reduction in the vacancy rate include:
 - Rising salaries for pharmacists, which has a positive impact on supply and a negative impact on demand for pharmacists (with pharmacies scaling back on the number of hours they are open and scaling back on staff due to rising labor costs);
 - Increased use of pharmacy technicians and technology that have boosted pharmacist productivity; and
 - An expansion in the scope of work performed by pharmacy technicians that has reduced the amount of time pharmacists spend dispensing medications.

Anecdotal evidence suggests that the vacancy rate has started to rise again and it is projected that the Nation will continue to experience a moderate shortfall of pharmacists.

- **The future supply of pharmacists is projected to grow at a rate similar to the projected growth in demand from changing demographics.** If per capita consumption of pharmaceuticals (adjusting for changing demographics) remains unchanged, then projected future supply will be adequate to meet the demands of a growing and aging population.

- If per capita consumption continues to grow at rates seen in the past few years, then the current shortfall will continue to grow.
- The baseline supply scenario assumes that expansion of the Nation's educational capacity will occur as planned, with output from the Nation's pharmacy programs increasing by approximately 100 new graduates per year (equivalent to approximately one new school of pharmacy per year).

The "best estimate" demand scenario assumes that the role of pharmacists will remain largely unchanged, and that increased time spent counseling and educating patients will be offset by increased productivity through greater use of pharmacy technicians and technology to improve dispensing efficiency. Over the next 2 decades, the projected average annual increase in demand for pharmacists will grow by approximately 1.4 percent per year due to population growth and aging. Increasing per capita consumption of pharmaceuticals could add another 2 percent to the annual growth. With moderate (approximately 1 percent) annual growth in pharmaceutical consumption per capita, demand could reach 289,000 in 2020. Supply is projected to be 260,000 pharmacists, resulting in a shortfall of 29,000 pharmacists (10 percent). By 2030 demand is projected to be 357,000; supply is expected to be 319,000 resulting in a shortage of 38,000 pharmacists (11 percent).

- **Supply and demand are projected with a level of uncertainty. Only under an optimistic supply projection combined with a conservative demand projection is future supply adequate to meet demand.**
 - If the planned expansion in the number and size of pharmacy programs fails to materialize (e.g., because of a faculty shortage), then supply might be lower than projected.
 - The demand projections are sensitive to assumptions of annual growth in per capita consumption of pharmaceuticals.
 - If the role of pharmacists changes where pharmacists spend substantially more time providing patient care management services, then demand will be higher than projected.
- **Additional findings** include the following:
 - Women constitute a growing proportion of active pharmacists. Currently, half of all active pharmacists are women. By 2020, approximately 62 percent of active pharmacists are expected to be women. Female pharmacists tend to work fewer hours per year than their male colleagues, so the full-time equivalent supply will grow at a slightly lower rate than active supply.
 - Racial minorities continue to be underrepresented in the pharmacist workforce. In the 2000 Census, 25 percent of the population indicated they are in a racial minority group, while only 18 percent of self-identified pharmacists indicated they are in a racial minority group. The percent of pharmacists who were Hispanic or Latino was 3.2 percent, compared to 12.5 percent of the U.S. population that was Hispanic or Latino in 2000.
 - Technologies that automate prescription dispensing and order processing are used by a majority of pharmacies. Most community pharmacies have automated pill-counting devices and can accept prescriptions through fax, interactive voice response systems, or over the Internet (e-prescribing), resulting in moderate increases in productivity, safety,

and convenience. Hospitals, mail order pharmacies, and larger volume pharmacies are increasing investing in sophisticated robotics systems, which can significantly increase pharmacist productivity but at a cost that is prohibitive for lower volume operations.

- The future role of pharmacists is linked to the adequacy of supply and to reimbursement rates. With competing demands on pharmacists' time, the work that must get done (dispensing) generally takes priority over work that pharmacists report wanting to do more of, such as patient education and monitoring. A greater role for pharmacists in patient care management is feasible only with a reimbursement system that compensates pharmacists for such services.

Although this study focused on the national adequacy of pharmacist supply, geographic disparities exist in access to pharmacist services. Consequently, there continues to be a role for programs such as the National Health Service Corps Chiropractor and Pharmacist Loan Repayment Demonstration that use financial aid as a means to recruit and retain pharmacists in hard-to-employ locations such as rural areas, low-income urban areas, and select Federal institutions such as prisons.

Projections of future supply and demand are made with some level of uncertainty about what the future holds. For example, advances in biotechnology and the impact on individualized drug therapy; the development of new pharmaceuticals; and development of improved methods for ordering and dispensing medications all have the potential to affect demand for pharmacists. Changes in government policies and programs, and changes in insurer approaches to manage prescription drug costs can affect demand for prescription drugs. On the supply side, the number of new graduates might deviate from projected levels, work patterns can change towards desiring to work fewer hours, and retirement patterns can change. The implications of uncertainty regarding these future trends is that supply and demand projections become less certain as the projection horizon increases. This uncertainty highlights the need to update the projections every few years to reflect changes in policies and trends.

The overall conclusion of this study is that the Nation has responded to earlier predictions of a growing shortfall of pharmacists, and to market forces that have raised pharmacist earnings, by expanding supply and increasing the use of technology and technicians. Still, the increase in supply will only be sufficient to keep pace with a rising demand due to changing demographics. Supply would need to increase further than currently projected to meet the demand caused by growth in per capita consumption of pharmaceuticals. Improvements in productivity through further employment of pharmacy aides and technicians and the application of evolving technologies should continue to help the supply meet these increases in demand.

I. BACKGROUND

The U.S. Department of Health and Human Services (HHS), Health Resource and Service Administration's (HRSA's) 2000 report on the pharmacist workforce documented the current and growing shortfall of pharmacists.¹ Health care providers and professional organizations also report evidence that suggests in recent years there has been a moderate shortfall of pharmacists, including reports of increased difficulty recruiting and retaining pharmacists, growing dissatisfaction by pharmacists with long hours worked, and rising costs to employ pharmacists.²

Since the 2000 report, the U.S. Bureau of the Census has revised upward its projections of population growth, the Federal Government enacted the Medicare Part D program which expands pharmacy insurance to more elderly, technology continues to advance, and minimum credentials for entry into the workforce for new pharmacists changed from baccalaureate to doctorate degrees. The Nation's educational capacity to train new pharmacists and pharmacy technicians continues to expand, enrollments in schools of pharmacy are at an all time high, and the role of pharmacists in providing care to patients continues to evolve.

Acknowledging the Federal Government's role and interest in ensuring an adequate supply of pharmacists, Congress issued a directive to

*...encourage the Department [HHS] to begin a study on comprehensive pharmacy services in light of changes in technology, distance and distributive learning models, the aging of the population and the Department's study on the severe pharmacist shortage in order to analyze how they may influence the nature of pharmaceutical education and interventions in healthcare.*³

In response to this directive, HRSA's Bureau of Health Professions conducted a study and developed the Pharmacist Supply and Requirements Model (PhSRM) to examine the current and projected future adequacy of pharmacist supply under alternate supply and demand scenarios. The trends and research underlying these forecasts, as well as supply and demand projections, are presented in this report. Section II describes the current supply of pharmacists, trends in supply determinants, and supply projections. Section III presents similar information for pharmacists requirements—current demand, trends in demand determinants, and projections. Section IV discusses the current and future adequacy of supply. Section V discusses key findings and implications, as well as the study strengths and limitations.

¹ *The Pharmacist Workforce: A Study of the Supply and Demand for Pharmacists* (Washington, D.C.: HRSA, Dec. 2000).

² *Supply of Selected Health Workers: Adequacy of Pharmacy, Laboratory, and Radiology Workforce Supply Difficult to Determine.* (Washington, D.C.: GAO-02-137R, Oct. 2001).

³ Senate Report 108-345.

II. PHARMACIST SUPPLY

An estimated 230,000 to 250,000 pharmacists currently practice in the United States accounting for approximately 86 percent of the estimated 280,000 licensed pharmacists.⁴ With all time highs in pharmacy school enrollment coupled with a relatively young pharmacy workforce, the supply of pharmacists is projected to continue rising both in total number of pharmacists and in terms of the pharmacist-to-population ratio. Some indicators of a pharmacist shortfall have moderated in recent years, but substantial growth in supply is still needed over the next 2 decades to meet the projected surge in demand for pharmacist services.

A. Current Supply

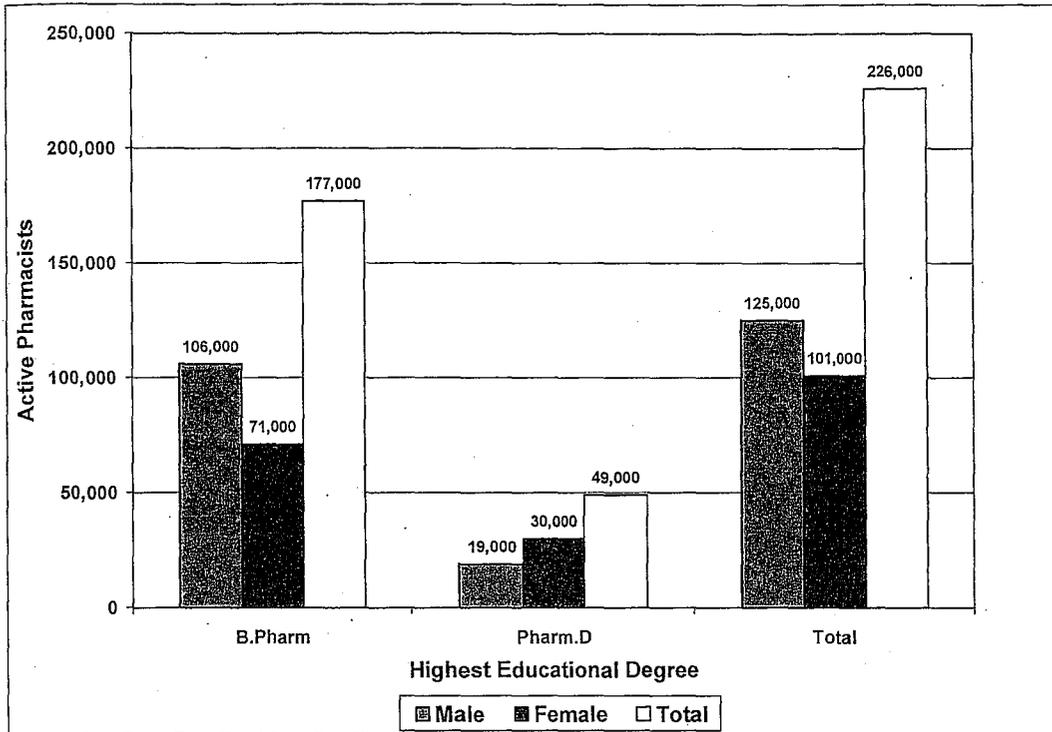
The current supply of pharmacists can be characterized in terms of their number, demographics, practice setting and practice patterns. In 2004, the base year for the PhSRM, there were an estimated 226,000 practicing pharmacists (*Exhibit 1*).⁵ Applying to this supply estimate the gender and age distribution of pharmacists as determined by the 2004 National Pharmacist Workforce Survey (NPWS), approximately 125,000 pharmacists (55 percent) are men, and 49,000 (22 percent) are prepared at the doctoral (Pharm.D) level. Reflecting the rising proportion of women entering pharmacy and the new minimum education level set at the Pharm.D degree, approximately 61 percent of pharmacists prepared at the Pharm.D level are women, while 40 percent of pharmacists prepared at the baccalaureate (B.Pharm) level are women.

Although a slight majority of active pharmacists are men, male pharmacists tend to be older (median age=51) than female pharmacists (median age=43) (*Exhibit 2*). Women constitute the majority of new pharmacy graduates, while men constitute the majority of older pharmacists (with older pharmacists often reducing their workload as they near retirement). Consequently, within the next few years the majority of full-time-equivalent (FTE) pharmacists will be women.

⁴ U.S. Bureau of Labor Statistics, Occupational Employment Statistics for May 2005, estimate there are approximately 230,000 pharmacists employed in the United States. Medical Marketing Service Inc's list of pharmacists as of June 2005 contains approximately 247,000 pharmacists. The estimate that 86 percent of licensed pharmacists are active comes from the Midwest Pharmacy Workforce Research Consortium (Mott et al.) report entitled *Final Report of the National Sample Survey of the Pharmacist Workforce to Determine Contemporary Demographic and Practice Characteristics*. September 2005.

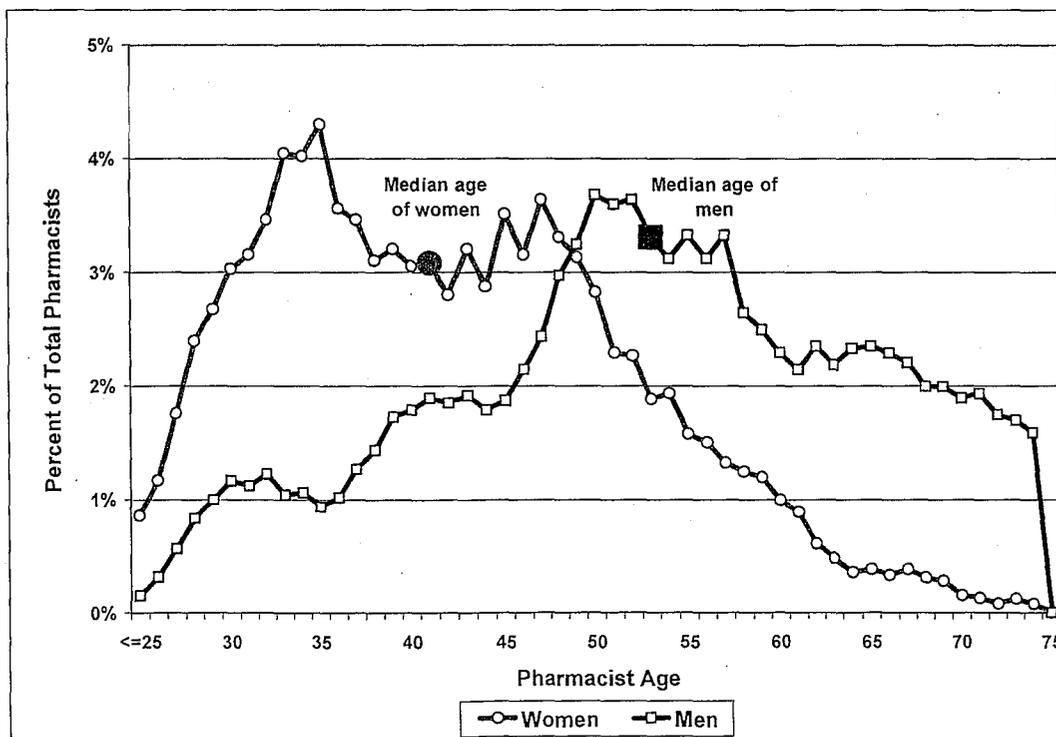
⁵ U.S. Bureau of Labor Statistics, Occupational Employment Statistics for November 2004.

Exhibit 1. Estimated Active Pharmacists, by Gender and Education: 2004



Source: Gender and education distribution based on analysis of the 2004 NPWS.

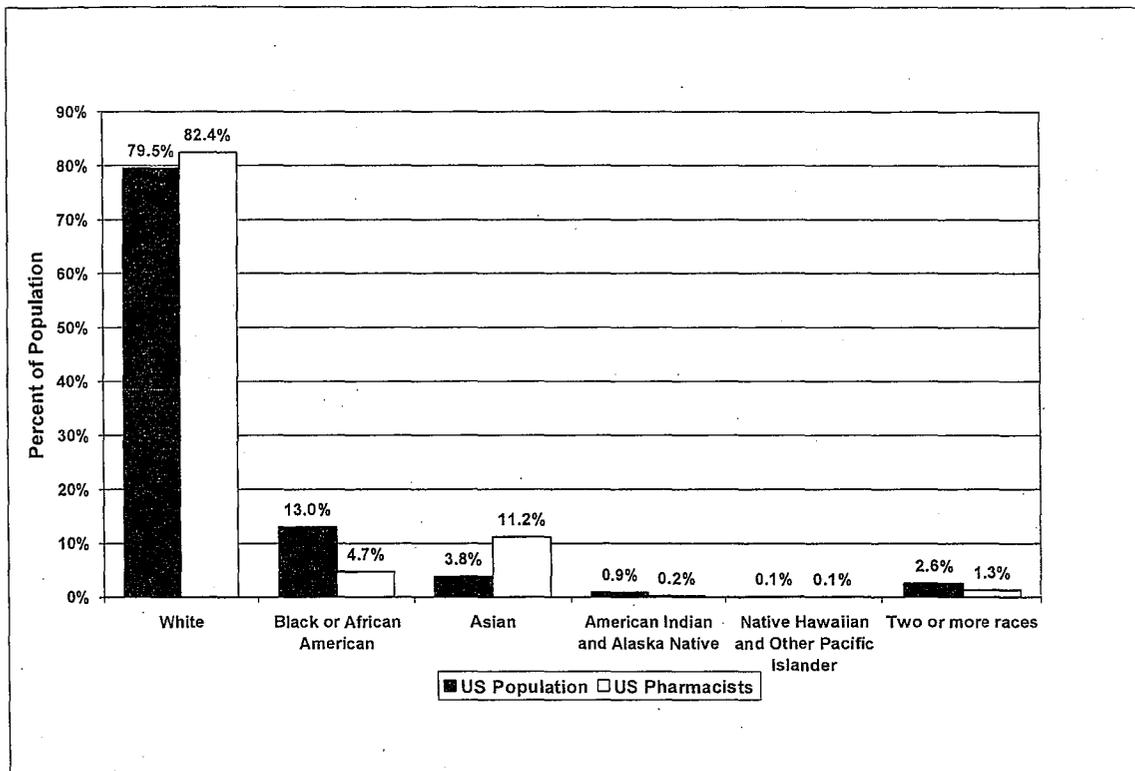
Exhibit 2. Pharmacist Age Distribution: 2004



Source: Analysis of the 2004 NPWS.

Racial minorities (with the exception of Asians) continue to be underrepresented in the pharmacist workforce (*Exhibit 3*). In the 2000 Census, 25 percent of the U.S. population indicated they are in a racial minority group, while only 18 percent of individuals self-identified as pharmacists indicated they are in a racial minority group. The percent of pharmacists who were Hispanic or Latino was 3.2 percent, compared to 12.5 percent of the U.S. population that was Hispanic or Latino in 2000.

Exhibit 3. Pharmacist Race Distribution: 2000



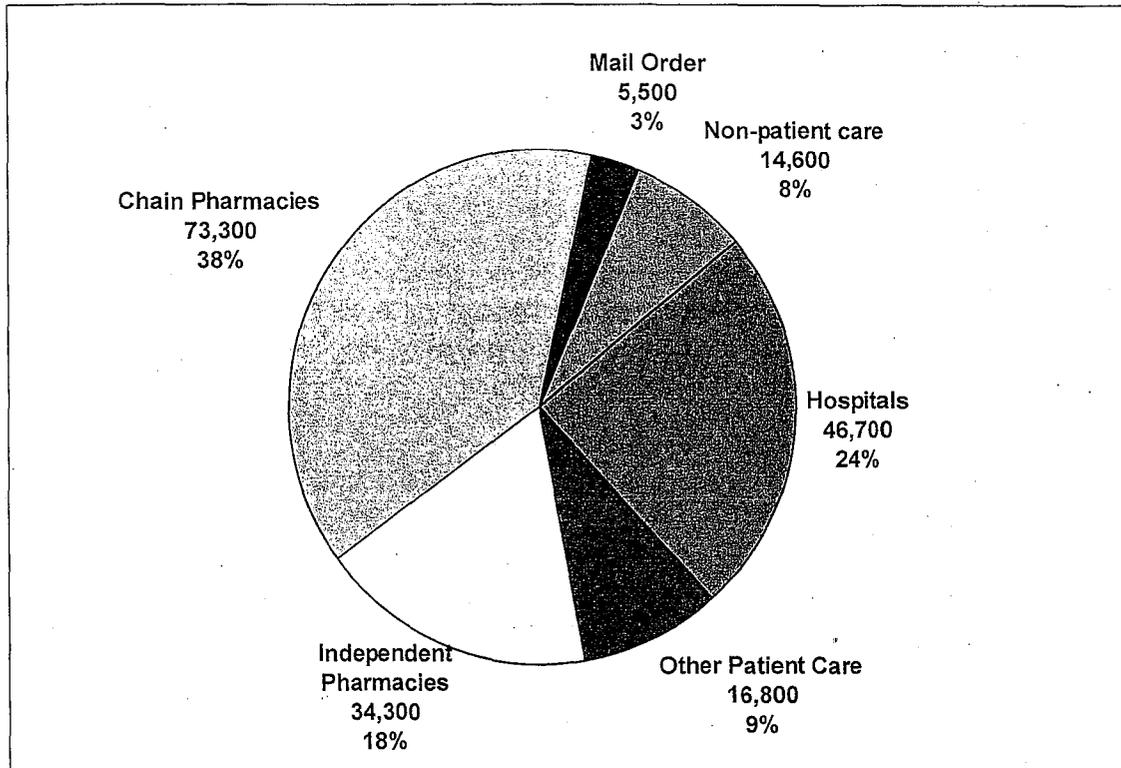
Source: 2000 U.S. Census

Note: The 2000 Census allows respondents to write in "some other race" in place of selecting the standard OMB single race categories included on the questionnaire. Of the 5.5 percent of the U.S. population who selected this category, 97 percent are of Hispanic origin. People in the "some other race" category are distributed across the standard OMB categories based on each standard category's prorated share of the total U.S. population.

Many of the estimated 226,000 active pharmacists in 2004 worked part time. Defining a FTE pharmacist as one who works, on average, approximately 1890 hours per year (40 hours per week times 47.2 weeks per year), the number of FTE pharmacists in 2004 was approximately 191,200 (*Exhibit 4*). Approximately 14,600 of these FTEs are primarily in non-patient care activities (e.g., teaching, research and administration), resulting in an estimated 176,600 FTEs in patient care. The majority of FTE pharmacists provide patient care work in community retail pharmacies (73,300 in chain pharmacies and 34,300 in independent pharmacies); an estimated

46,700 work in hospitals; 16,800 work in other patient care settings (e.g., nursing homes, clinics); and 5,500 work in mail order.⁶

Exhibit 4. Distribution of FTE Pharmacists by Dispensing Setting: 2004



Source: Analysis of the 2004 NPWS.

B. Trends in Supply Determinants

The size of the pharmacist workforce continually changes depending on the number of entrants and reentrants to the pharmacist workforce, as well as the number of pharmacists who leave the workforce either temporarily or permanently. Major trends with implications for the future supply of pharmacists include interest in becoming a pharmacist, the capacity of schools of pharmacy to train new graduates, the changing demographics of the pharmacist workforce (particularly the increasing proportion of pharmacists who are women), pharmacist work hours, and attrition from the pharmacist workforce.

⁶ The major dispensing settings modeled in this study include hospitals (non-government hospitals, HMO-operated pharmacy, government hospitals), independent pharmacies, chain drug stores (which includes supermarkets and mass merchandisers), mail order, other patient care (clinic pharmacies, home health, nursing homes), and non-patient care (industry, MCB/PBM, Armed Services, education, government, other).

1. New Graduates and Training Capacity

In 2004, 8,158 people graduated from schools of pharmacy with entry-level degrees, of which two thirds (n=5,437) were women.⁷ The year 2004 saw the final graduating class of pharmacists prepared at the baccalaureate level (n=338), with the remainder (n=7,770) prepared at the Pharm.D level. From 2005 onward all new graduates will be prepared at the Pharm.D level, the new minimum credential for entry into the workforce. Each year approximately 600 foreign-trained pharmacists begin practice in the United States.⁸

Since HRSA's 2000 report, there have been significant increases in the capacity of pharmacy schools due to both growth in existing programs and creation of new programs. The number of colleges and schools of pharmacy with accredited professional degree programs rose from 82 in 2000 to 92 by 2005. By Fall 2010 there will likely be 110 programs in operation.⁹ Projections of new pharmacy degrees conferred in future years (and used in the baseline supply projections presented in this report) are based on the number of students currently enrolled in schools of pharmacy and the assumption that the number of degrees conferred will increase by approximately 100 per year after 2008. One hundred new graduates per year is equivalent to opening about one new school of pharmacy per year and is consistent with current plans to expand the Nation's capacity to train new pharmacists by opening new programs and expanding current programs through expansion of traditional programs and the use of distance and distributive learning models. The projected number of Pharm.D degrees conferred in 2008 is approximately 10,000, and under the above assumptions this number would gradually increase to approximately 12,000 per year by 2030 (*Exhibit 5*). Since 1994, approximately 2 out of every 3 new graduates are women, and this trend will likely continue.

Alternate supply projections presented make different assumptions about the future number of new graduates to show how the future adequacy of supply would be affected by a deviation from continued efforts to expand the Nation's educational capacity.

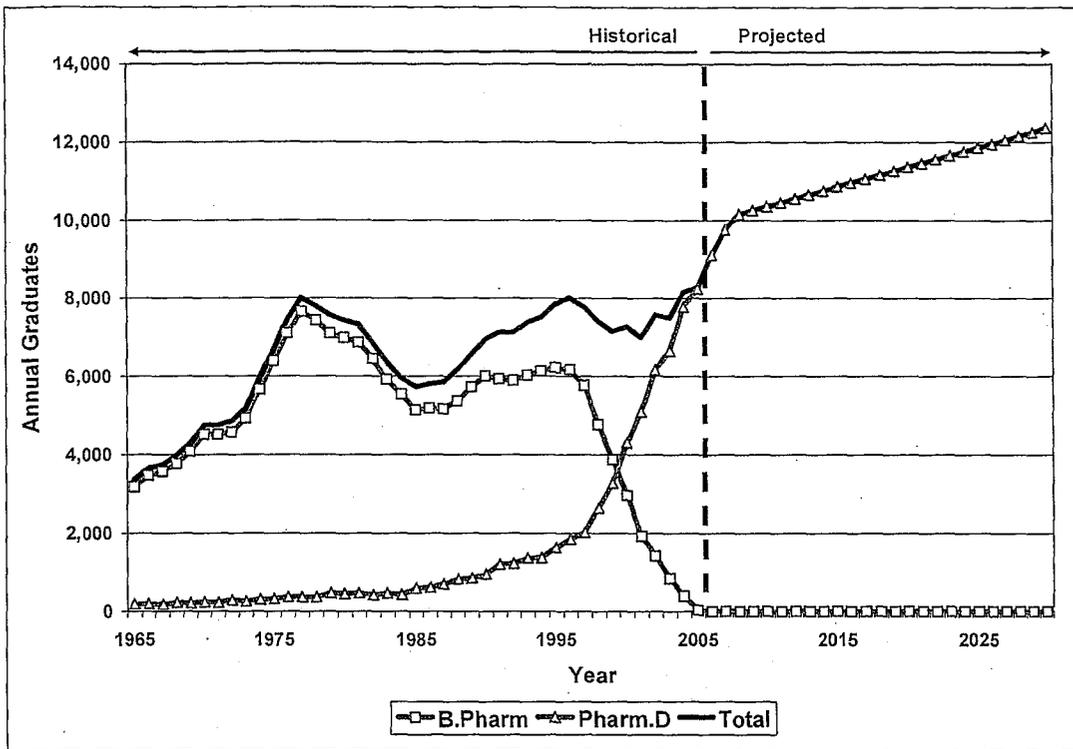
Each year a small percentage of pharmacists trained at the baccalaureate level return to school to complete a Pharm.D degree. With the discontinuation of the B.Pharm degree and a diminishing number of pharmacists prepared at the baccalaureate level interested in completing a doctorate degree, the number of pharmacists completing a post-baccalaureate Pharm.D degree is projected to decline rapidly. In 2000, 1269 post-baccalaureate Pharm.D degrees were awarded. This number fell to 668 in 2005 and is likely to continue declining (*Exhibit 6*). Analysis of the National Pharmacist Workforce Survey (NPWS) finds that workforce participation and retirement patterns for pharmacists prepared at the baccalaureate (B.Pharm) level are similar to patterns for pharmacists prepared at the doctoral (Pharm.D) level, so the education distribution of the workforce does not affect projections of overall supply of pharmacists.

⁷ American Association of Colleges of Pharmacy (AACP) Profile of Pharmacy Students (Fall 2005).

⁸ Source: Based on discussions with the National Association of Boards of Pharmacy (NABP).

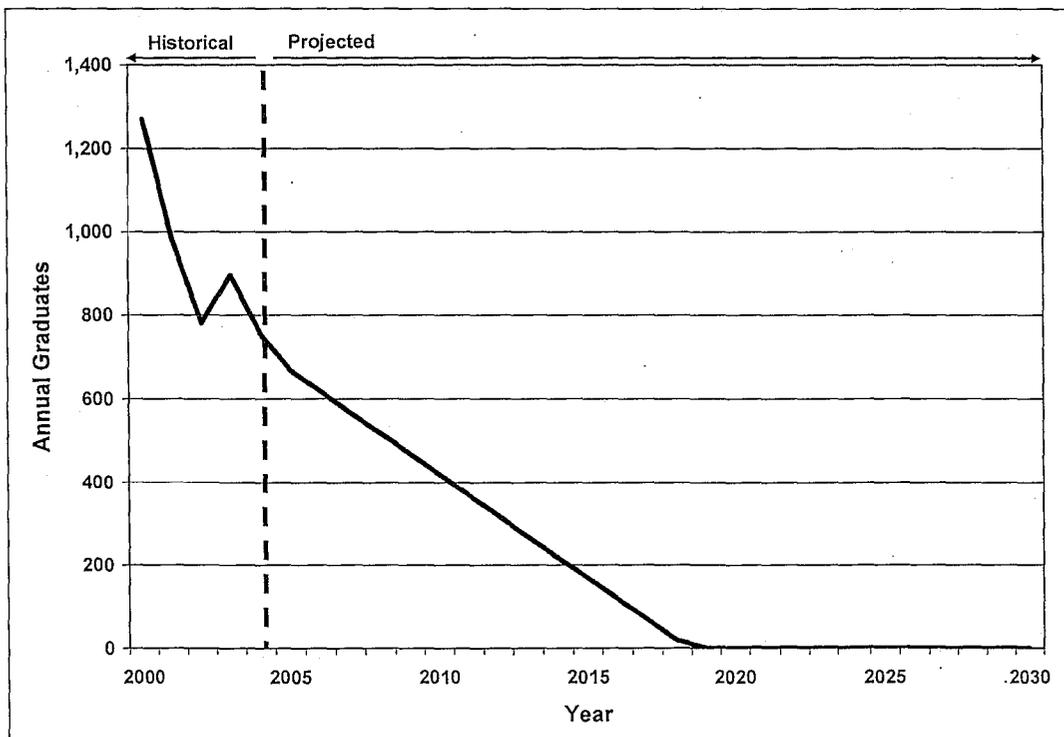
⁹ Source: Estimates for 2007 and 2010 are based on personal communication with Lucinda Maine, AACP.

Exhibit 5. Number of First-time Pharmacy Degrees Conferred



Source: Historical (1965 to 2005) data from AACP Profile of Pharmacy Students (Fall 2005).

Exhibit 6. Number of Post-baccalaureate Pharm.D Degrees Conferred



Sources: Historical data from AACP Profile of Pharmacy Students (Fall 2005).

2. Distance and Distributive Learning Models

The use of distance learning models in pharmacy education has expanded since the 2000 report and has contributed to the growth in existing training programs. Distance or distributed learning is defined as a separation between the student and the instructor by time or place. U.S. pharmacy schools first began applying a distance-learning model of education nearly 20 years ago in programs designed to increase the practice competency of working pharmacists.

The distance-learning model also has been used for many years to offer continuing education classes to practicing pharmacists or classes that confer certification in a particular practice competency. For example, States such as Wisconsin require continuing education credits for license renewal. The University of Wisconsin School of Pharmacy offers continuing education teleconference courses each year that reach every county in the State.¹⁰

Against a backdrop of growing concern about a significant shortage of pharmacists, the use of distance learning has been expanded in recent years to first-degree Pharm.D programs at a number of institutions around the country. Currently, at least five programs offer a distinct distance-learning pathway for their first-degree Pharm.D programs (*Exhibit 7*). These schools are Creighton University, Nova Southeastern University, the University of Florida, the University of Minnesota, and the University of Oklahoma. Overall, about 400 students are enrolled each year in a distinct distance-learning pathway under the first-degree Pharm.D programs at these five schools.

Exhibit 7. Programs with Distinct Distance Learning Pathways for First Pharm.D

First-Degree Pharmacy Program	Distance Learning Slots
Creighton University	55
University of Florida	170
University of Minnesota	54
Nova Southeastern University	60
University of Oklahoma	60
Total	399

Source: Individual school Web sites accessed June 2006

According to information published on the individual pharmacy program Web sites, Creighton University enrolls about 110 students each year on their main campus and an additional 55 students in a Web-based pathway. Nova Southeastern University enrolls 120 students at the main campus in Ft. Lauderdale and another 60 in West Palm Beach and other distant locations. The University of Florida enrolls about 130 students on the main campus in Gainesville, and an additional 170 students in satellite locations in Jacksonville, Orlando, and St. Petersburg. The University of Minnesota enrolls about 105 students at the main campus in the Twin Cities, and another 54 students at the Duluth campus of the university. Finally, the University of Oklahoma enrolls about 78 students on the main campus in Oklahoma City, plus an additional 60 students in Tulsa.

¹⁰ Bruskiwitz MS, DeMuth J. Availability and Acceptability of Distance-Learning Delivery Systems for Continuing Pharmaceutical Education. *American Journal of Pharmaceutical Education*. 2005; 69(2): Article 25.

Creighton's distance learning program is unique in offering an almost entirely Web-based program, allowing the student to earn their degree largely out of their home location.¹¹ The Creighton program requires attendance at 1- to 2-week lab sessions during the summer on campus. Eight 5-week clinical rotations are required, and are offered at a variety of locations around the country. Students applying to Creighton for pharmacy school may apply either to the regular campus-based program or the Web-based program, but not both.

The distance-learning model offered at Nova, Florida, Minnesota, and Oklahoma offers students the opportunity to study out of a satellite location separate from the main campus. Often some portion of the course material is delivered via distance learning technologies such as interactive television.¹² Generally, students apply to the program as a whole, and indicate or rank their choice of location.

In addition to the first-degree pathways offered by these schools, many other Pharm.D programs offer a distance-learning component to their first-degree programs, particularly in the later years of study. For example, Texas Tech offers third and fourth year Pharm.D students the opportunity to complete their training at a regional site such as Dallas or Lubbock, after spending the first 2 years at the main campus in Amarillo.

It is likely that the greater use of distance learning models in pharmacist education has contributed to the expansion in pharmacy program enrollments in recent years. Together, Creighton, Nova, Florida, Minnesota, and Oklahoma have grown their first degree enrollments by 85 percent since 2000, going from 2,013 enrollments in 2000 to 3,714 in 2005 (*Exhibit 8*). During this same time period, total enrollments at all schools increased by 35 percent from 34,481 to 46,527.

Exhibit 8. First Degree Enrollments at Pharmacy Schools with Distinct Distance Learning Pathways

	2000	2001	2002	2003	2004	2005
University of Florida	484	507	661	836	992	1,147
Creighton University	402	463	518	591	651	663
University of Oklahoma	232	290	346	393	455	514
Nova SE University	504	569	647	714	792	807
University of Minnesota	391	383	418	466	530	583
Total	2,013	2,212	2,590	3,000	3,420	3,714

Source: AACP Profile of Pharmacy Students (Fall 2005).

Distance learning models address a number of potential constraints to increasing enrollment. First, these programs allow pharmacy schools to offer students greater flexibility in their study location, making the programs more attractive to applicants. Second, where space constraints exist on the main campus, these pathways offer a way to expand by adding facilities in other locations, or, in the case of Web-based pathways, requiring only technical infrastructure

¹¹ Malone P, Glynn G, Stohs S. The Development of Structure of a Web-based Entry-level Doctor of Pharmacy Pathway at Creighton University Medical Center, *American Journal of Pharmaceutical Education*, 2004; 68(2): Article 46.

¹² Ward C, Rey J, Mobley C, Evans C. Establishing a Distance Learning Site for a Traditional Doctor of Pharmacy Program. *American Journal of Pharmaceutical Education*. 2003; 67(1): Article 20.

A third constraint to increased enrollments has been faculty shortages in pharmacy education.¹³ Where distance learning may be particularly effective in leveraging scarce faculty is in allowing faculty with specialized knowledge or experience to share that expertise with larger numbers of students. However, it should be noted that early experiences with these models have shown that they do not require fewer faculty as much as a different deployment of faculty. Adding a distance-learning component to a campus-based class may actually increase the workload for existing staff, especially when the program is first implemented. A greater commitment to course planning and course readiness is required, and the expectations of remote students regarding immediate electronic access to faculty need to be managed. In addition to instructional staff, satellite locations may require liaisons, facilitators, and counselors. A technical staff is also needed to implement and maintain the distance learning tools and technologies

As distance learning in pharmaceutical education continues to expand, it will be important to continue to monitor and evaluate the quality of such programs and to share lessons learned. Researchers at the Nova Southeastern University School of Pharmacy published a comprehensive white paper in 2003 on issues relevant to ensuring excellence in distance pharmaceutical education.¹⁴ The Accreditation Council for Pharmacy Education (ACPE) released revised accreditation standards guidelines in February 2006 that contain explicit guidelines on the use of distance learning in a pharmacy education program.¹⁵

Studies to date have found that outcomes from distance learning programs are comparable to traditional campus-based programs.¹⁶ The first graduating classes coming out of these programs are passing licensure exams at rates equal to or better than traditional students. Because students currently self-select for participation in distance learning pathways, there will be a continued need to monitor and evaluate the impact on performance, especially if students have less choice about participating. Given the success of distance learning in increasing enrollment while maintaining outcomes, these technologies will likely continue to play a role in pharmaceutical education.

3. Increasing Number of Women in Pharmacy

The proportion of pharmacists who are women has increased from below 13 percent in 1970 to almost half of all pharmacists today. Because two thirds of new graduates are women and because most pharmacists nearing retirement are men, the proportion of pharmacists who are women will continue rising. By 2025, two out of three pharmacists are likely to be women (*Exhibit 9*).

¹³ Traynor K, Staffing Shortages Plague Nation's Pharmacy Schools. *American Journal of Health-System Pharmacy*. 2003; 60: 1822.

¹⁴ Hunter RS, Deziel-Evans, L, March WA. Assuring Excellence in Distance Pharmaceutical Education. *American Journal of Pharmaceutical Education*. 2003; 67(3): Article 94.

¹⁵ Accreditation Council for Pharmacy Education (ACPE). *Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree*. Adopted: January 15, 2006. Effective: July 1, 2007.

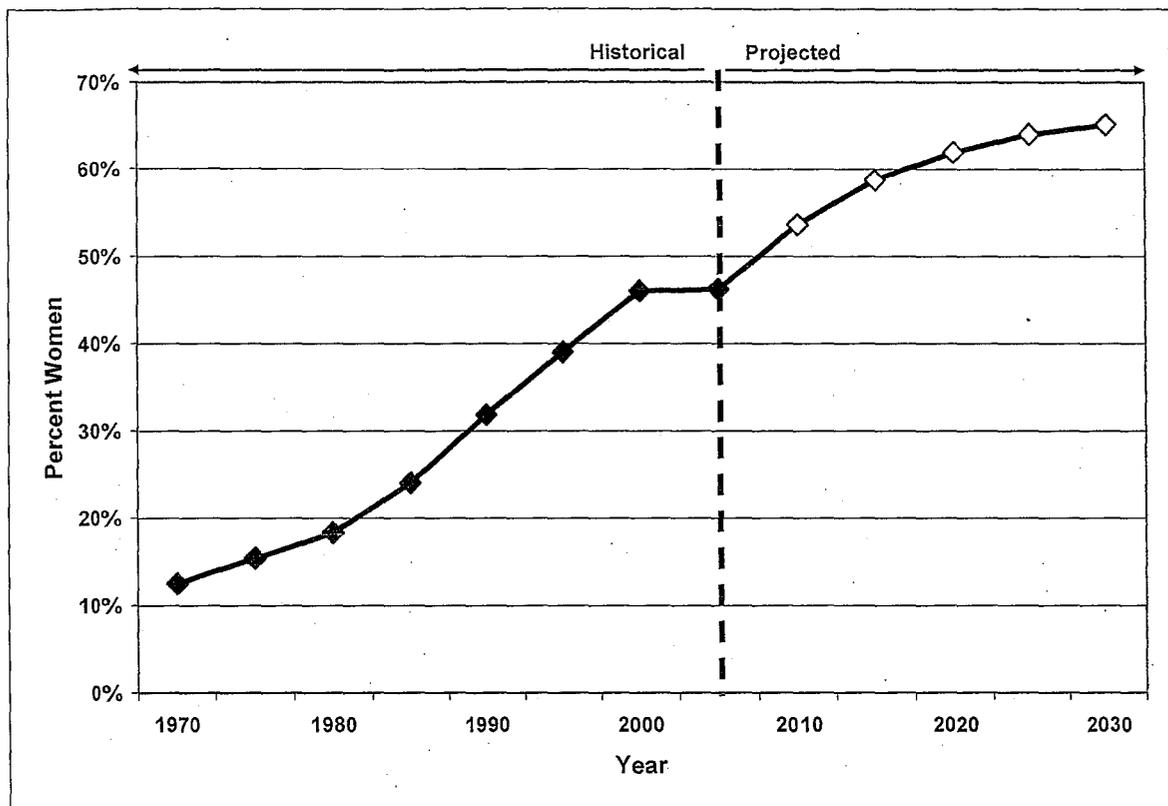
¹⁶ Faulkner TP, Christoff JJ, Sweeney MA, Oliver N. Pilot Study of a Distance-Learning Methodology Used on Campus for First Professional Degree Pharmacy Students in an Integrated Therapeutics Module. *American Journal of Pharmaceutical Education*. 2005; 69(1): Article 7.

Ried LD, McKenzie M. A Preliminary Report on the Academic Performance of Pharmacy Students in a Distance Education Program. *American Journal of Pharmaceutical Education*. 2004; 68(3): Article 65.

Breslow RM. A Comparison of Academic Performance of Off-Campus Nontraditional PharmD Students With Campus-Based PharmD Students. *American Journal of Pharmaceutical Education*. 2005; 69(1): Article 8.

Women are more likely than their male colleagues to work part time, so in percentage terms total hours of pharmacist services supplied will rise more slowly than the number of active pharmacists.

Exhibit 9. Percent of Pharmacists who are Women



Sources: HRSA (2000) and projections from the PhSRM.

4. Pharmacist Hours Worked

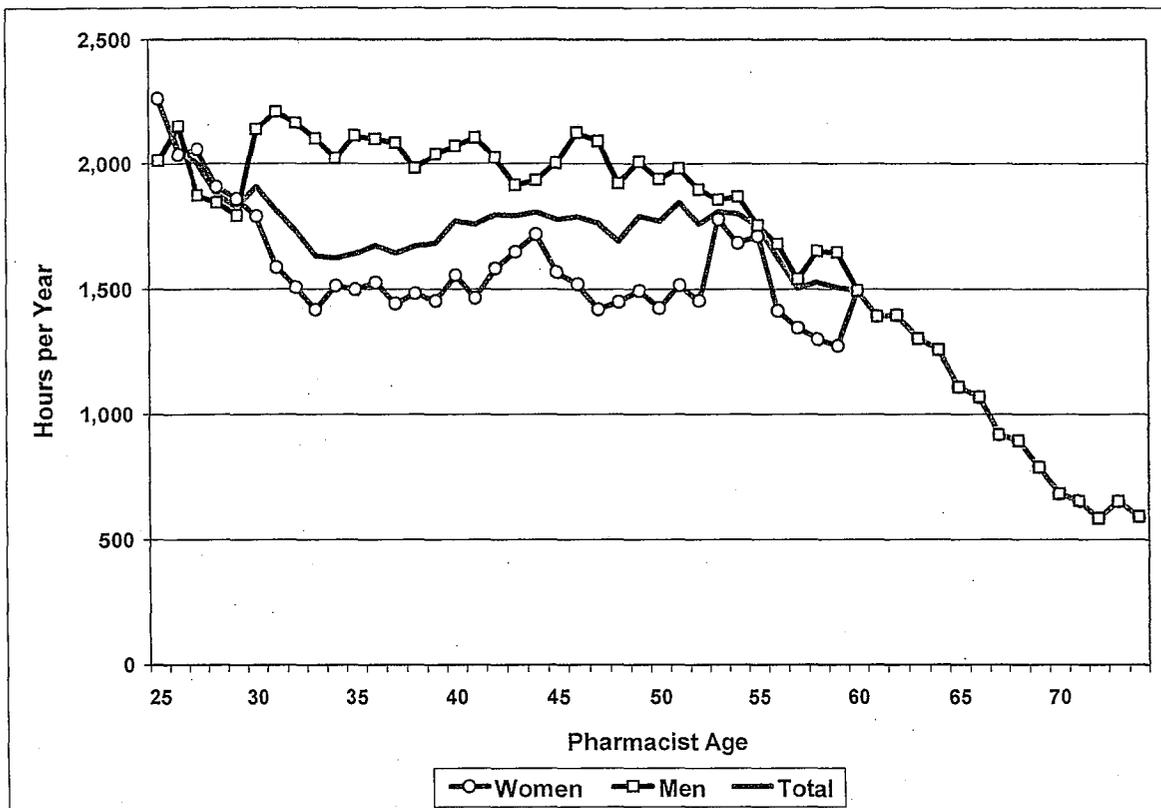
In 2004, an estimated 20.6 percent pharmacists worked part time (defined as working 30 or fewer hours per week. For this study a FTE pharmacist is defined as one providing approximately 1890 hours per year of pharmacist-related services. This estimate was obtained through an analysis of the 2004 NPWS by estimating the average weeks worked per year for pharmacists working 40 or more hours per week (47.2 weeks), and multiplying this number by 40 hours per week. Pharmacists age 28 and younger, on average, work more than 1890 hours per year. Among active pharmacists, average hours worked tends to decrease with age (*Exhibit 10*).

Many pharmacists work more than 1890 hours per year, either through long hours on their primary job or by working multiple jobs. Male pharmacists tend to work more than 1890 hours per year and, on average, are counted as slightly more than one FTE through age 55.¹⁷ Female

¹⁷ Pharmacists working more than 1890 hours per year are counted as greater than 1 FTE, while pharmacists working less than 1890 hours per year are counted as a partial FTE. The total number of FTE pharmacists of a the formula: $\text{Total FTEs}_{\text{age}} = (\text{Total Active Pharmacists}_{\text{age}}) \times \left(\frac{\text{Average annual hours}_{\text{age}}}{1890} \right)$

pharmacists are more likely to be working part time and, on average, count as approximately 0.8 FTE between the ages of 32 and 60. For pharmacists age 60 and older, the sample size in the 2004 NPWS is relatively small so FTE rates for men and women are combined for modeling.

Exhibit 10. Average Hours Worked per Year: 2004



Source: Analysis of the 2004 NPWS. Note: Hours for women and men age 60 and older are combined because small sample size makes gender-specific rates unreliable.

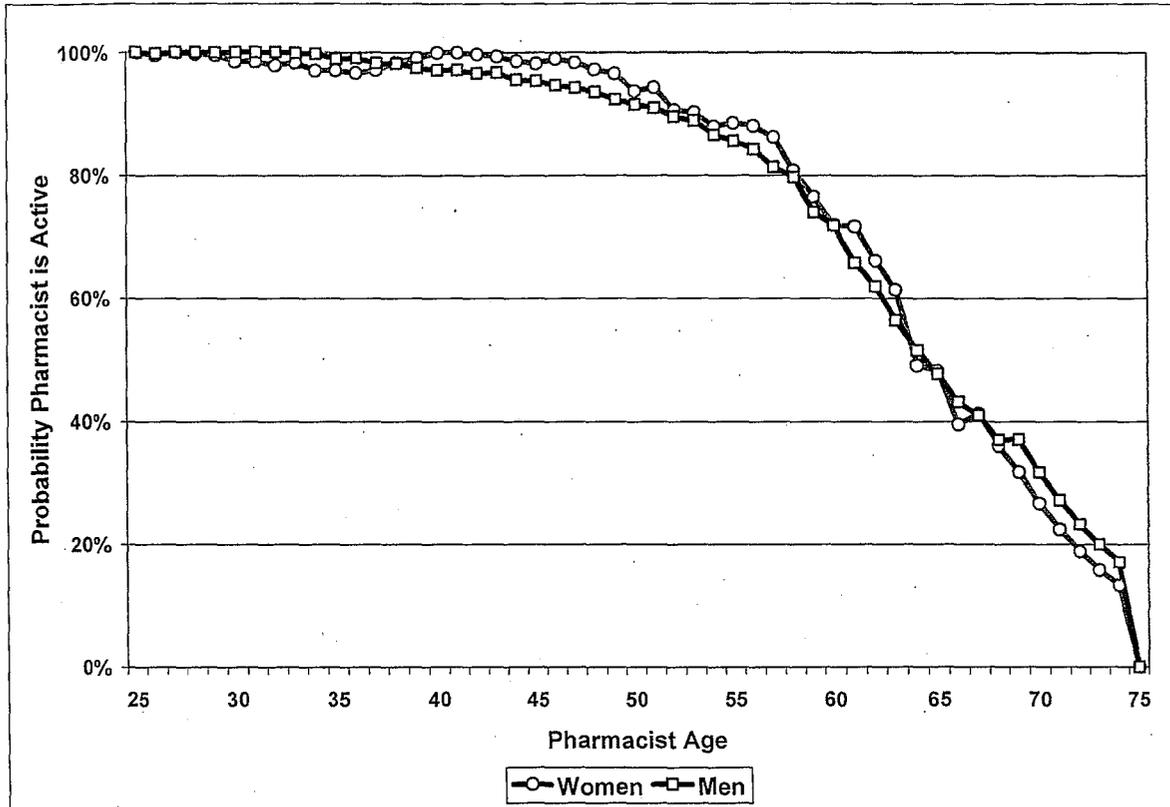
In addition to differences in average hours by pharmacist age and gender, anecdotal evidence suggests that average hours worked might be declining over time—in part due to lifestyle choices. A comparison of NPWS findings shows a drop in FTE rates for both male and female pharmacists between 2000 and 2004, although it is uncertain whether this drop is due to lifestyle choices, market conditions, or other factors.

5. Attrition from the Pharmacist Workforce

Few sources provide data on pharmacist retirement patterns, and for this analysis data from the 2000 Census were analyzed to estimate the probability that a pharmacist was employed during the previous year. The Census data on occupation and employment status are self reported, and the assumption is made that a person who self-identifies as a pharmacist and reports that they are working is, in fact, working in a pharmacy-related job. This information is supplemented with data from the Centers for Disease Control and Prevention on the mortality risk for men and women, which is used as a proxy for mortality rates of pharmacists.

Most pharmacists remain active in their profession for 35 or more years (*Exhibit 11*). Over 85 percent of pharmacists who reach age 55 are still active, but this percentage declines to less than 50 percent by age 65. Between age 65 and age 75, the likelihood that a pharmacist is still active declines precipitously, and for modeling purposes it is assumed that by age 75 all pharmacists have retired. Labor force activity rates for male and female pharmacists of the same age are relatively similar, although women age 30 to 37 are slightly less likely than men to be active and women age 40 to 65 are slightly more likely than men to be active.

Exhibit 11. Probability Pharmacist is Active in Pharmacy



Source: Analysis of 2000 U.S. Census and CDC mortality statistics. Note: All pharmacists assumed retired by age 75.

C. The Future Pharmacist Supply

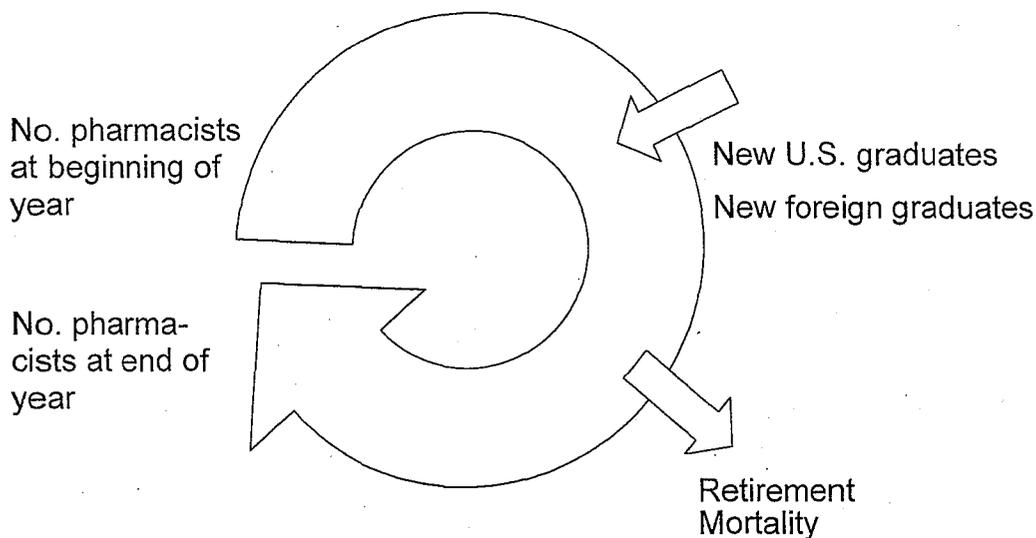
Numerous factors influence the decision to become a pharmacist and the decisions by pharmacists regarding how many hours to work, where to work, and when to retire. The supply model tries to capture the major trends that affect supply. Following a brief description of how future supply is modeled, projections through 2030 for a baseline and alternate scenarios are presented.

1. Modeling Future Supply

Future supply is projected using an inventory model that tracks the number of active and FTE pharmacists by age, gender, education level, and year. An inventory model starts with the number of active pharmacists in a particular age, gender and education level (*Exhibit 12*). Each

year new entrants are added to the pharmacist workforce using an age and gender distribution that reflects current and projected trends. Also, each year some pharmacists separate from the workforce due to retirement and mortality, with the probability of separating increasing with age. The number of pharmacists at the beginning of the year plus the net change in number of pharmacists during the year determines the supply of pharmacists at the end of the year (which becomes the starting point for the next projection year).

Exhibit 12. Inventory Model of Supply

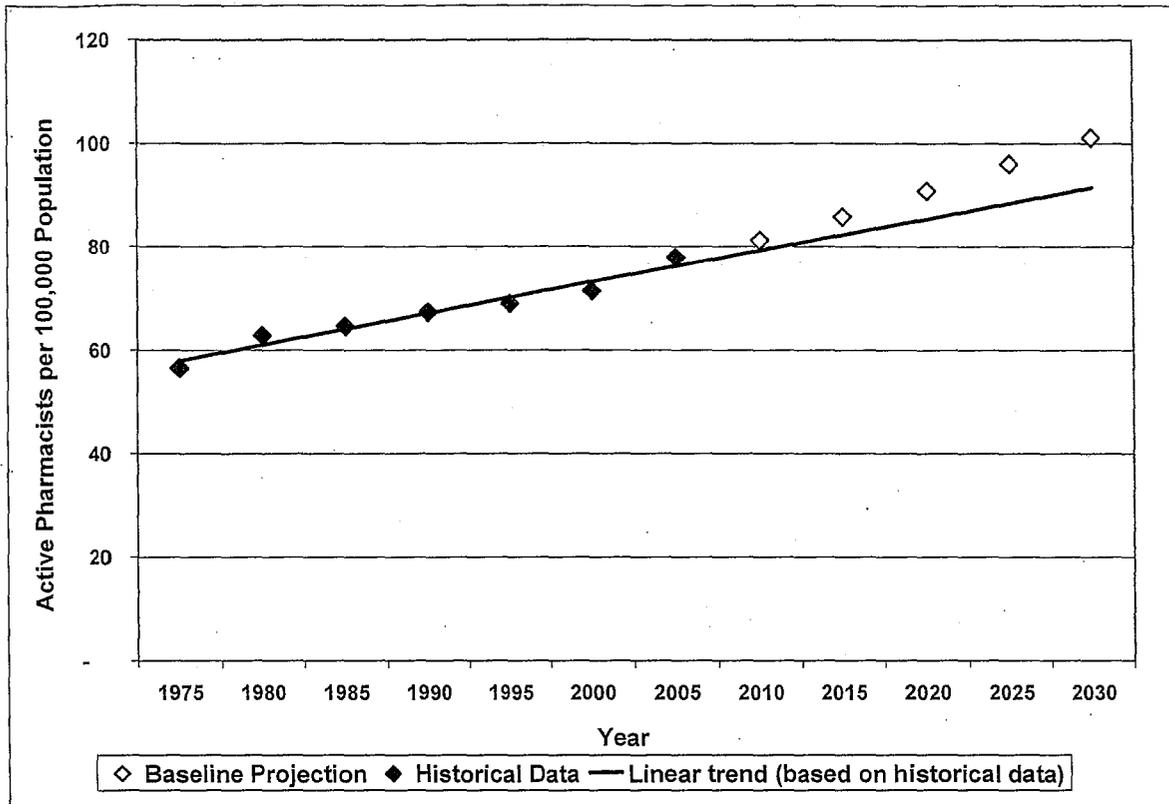


2. Baseline Supply Projections

The baseline scenario is our best estimate of future supply under the assumptions presented above regarding the number of new pharmacist graduates, average hours worked, and separation rates. This scenario assumes that the number of entry-level degree graduates from schools of pharmacy will experience moderate growth, that pharmacists of a given age and gender will continue to work the same number of hours as their counterparts today, and that retirement patterns will remain unchanged over time.

Under this scenario, the number of active pharmacists will grow at a slightly faster rate than the overall resident population. The number of pharmacists per 100,000 population grew from approximately 56 in 1975 to a current estimate of approximately 78. This number is projected to increase to approximately 101 by 2030 (*Exhibit 13*). These projections through 2030 are slightly higher than suggested by a linear projection of the pharmacist-to-population ratio based on data from 1975 to present.

Exhibit 13. Active Pharmacists per 100,000 Resident Population in the US

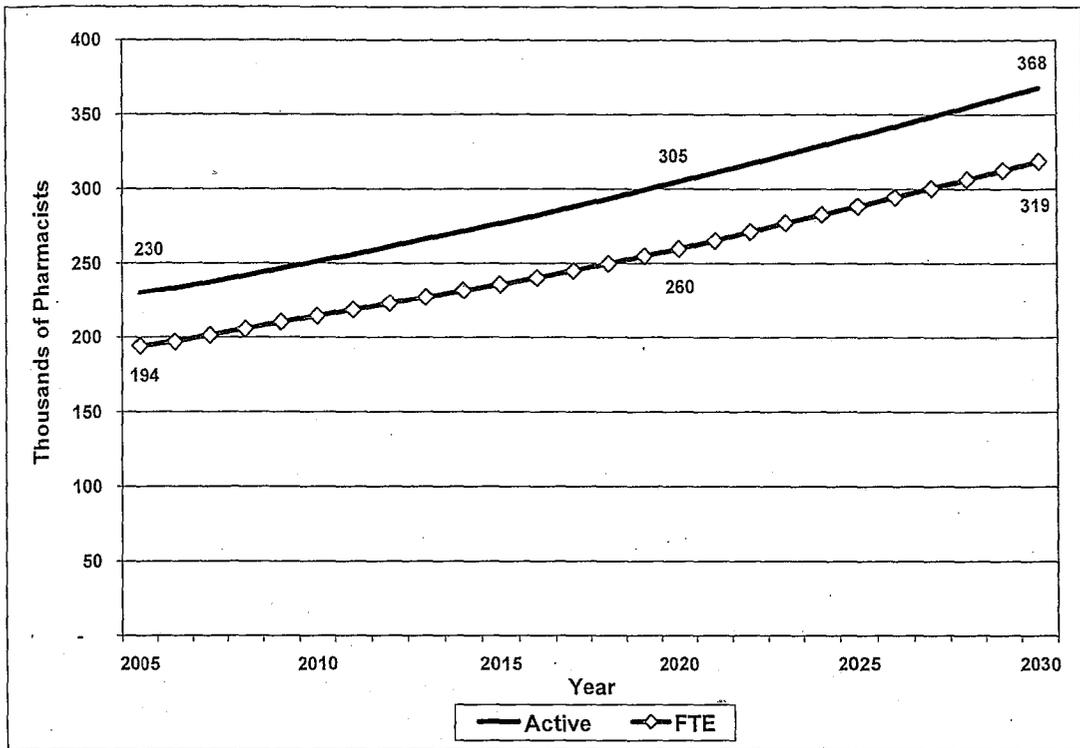


Source: Historical data combines U.S. Bureau of Labor Statistics data on pharmacists with U.S. Census Bureau population estimates. Projections from the PhSRM.

The baseline supply projections suggest that the number of active pharmacists will increase from approximately 230,000 in 2005 to 305,000 by 2020 and 368,000 by 2030 (*Exhibit 14*). The FTE supply estimates remain approximately 85 percent of active supply over this projection horizon, increasing from 194,000 in 2005 to 260,000 by 2020 and 319,000 by 2030.

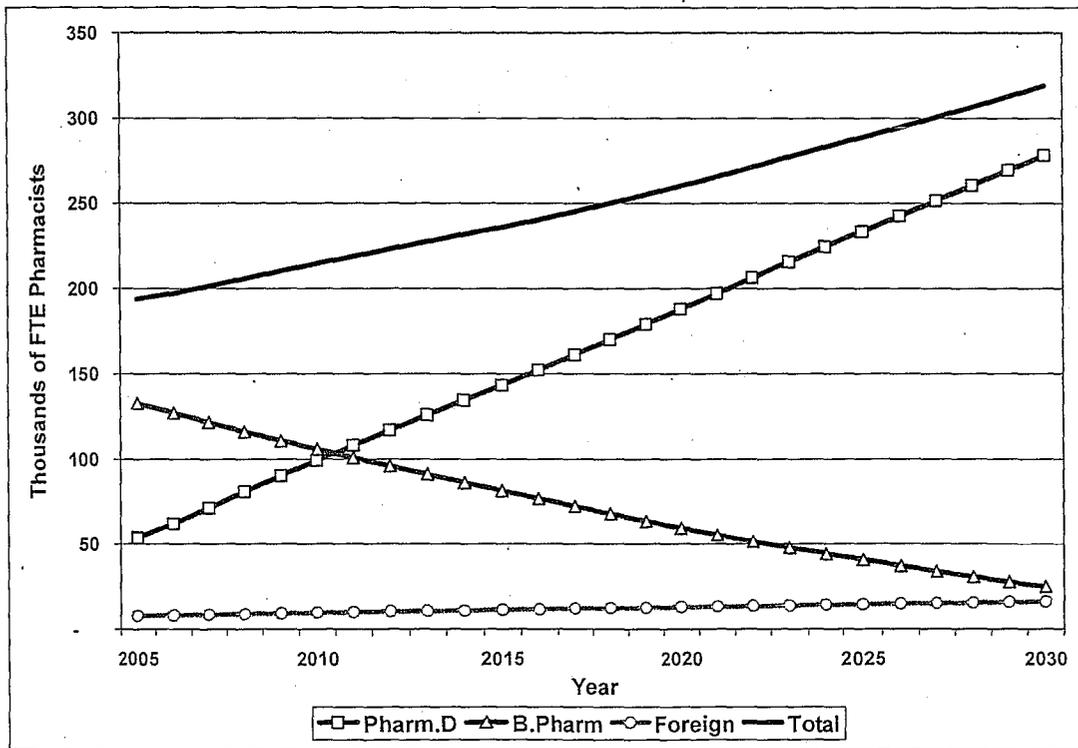
All entry-level degree graduates of pharmacy schools now graduate with a Pharm.D degree. In addition, each year hundreds of pharmacists originally prepared at the baccalaureate level earn their Pharm.D degree through distance learning and other programs. The percentage of pharmacists trained at the Pharm.D level is projected to continue rising from its current level of 30 percent to an estimated 90 percent by 2030 (*Exhibit 15*).

Exhibit 14. Total Active and FTE Pharmacists: Baseline Supply Projections



Source: Projections from the PhSRM.

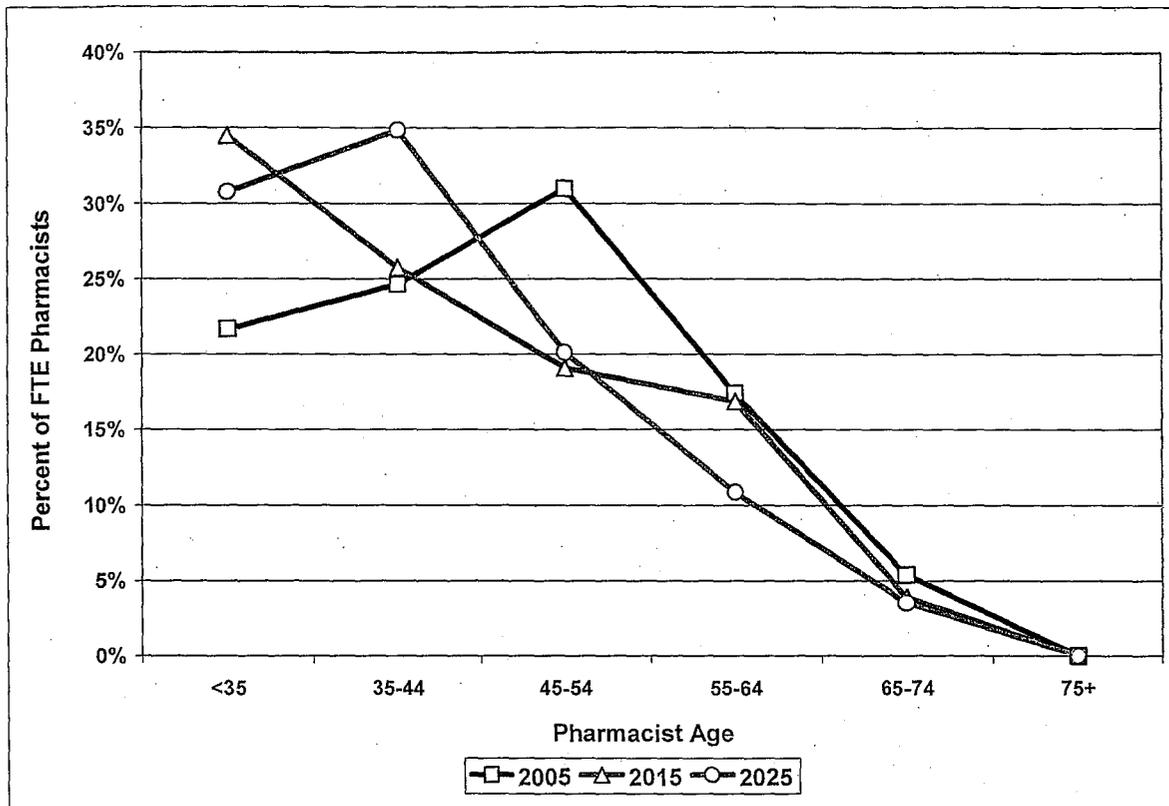
Exhibit 15. Total FTE Pharmacists: Baseline Supply Projections



Source: Projections from the PhSRM.

The recent increase in number of new entry-level degree pharmacy graduates is projected to result in a pharmacist workforce that in 2015 has a larger proportion of young (under age 35) pharmacists than existed in 2005 (*Exhibit 16*). While young pharmacists tend to work more hours per week than their older colleagues, a growing proportion of these new pharmacists are women who tend to work fewer hours per week than their male colleagues.

Exhibit 16. Age Distribution of FTE Pharmacists



Source: Projections from the PhSRM.

3. Alternate Supply Projections

Most people who train in a specialized field such as pharmacy remain in that profession throughout their career, so national supply projections tend to be relatively stable. Actual future supply might diverge from the baseline projections if trends in supply determinants deviate from current or expected levels. To test the sensitivity of the supply projections to key supply determinants the following alternate scenarios are modeled:

1. What is the impact on FTE supply of increasing (by 2010) the number of new graduates from pharmacy schools by 10 percent and by 20 percent above the baseline assumptions, and what is the impact if educational capacity stops growing past 2008 (*Exhibit 17*)?
2. What is the impact on FTE supply if pharmacist retirement patterns were to change such that pharmacists decided, on average, to retire 2 years earlier or to delay retirement for 2 years compared to current patterns (*Exhibit 18*)?

3. What is the impact on FTE supply if pharmacists increase/decrease their hours worked annually by 10 percent (*Exhibit 19*)?

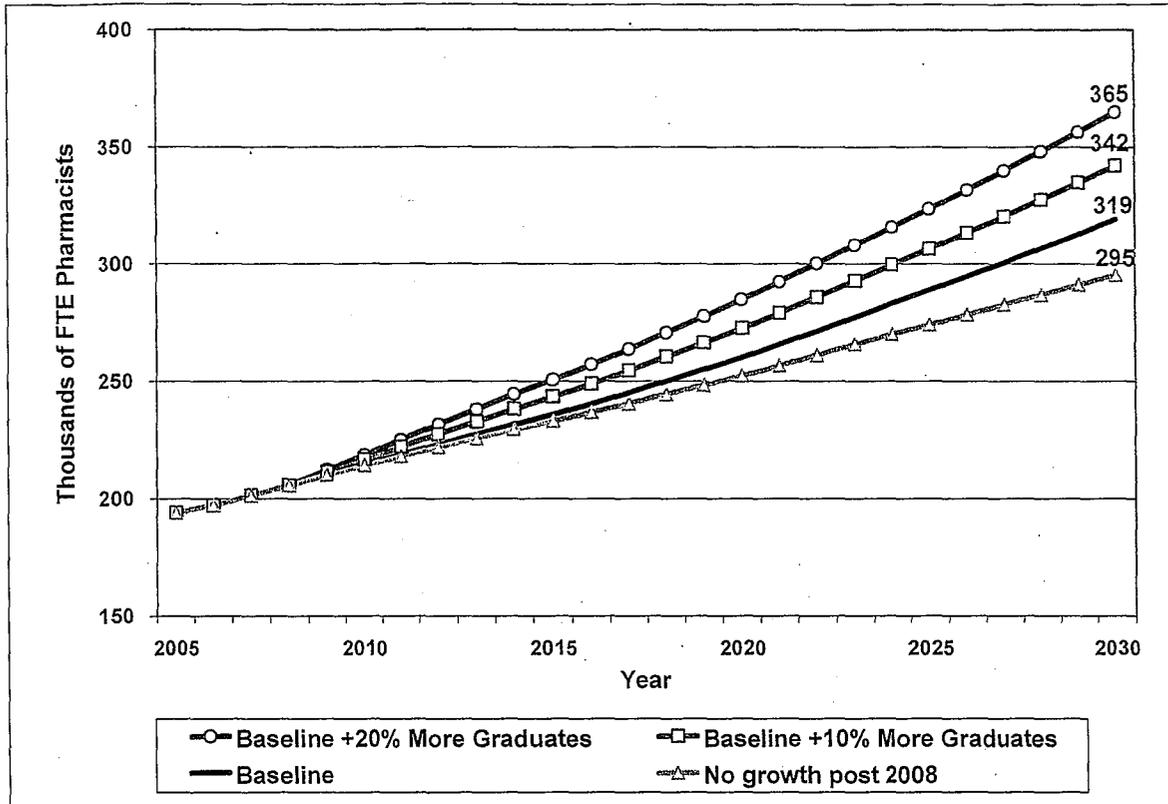
Supply projections for the baseline scenario and alternate scenarios are summarized in *Exhibits 20 and 21*.

Applications to first professional degree pharmacy programs more than tripled since the late 1990s, rising from 23,500 applications for the 1998-1999 school year to over 79,000 for the 2004-2005 school year. During this time, enrollment in first professional degree programs increased by about a third, from 34,500 in 2000 to 46,500 in 2005. The large increase in number of applicants suggests that interest in becoming a pharmacist is high, although the more moderate increase in enrollment suggests the presence of training capacity constraints. If capacity increased such that from 2010 onward the number of new U.S. graduates remained 10 percent to 20 percent above the baseline graduate assumptions, by 2030 the number of FTE pharmacists would be approximately 23,000 to 46,000 higher than the baseline projections (*Exhibit 17*).

A possible constraint to future increases in pharmacy graduates is a shortage of pharmacy faculty. According to the annual AACP Survey of Vacant Budgeted and Lost Faculty Positions, total reported vacant or lost faculty positions have increased from 354 in 2002-03 to 406 in 2004-05.¹⁸ If faculty shortages or other factors prevent further expansion of colleges and schools of pharmacy past the 2008 graduating year, then the number of FTE pharmacists would be 24,000 fewer than the baseline projection for 2030.

¹⁸ Data cited in AACP Institutional Research Briefs Vols. 5 & 6, posted on www.aacp.com, accessed March 2007. Percent of pharmacy programs responding to the survey ranged from 77 percent to 85 percent.

Exhibit 17. Sensitivity of FTE Supply to Number of Graduates from US Schools of Pharmacy

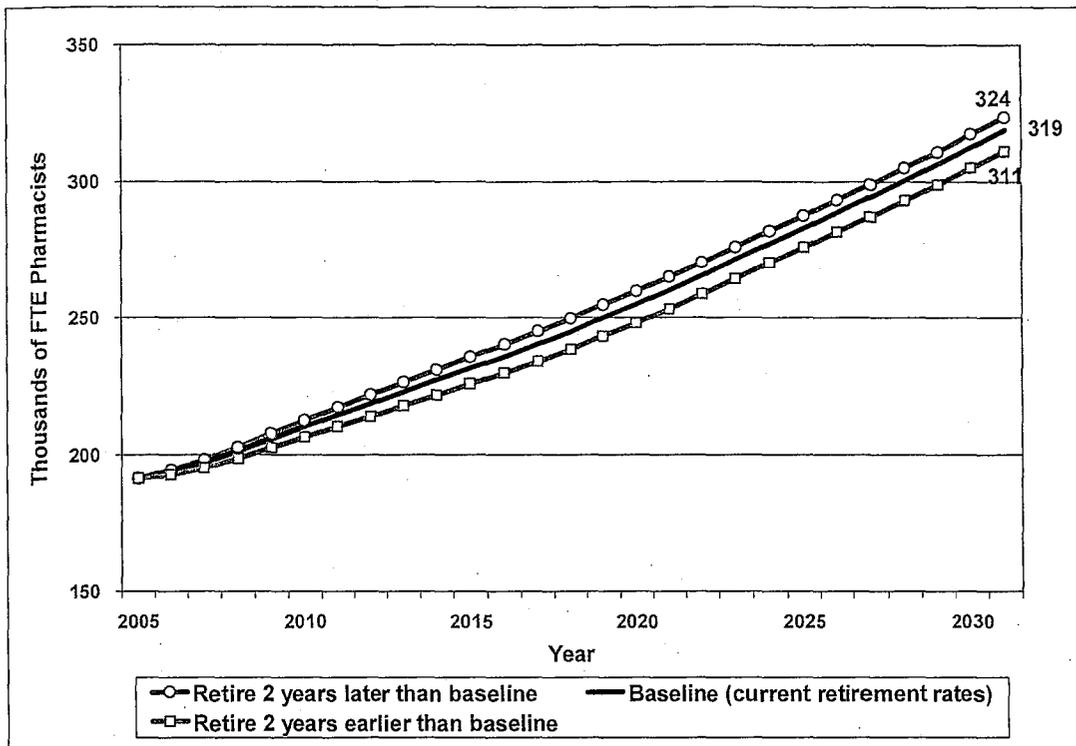


Source: Projections from the PhSRM.

Another factor that could influence supply is when pharmacists decide to retire. Factors that could delay retirement include increases in the age for Social Security and Medicare eligibility, and continued high demand for pharmacist services that raises the opportunity cost of retirement. Factors that could contribute to retiring earlier than historical patterns include the increasing number of people caring for elderly parents, lifestyle changes, and economic prosperity. Under a scenario where pharmacists retire, on average, 2 years earlier or 2 years later than historical patterns, by 2030 the number of FTE pharmacists would fluctuate by only 5,000 to 8,000 from the baseline projections (*Exhibit 18*).

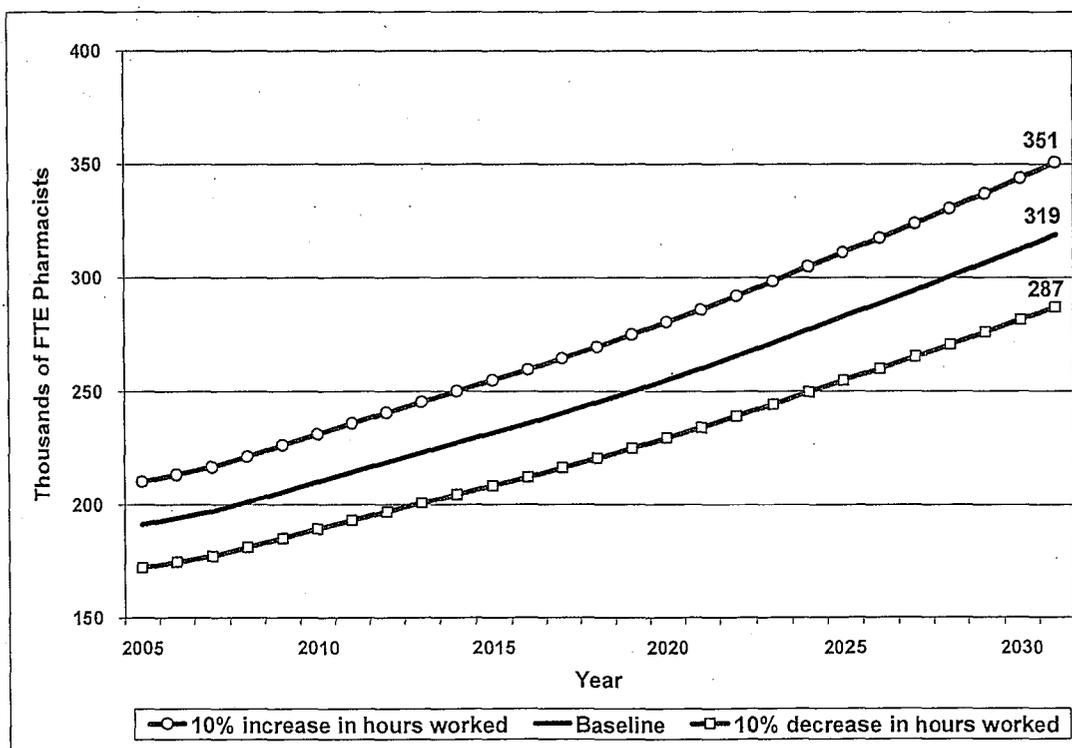
The baseline projections take into consideration the changing gender and age distribution of the pharmacist workforce and the implications for hours worked. Factors that might contribute to a change in average hours worked include lifestyle decisions and the adequacy of pharmacist supply (e.g., a shortfall might increase hourly earnings, providing a financial incentive to work more hours). If pharmacists change their hours worked by +/- 10 percent relative to the baseline assumptions, the number of FTE pharmacists will shift up/down by 10 percent reflecting some ability of supply to expand or contract (in the short term) to meet demand (*Exhibit 19*).

Exhibit 18. Sensitivity of FTE Supply to Retirement Patterns



Source: Projections from the PhSRM.

Exhibit 19. Sensitivity of FTE Supply to Shifts in Average Hours Worked



Source: Projections from the PhSRM.

Exhibit 20. Active Supply Projections (Baseline Scenario)

Year	US Pharm.D	US B.Pharm	Foreign Graduate	Total*	% Female	Pharmacists per 100,000 population
2004	49,400	168,000	9,100	226,400	45%	77.3
2005	57,800	162,900	9,400	230,100	46%	77.9
2006	67,000	156,300	9,700	233,100	48%	78.2
2007	76,800	150,100	10,100	237,000	50%	78.8
2008	86,900	144,200	10,400	241,500	51%	79.5
2009	97,000	138,400	10,700	246,200	52%	80.4
2010	107,200	132,900	11,100	251,100	54%	81.3
2011	117,200	127,400	11,400	256,000	55%	82.2
2012	127,300	122,000	11,800	261,100	56%	83.1
2013	137,400	116,700	12,100	266,200	57%	84.0
2014	147,400	111,500	12,400	271,400	58%	84.9
2015	157,400	106,400	12,800	276,700	59%	85.8
2016	167,500	101,500	13,100	282,100	60%	86.8
2017	177,600	96,700	13,400	287,700	60%	87.8
2018	187,700	91,900	13,800	293,300	61%	88.8
2019	197,900	87,200	14,100	299,200	61%	89.8
2020	208,100	82,500	14,500	305,000	62%	90.8
2021	218,300	77,900	14,800	311,000	62%	91.9
2022	228,600	73,300	15,100	317,000	63%	92.9
2023	238,900	68,700	15,500	323,100	63%	93.9
2024	249,200	64,200	15,800	329,200	64%	95.0
2025	259,500	59,800	16,100	335,500	64%	96.0
2026	269,800	55,500	16,500	341,900	64%	97.1
2027	280,100	51,400	16,800	348,300	65%	98.1
2028	290,300	47,200	17,100	354,700	65%	99.1
2029	300,500	43,300	17,500	361,300	65%	100.2
2030	310,700	39,300	17,800	367,800	65%	101.2

* Columns might not sum to total because of rounding.

Exhibit 21. FTE Supply Projections

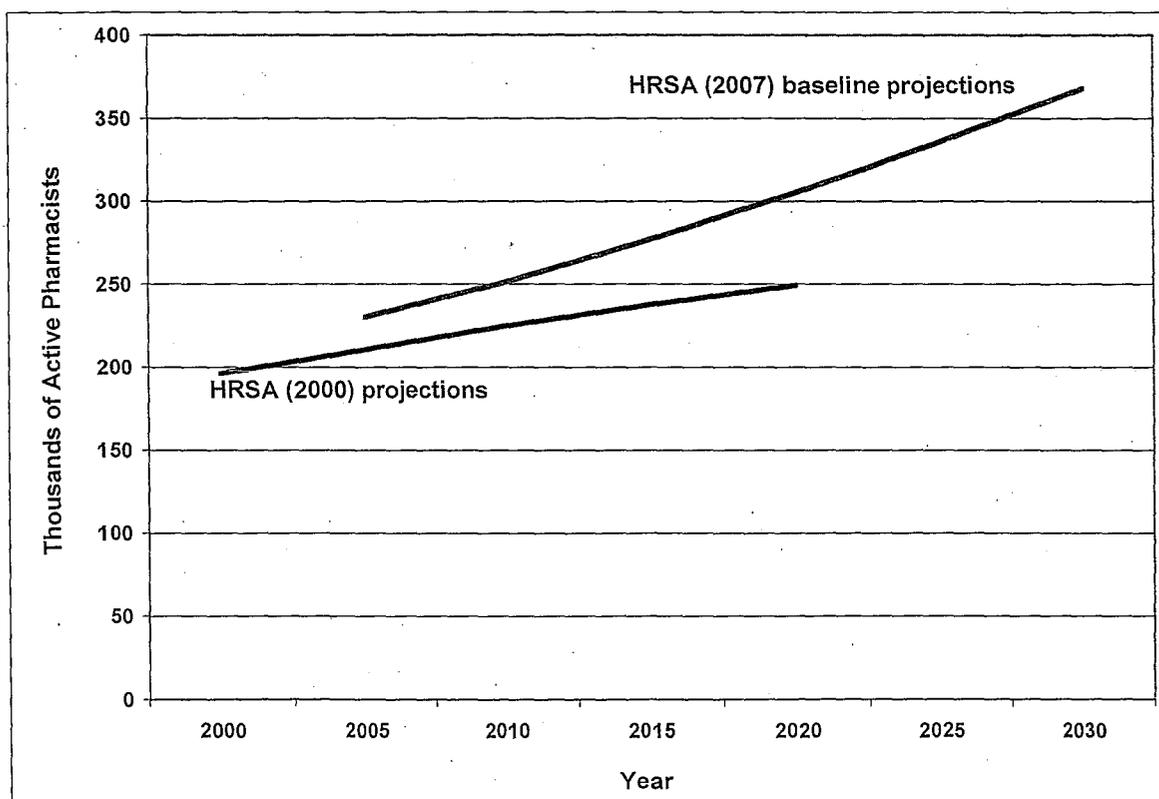
Year	Baseline Scenario		Alternate Supply Scenarios						
	Total FTE	Pharmacists per 100,000 population	No growth in educational capacity post 2008	10% More Graduates than in Baseline	20% More Graduates than in Baseline	Retire 2 years earlier than baseline	Retire 2 years later than baseline	10% increase in hours worked	10% decrease in hours worked
2004	191,200	65.3	191,200	191,200	191,200	191,200	191,200	210,300	172,100
2005	193,900	65.8	193,900	193,900	193,900	192,500	194,400	213,300	174,500
2006	196,900	66.4	196,900	196,900	196,900	194,900	198,100	216,600	177,200
2007	201,200	67.4	201,200	201,200	201,200	198,400	202,700	221,300	181,100
2008	205,600	68.4	205,600	205,600	205,600	202,400	207,700	226,200	185,000
2009	210,100	69.4	210,000	211,100	212,100	206,200	212,500	231,100	189,100
2010	214,400	70.3	214,100	216,500	218,500	210,100	217,300	235,800	193,000
2011	218,600	71.2	218,000	221,700	224,900	213,700	221,800	240,500	196,700
2012	222,900	72.0	221,900	227,100	231,300	217,700	226,400	245,200	200,600
2013	227,200	72.9	225,700	232,400	237,600	221,600	231,000	249,900	204,500
2014	231,500	73.7	229,400	237,700	243,900	225,700	235,700	254,700	208,400
2015	235,700	74.5	233,000	242,900	250,000	229,700	240,200	259,300	212,100
2016	240,300	75.4	236,700	248,400	256,600	233,900	245,000	264,300	216,300
2017	244,900	76.2	240,500	254,000	263,100	238,400	249,700	269,400	220,400
2018	249,800	77.1	244,500	259,900	270,000	243,200	254,700	274,800	224,800
2019	254,800	78.0	248,400	265,900	277,000	247,900	259,700	280,300	229,300
2020	259,900	78.9	252,400	272,000	284,100	253,000	264,900	285,900	233,900
2021	265,400	79.8	256,700	278,500	291,600	258,500	270,200	291,900	238,900
2022	271,200	80.9	261,200	285,300	299,500	264,100	275,900	298,300	244,100
2023	277,100	81.9	265,700	292,300	307,400	270,000	281,800	304,800	249,400
2024	282,800	83.0	270,000	299,100	315,300	275,800	287,600	311,100	254,500
2025	288,500	83.9	274,100	305,800	323,100	281,400	293,300	317,400	259,700
2026	294,400	84.9	278,400	312,800	331,200	287,000	299,000	323,800	265,000
2027	300,400	85.9	282,600	319,900	339,400	292,900	305,000	330,400	270,400
2028	306,400	86.9	286,700	327,000	347,500	298,800	310,900	337,000	275,800
2029	312,500	88.0	291,000	334,200	355,800	304,900	317,400	343,800	281,300
2030	318,800	89.0	295,200	341,500	364,200	310,900	323,500	350,700	286,900

4. Comparison to Previous Supply Projections

The baseline supply projections suggest that pharmacist supply will grow faster than previously predicted, with these latest projections for 2020 suggesting pharmacist supply will be 50,000 higher than projected for the HRSA (2000) report (*Exhibit 22*). This finding is not unexpected given the attention pharmacy has received since release of the 2000 report. The new projections reflect the growing interest in pharmacy as a career choice, the rise in pharmacist average annual earnings, and the Nation's renewed interest in expanding pharmacy training capacity in response to the current shortfall and earlier projections of a growing shortfall, and updated pharmacist retirement patterns.¹⁹

In the late 1990s, the Nation was graduating approximately 8,000 new pharmacists per year and the HRSA (2000) projections assumed that the annual number of new graduates would continue increasing to approximately 8,500 by 2020. In reaction to the predicted growing pharmacist shortage, enrollment in pharmacy programs rose such that the Nation will soon be graduating close to 10,000 new pharmacists per year, with plans for expansion of pharmacy schools expected to gradually increase the number of entry-level degree graduates to about 12,000 per year.

Exhibit 22. Comparison of Active Pharmacist Supply Projections



Sources: Projections from the PhSRM and HRSA (2000).

¹⁹ Katherine K. Knapp and James M. Cultice (2007). New pharmacist supply projections: Lower separation rates and increased graduates boost supply estimates. *Journal of the American Pharmacists Association*, 47(4):463-470.

III. PHARMACIST REQUIREMENTS

The term “requirements” is a broad definition of the number of pharmacists necessary to provide an adequate supply, and health workforce researchers have used various approaches to estimate future requirement. Needs-based requirements estimates are based on what someone thinks is needed or is ideal—e.g., based on epidemiological considerations and desired pharmacist work patterns. Demand-based requirements estimates are based on future projections of the number of prescriptions that consumers will want filled and the anticipated role of pharmacists to meet this demand for pharmaceuticals. For this study a demand-based definition and approach was used to estimate requirements.

National requirements for pharmacists continue to rise to meet the demands of a population that is growing and aging, increased per capita utilization of pharmacy services that accompanies technological advances in number and complexity of new pharmaceuticals, increased need for education and monitoring as patients consume more pharmaceuticals, and expanded pharmacy benefits afforded by Medicare Part D and other programs. This growth in demand is tempered somewhat by advances in dispensing technology and improved communication systems that increase pharmacist productivity, as well as increased use of pharmacy technicians. This section summarizes current demand for pharmacists and trends in demand determinants, and presents projections of pharmacist requirements under alternate scenarios.

A. Current Demand

Demand for pharmacists is derived from the demand for pharmaceuticals and the role of pharmacists in providing the dispensing, counseling, monitoring, and other services that patients require. Demand-based health workforce studies typically use recent, historical health care utilization and delivery patterns to estimate demand for services. The evidence suggests that the Nation currently has a moderate shortfall of pharmacists, and the implications of this shortfall are reflected in determining base year (2004) pharmacist requirements. These implications include that pharmacists might be working longer hours or spending less time per patient than is socially desirable, or that pharmacies have had to reduce services because of unfilled pharmacy positions.

Because rates of growth over time in demand for pharmacy services and changes in pharmacist productivity can vary across settings that employ pharmacists, the PhSRM models demand for pharmacists in six settings: hospitals, other patient care (e.g., clinics, nursing homes), chain pharmacies and food stores, independent pharmacies, mail order, and non-patient care.

In 2004, there were an estimated 191,200 FTE pharmacist positions filled and an estimated 10,400 unfilled positions (*Exhibit 23*). Estimates of the number of FTE positions filled in each dispensing setting were calculated by multiplying total FTE pharmacist supply by each setting’s proportion of FTE pharmacists (with the setting distribution determined by analysis of the 2004 NPWS).

There were an estimated 10,400 unfilled FTE positions in 2004, or a vacancy rate of approximately 5 percent. A 2004 study by the American Society of Health-System Pharmacists

(ASHP) reports that 5 percent of hospitals' budgeted pharmacist positions were vacant.²⁰ While the number of vacancies continued to decline from a recent high of 8.9 percent in 2000, a 5 percent vacancy rate suggests that approximately 2,500 budgeted positions in hospitals were unfilled. ASHP's 2005 and 2006 surveys find that vacancy rates rose to 6.2 percent in 2005 and 7 percent in 2006. A July 2004 survey by the National Association of Chain Drug Stores (NACDS) Foundation found that chain store pharmacies reported approximately 4,000 vacancies.²¹ Vacancy estimates are unavailable for "other patient care" settings (e.g., clinics), independent pharmacies, mail-order pharmacies, and non-patient care. It is assumed that the vacancy rate for other patient care settings is similar to that of hospitals; that the vacancy rate for independent pharmacies is similar to that of chain pharmacies, and that the vacancy rates for mail order and non-patient care are similar to the overall vacancy rate of 5 percent from the NACDS and ASHP combined results.

Exhibit 23. Estimated FTE Demand for Pharmacists: 2004

Setting	FTEs Positions, 2004		
	Filled ^a	Unfilled	Total Demand
Hospitals	46,700	2,500 ^b	49,200
Other Patient Care	16,800	900 ^c	17,700
Chain Pharmacies	73,300	4,000 ^d	77,300
Independent Pharmacies	34,300	1,900 ^e	36,200
Mail Order	5,500	300 ^f	5,800
Non-patient care	14,600	800 ^f	15,400
Total	191,200	10,400	201,600

Sources: (a) Analysis of 2004 NPWS and 2004 Bureau of Labor Statistics Occupational Employment Statistics. (b) American Society of Health-System Pharmacists (ASHP) 2004 Survey. (c) Assumes same vacancy rate as for hospitals. (d) National Association of Chain Drug Stores (NACDS) Foundation July 2004 Chain Pharmacy Employment Survey. (e) Assumes same vacancy rate as for chain pharmacies. (f) Assumes 5 percent vacancy rate based on average of ASHP and NACDS surveys.

B. Trends in Demand for Pharmaceuticals

Future requirements for pharmacists are dependent, in part, on the future demand for pharmaceuticals. Major trends in demand for pharmaceuticals include population growth and aging, changes in per capita utilization of pharmaceuticals due to technological advances and other factors, and the impact of Medicare's new prescription drug program.

1. Population Growth and Aging

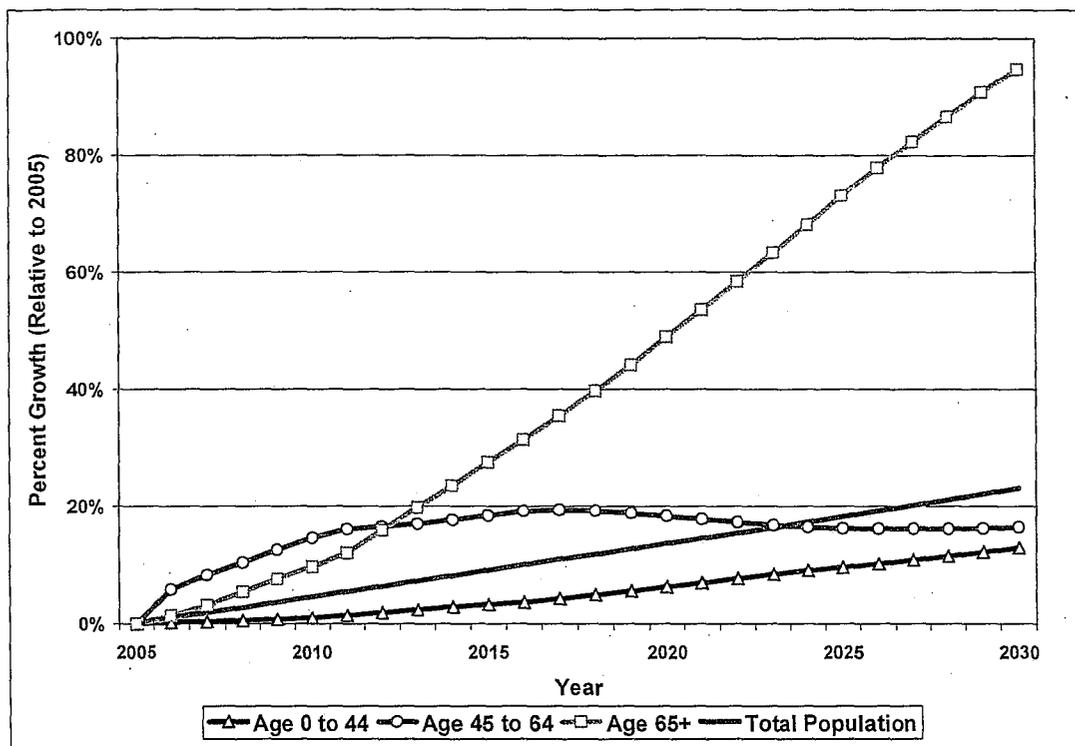
The U.S. population is growing and aging. Between 2005 and 2030, the population will grow by an estimated 68 million (23 percent). In percentage terms, the population age 65 and older is

²⁰ Annual Pharmacy Staffing Survey Results for 2004, 2005 and 2006. <http://www.ashp.org>. Accessed March 2007.

²¹ NACDS Foundation July 2004 Chain Pharmacy Employment Survey Results. <http://www.nacds.org>. Accessed March 2007.

growing significantly faster than the non-elderly population and will nearly double over the next 25 years (*Exhibit 24*).

Exhibit 24. Percent Growth in the U.S. Population: 2005 to 2030



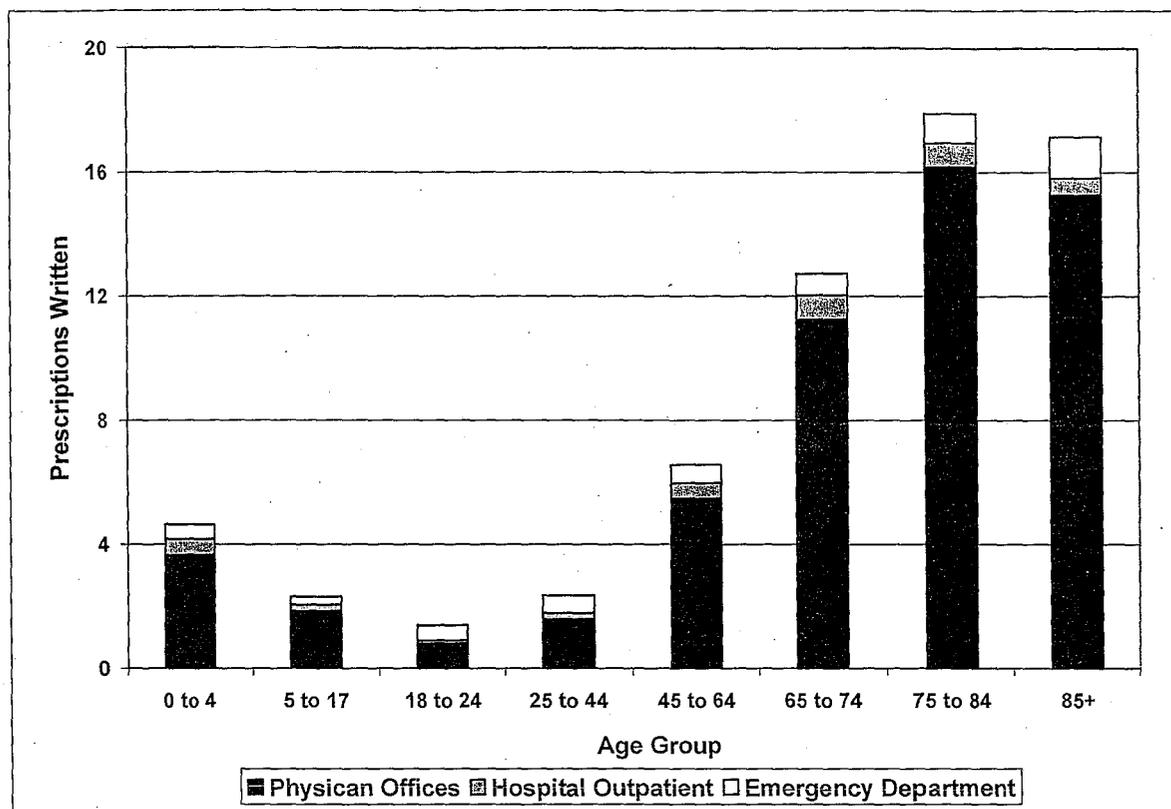
Source: U.S. Census Bureau population projections.

The elderly consume a disproportionate share of pharmacy services because of their much higher use of prescription medications and greater risk of complications and drug interactions (*Exhibits 25 and 26*). Analysis of the 2004 National Ambulatory Care Survey (NAMCS) and the 2004 National Hospital Ambulatory Care Survey (NHAMCS) provides estimates of the average, annual number of patient visits with a physician in ambulatory settings (i.e., physician office visits, and hospital outpatient and emergency visits), and the average number of prescriptions written per visit. Dividing total, annual prescriptions written for people in each age and gender group by the number of people in that population group produces estimates of average annual prescriptions per capita (excluding refills), although some prescriptions written go unfilled.

The population with the highest average, annual prescriptions per capita written in ambulatory settings is men age 75 to 84 (with 18.8 prescriptions), while the population with the lowest is men age 18 to 24 (with 1.4 prescriptions). The population under age 65, which is projected to grow by less than 20 percent between 2005 and 2030, averages 4.3 new prescriptions per person per year. The population age 65 and older, which is projected to grow by close to 90 percent between 2005 and 2030, averages 15.2 new prescriptions per person per year. Changing demographics alone is projected to increase the number of new prescriptions generated through physician office and hospital visits by approximately 44 percent between 2005 and 2030.

About half of all prescriptions filled in retail settings are refills.²² Comparison of prescriptions written during outpatient visits (and primarily filled in a retail pharmacy) with total prescriptions dispensed in a retail setting (using IMS Health data) suggests that new prescriptions written equal approximately 54 percent of total prescriptions filled in retail settings.

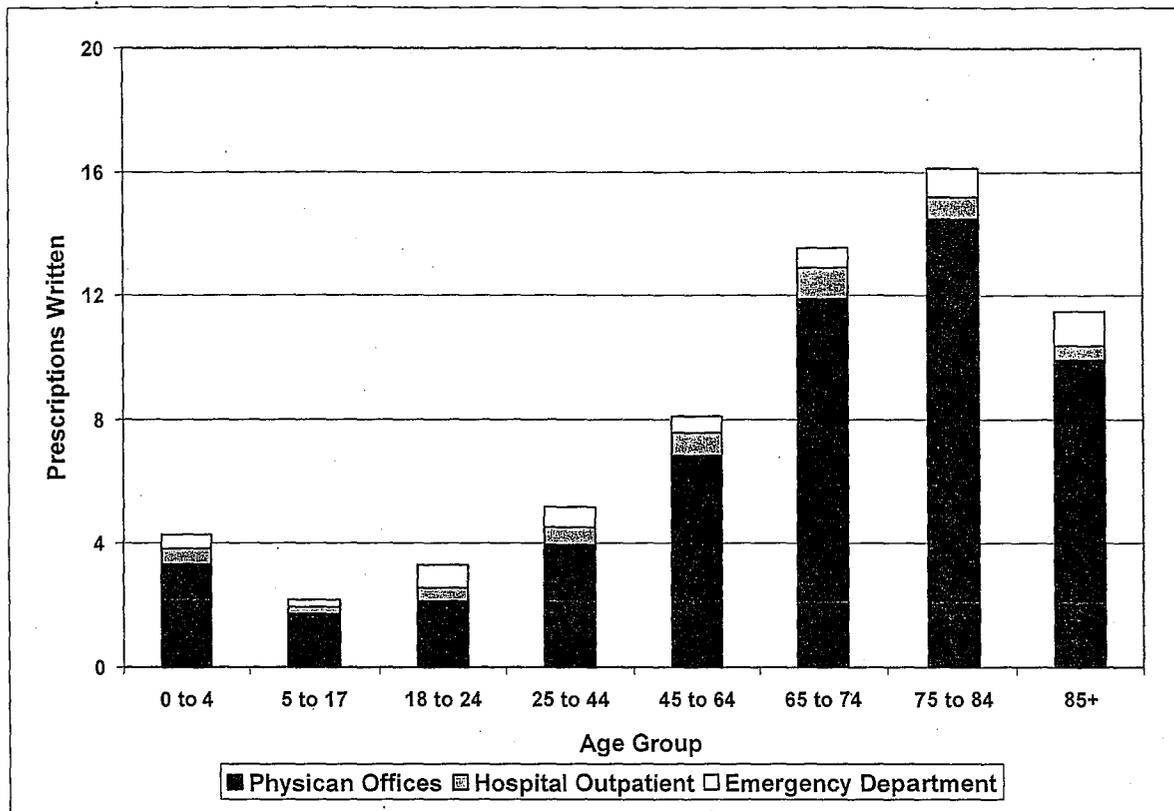
Exhibit 25. Annual Per Capita Prescriptions Written During Ambulatory Visits: Males



Source: Analysis of the 2004 National Ambulatory Care Survey and 2004 National Hospital Ambulatory Care Survey.

²² Knapp, DA. Professionally Determined Need for Pharmacy Services in 2002. *American Journal of Pharmaceutical Education*. Vol 66 (Winter 2002): 421-429.

Exhibit 26. Annual Per Capita Prescriptions Written During Ambulatory Visits: Females



Source: Analysis of the 2004 National Ambulatory Care Survey and 2004 National Hospital Ambulatory Care Survey.

2. Trends in per Capita Use of Pharmaceuticals

Accounting for demographic changes alone would likely under predict future demand for pharmaceuticals. From 1994 to 2005, the number of prescriptions dispensed increased 71 percent (from 2.1 billion to 3.6 billion), compared to population growth of 9 percent.²³ The average number of retail prescriptions per capita increased from 7.9 to 12.3 during this period. This trend of rising per capita use of pharmaceuticals will likely continue for the following reasons:

- New and More Complex Pharmaceuticals.** Scientific advancements continue to provide health professionals with the means to treat a growing range of health problems that previously were not treated with drugs. This includes new drugs to treat rare diseases, as well as new medications such as cholesterol lowering drugs to provide preventive care. Medco reports that utilization of specialty drugs—used to treat complex diseases such as rheumatoid arthritis, hemophilia, cancer, hepatitis C, anemia, cystic fibrosis, and growth hormone deficiency—grew by 19 percent in 2003, 16 percent in

²³ Prescription Drug Trends, June 2006. Henry J. Kaiser Family Foundation, publication #3057-05 at www.kff.org, accessed March 2007.

2004, and 10 percent in 2005.²⁴ Medco also reports that the world's top 50 pharmaceutical companies are currently awaiting Food and Drug Administration (FDA) approval for about 125 new and supplemental drug applications, with an estimated 100 new drugs in the pipeline that could win FDA approval by 2008. In addition, new uses are sometimes found for existing drugs.

- **Evolving societal attitudes.** Societal attitudes towards the use of pharmaceuticals have kept pace with scientific advances. Defensive medicine, direct-to-consumer advertising by drug companies, and a general acceptance to treat every ache and pain has contributed to a culture to use whatever drugs are available to alleviate health problems. Prescription drug coverage has expanded over time, and this trend will likely continue.
- **Increased affordability and availability of generic drugs.** The drop in drug prices that accompany the increase in availability of generic drugs makes many drugs more affordable, increasing both the likelihood that physicians will prescribe a medication and that patients will fill their prescription.

Counter to these trends is that some drugs previously sold only by prescription are now available over the counter. Also, as prescription drugs consume a larger proportion of health care expenditures this segment of care is coming under increasing scrutiny by insurers and employers trying to contain rising health care costs.

A Medco (2006) Drug Trend Report shows that as a trend driver of retail pharmaceutical sales, annual increases in prescriptions dispensed have been trending down in recent years. Prescriptions dispensed increased 4.6 percent 2002, 3.8 percent in 2003; 5.4 percent in 2004, and 2.7 percent in 2005 (*Exhibit 27*). Express Script (2004 and 2006) Drug Trend Reports show similar findings—a downward trend in the annual increase in volume of prescriptions dispensed.²⁵ Although the annual increases in prescriptions dispensed are shrinking, these annual increases are larger than can be explained by changing demographics alone.

Analysis of the average number of prescriptions written per visit to a physician show that prescriptions written per visit have been increasing over time for office visits (*Exhibit 28*), hospital/clinic outpatient visits (*Exhibit 29*), and emergency visits (*Exhibit 30*).²⁶ For example, for people age 65 and older the average number of prescriptions written per physician office visit grew from 1.3 to 1.7 (27 percent) between 1995 and 2004.

Projected pharmacist requirements are sensitive to assumptions of future prescriptions dispensed per capita. Demand is modeled under three scenarios: 1) a low prescription per capita growth scenario assumes that prescriptions written per physician visit remains at their 2004 levels, so increases in per capita consumption of pharmaceuticals is driven purely by changing demographics; 2) a high prescription per capita growth scenario where prescriptions written per physician visit increase annually at the historical (1995 to 2004) rate of increase for each age group modeled and for each

²⁴ Medco Drug Trend Report, 2006 (volume 8). Posted at www.drugtrend.com, accessed March 2007.

²⁵ Posted at <http://www.express-scripts.com/ourcompany/news/industryreports/>, accessed March 2007.

²⁶ These findings are based on a poisson regression analysis. The NAMCS analysis used data from 1995 to 2004, with prescriptions per office visit as the dependent variable and age group, gender, having medical insurance, and year as the explanatory variables. An analysis of prescriptions per hospital/clinic outpatient and per emergency visit uses a similar approach with data from the 1995 to 2004 NHAMCS.

outpatient setting modeled; and 3) a moderate-growth scenario which assumes that prescriptions written per physician visit increase annually at half the historical rate of increase. In support of this third scenario, Medco and Express Scripts data show that the rate of growth in prescriptions dispensed in retail settings has diminished in recent years. Also, anecdotal evidence suggests that insurers have begun to more aggressively manage pharmaceuticals in order to control rapidly rising health care costs.

Exhibits 28 through 30 show the range in projected prescriptions written per visit. The trends in prescriptions dispensed assume a one-time 6 percent permanent increase in prescriptions per visit starting in 2006 to account for the impact of Medicare Part D (discussed in more detail later).

Exhibit 27.

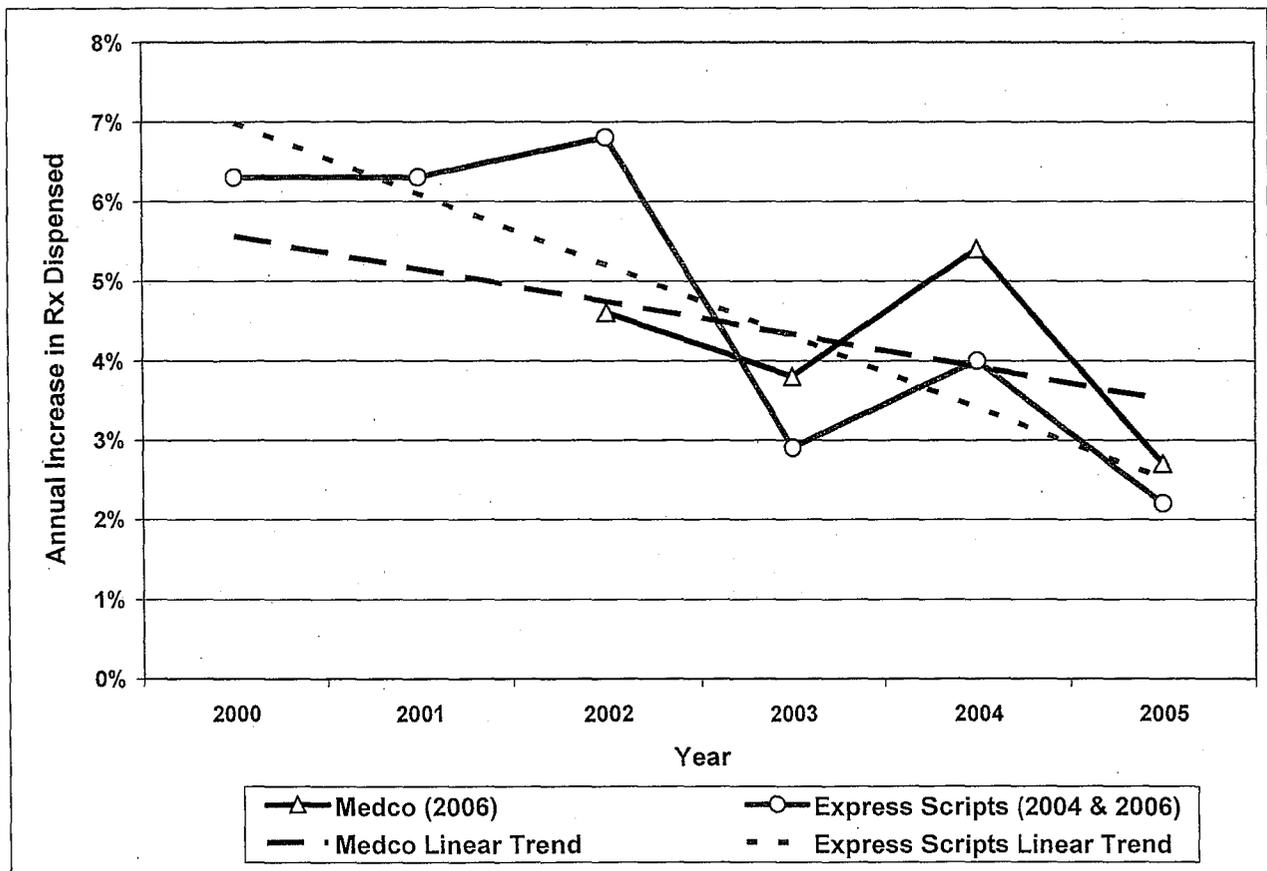
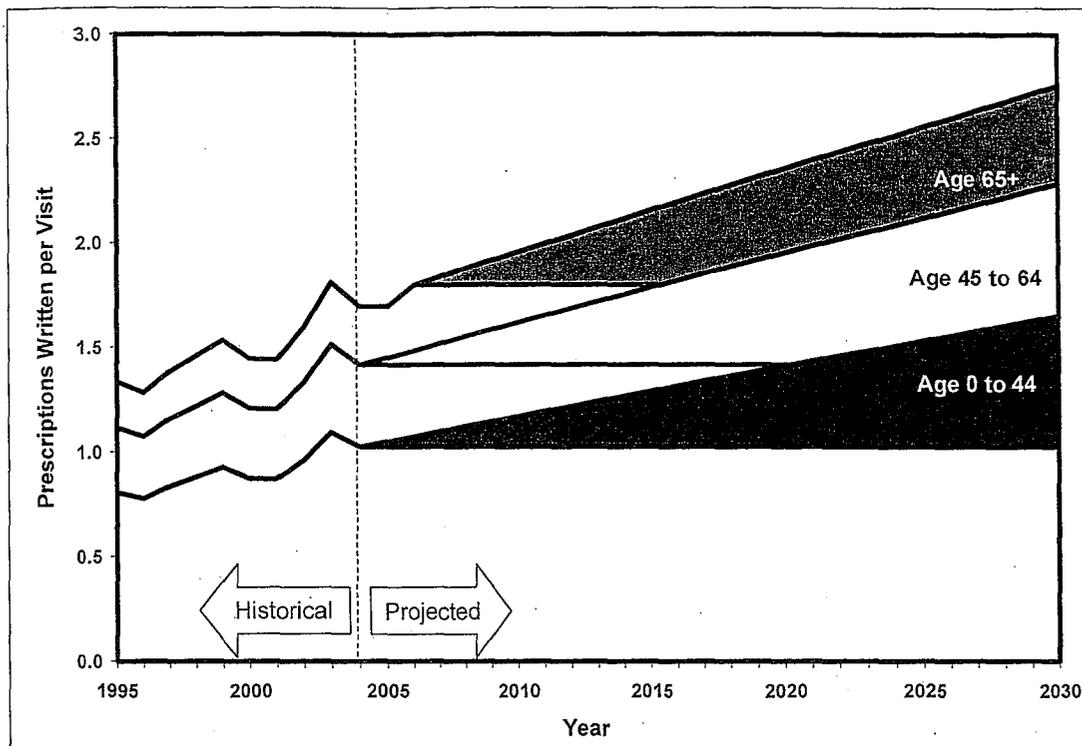
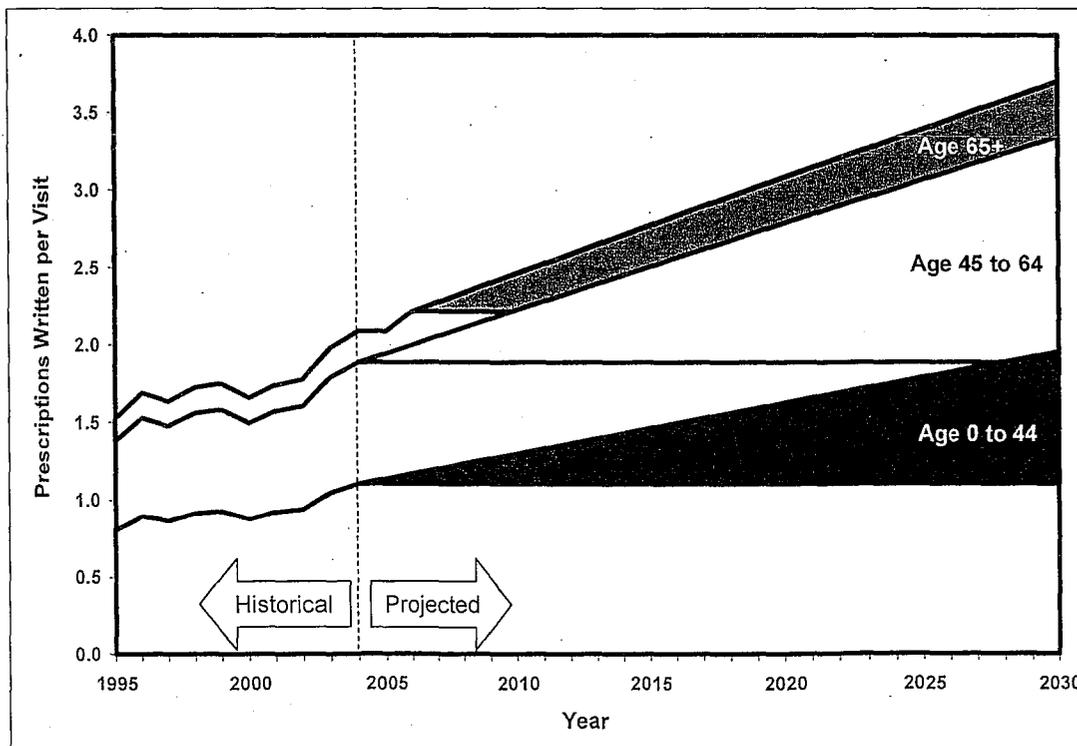


Exhibit 28. Prescriptions Written per Physician Office Visit



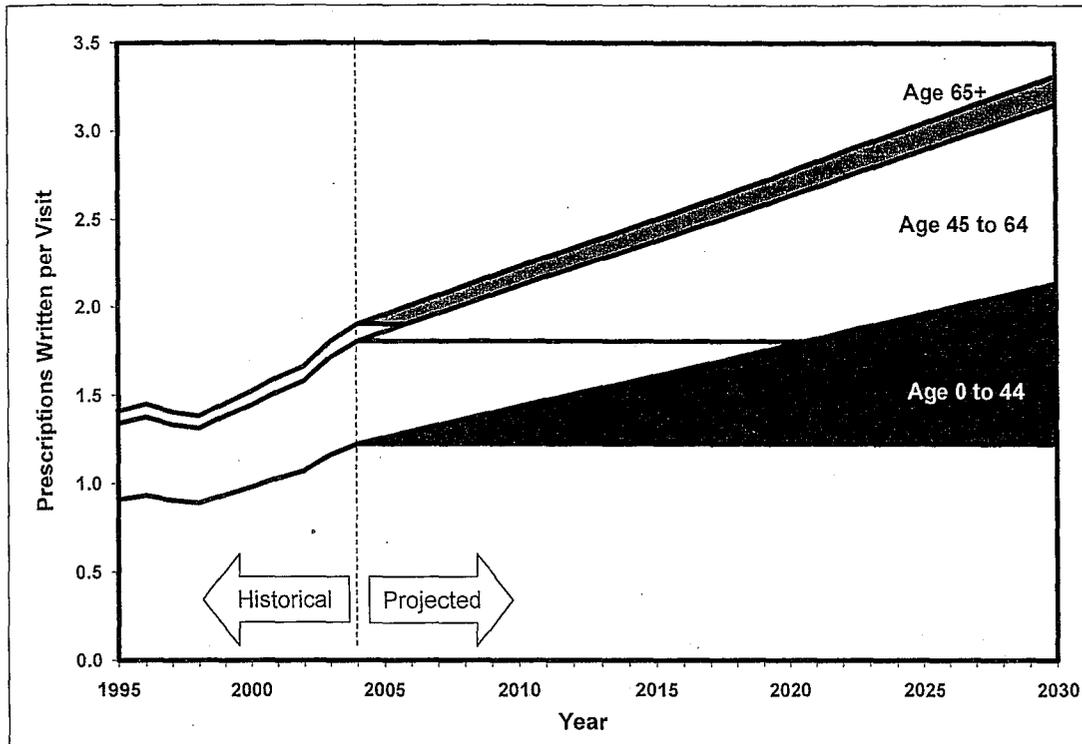
Source: Analysis of the NAMCS 1995 to 2004; trend extrapolated 2005 to 2030.

Exhibit 29. Prescriptions Written per Hospital/Clinic Outpatient Visit



Source: Analysis of the NHAMCS 1995 to 2004; trend extrapolated 2005 to 2030.

Exhibit 30. Prescriptions Written per Emergency Visit



Source: Analysis of the NHAMCS 1995 to 2004; trend extrapolated 2005 to 2030.

3. Medicare Part D

Medicare Part D, the Medicare prescription drug benefit, was implemented in January 2006, with an initial enrollment period through May 2006. According to HHS figures, as of June 2006 a total of 22.5 million people were enrolled in some type of Part D plan.²⁷ Another 15.8 million Medicare beneficiaries were reported to have creditable coverage from other sources. An estimated 4 to 5 million people, or about 10 percent of Medicare beneficiaries, have chosen not to enroll, and do not appear to have creditable prescription drug coverage.

Of the roughly 38 million Medicare beneficiaries who now have coverage through either Part D or some other creditable source, most had drug coverage in 2005, either through Medicaid, Medicare Advantage plans, or employer plans. Those most likely to have been uncovered are those who enrolled in a stand-alone Part D plan (10.4 million) or who are newly enrolled in a Medicare Advantage prescription drug plan (1.2 million). While the exact number who previously had no drug coverage is unknown, it is likely that some if not most of these 11.6 million people had no coverage prior to enrolling in a Part D plan. Numerous studies and surveys have shown that prescription drug use is higher for those with health insurance than for the uninsured.

To forecast the impact of Medicare Part D on prescription drug utilization, analysts at the Centers for Medicare and Medicaid Services (CMS) were consulted. CMS predicted that total

²⁷ Medicare Prescription Drug Coverage Enrollment Update, June 2006. Henry J. Kaiser Family Foundation, publication No. 7453, posted at www.kff.org, accessed March 2007.

retail prescription drug spending would increase by 7.7 percent between 2005 and 2006.²⁸ This estimate included the impact of Part D implementation. Without Part D, CMS analysts predicted that there would have been an 8.1 percent growth in spending. While Medicare will fund a larger share of drug expenditures under part D, the overall rate of spending growth would be reduced due to price discounts and rebates under the program on the order of 27 percent, which would more than offset the increase in utilization.

While the focus of the CMS models and analyses was on predicting changes in drug spending, not utilization, CMS analysts provided a breakdown of the components underlying the projected increases (*Exhibit 31*).²⁹

Exhibit 31. Estimated Impact of Medicare Part D

	Population Changes	Increase in Drug Prices	Residual	Total Nominal Spending Increase
With Part D	0.9%	1.5%	5.2%	7.7%
Without Part D	0.9%	3.8%	3.2%	8.1%

After accounting for population changes and increases in drug prices, the residual is an approximation of the assumed increase in prescription drug utilization. Comparing the 5.2 percent residual growth in spending with Part D to the 3.2 percent residual without Part D suggests a 2 percent increase in overall retail drug utilization attributed to Part D.

Given that the majority of Medicare beneficiaries are age 65 and older and that the elderly consume approximately 35 percent of retail prescription drugs³⁰, an increase in retail prescriptions of 6 percent for the over 65 population was found to be consistent with the 2 percent overall increase.³¹ IMS Health reports that during January 2006, prescription volume for the age 65+ population was up 4 to 5 percent over the same period last year.³² For modeling, a permanent upward shift of 6 percent in prescriptions per physician office and per hospital outpatient visit for the age 65 and older population starting in 2006 was assumed.³³

C. Trends in Dispensing Setting, Practices, and Efficiency

The efficiency with which prescriptions are dispensed and the amount of time pharmacists spend per patient determines the number of pharmacists required given the demand for pharmaceuticals. Efficiency and time spent per patient varies by dispensing setting and practice, and the proportion of total prescriptions dispensed by setting will likely change over time.

²⁸ C. Borger et al, Health Spending Projections Through 2015: Changes on the Horizon. *Health Affairs* 25 (2006): w61-w73 (published online 22 February 2006; 10.1377/hlthaff.25.w61).

²⁹ Personal communication with John Poisal, Deputy Director, National Health Statistics Group, Office of the Actuary, Centers for Medicare and Medicaid Services, April 2006.

³⁰ Analysis of MEPS 2004 data.

³¹ 35 percent * r = 2 percent, which equates to r = 6 percent

³² IMS Health press release dated February 22, 2006.

³³ The estimated 6 percent increase in utilization comes primarily from the 10.4 million beneficiaries who enrolled in a stand-alone plan, as these people were less likely to have other coverage prior to part D. These stand-alone enrollees are about a quarter of the over 65 population, so a 6 percent overall increase would correspond to a 25 percent increase in utilization for the stand-alone enrollees.

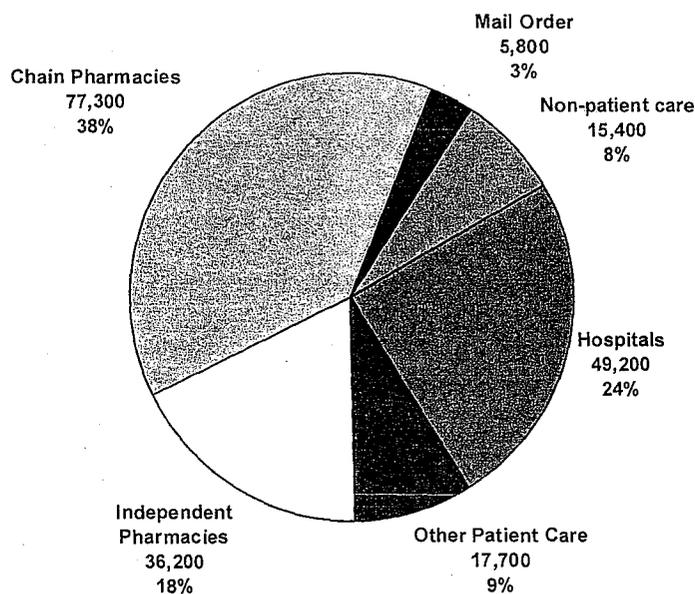
Consequently, in addition to modeling demand for pharmacists in non-patient care settings, demand for pharmacists in five dispensing settings: hospitals, independent pharmacies, chain drug stores (which is grouped with supermarkets and mass merchandisers), mail order, and other patient care (clinic pharmacies, home health, and nursing homes) were also modeled.

This section describes current practice patterns and trends in dispensing setting. Issues detailing with the role of pharmacists are discussed in a subsequent section.

1. Trends in Dispensing Location

Of the estimated 201,600 budgeted FTE pharmacist positions in 2004, the settings with the largest number of positions are chain pharmacies (77,300), hospitals (49,200), and independent pharmacies (36,200) (*Exhibit 32*).

Exhibit 32. FTE Pharmacist Demand by Dispensing Location: 2004



While demand for pharmaceuticals is projected to grow in each setting, this growth likely will be uneven for the following reasons:

- **Increase in pharmaceuticals for chronic conditions.** The elderly have higher prevalence of chronic conditions that require the continued use of pharmaceuticals. Mail order pharmacies will likely gain slightly in market share as a result of the increasing demand for medications to treat chronic conditions.
- **Efficiencies and cost competitiveness.** Hospitals and mail order pharmacies, as compared to retail pharmacies, are better able to take advantage of new technology that reduces the cost of filling prescriptions. The efficiency of mail order pharmacies allows them to fill prescriptions at lower cost than retail pharmacies. Insurers often require or set lower copays for prescriptions filled by mail order to help direct patients to use mail order when possible.

- **Market forces.** Mergers and acquisitions could result in some reallocation of market share between chain and independent pharmacies. Discount drug prices by stores such as Walmart could increase the proportion of prescriptions dispensed by mass merchandizers.

An analysis of IMS Health National Prescription Audit™ Plus data on retail (non-hospital) total dispensed prescriptions finds that each year between 2001 and 2005 market share (*Exhibit 33*):

- declined approximately 0.3 percentage points for chain pharmacies and food stores,
- declined approximately 0.4 percentage points for independent pharmacies,
- increased approximately 0.3 percentage points for nursing homes, and
- increased approximately 0.4 percentage points for mail order pharmacies.

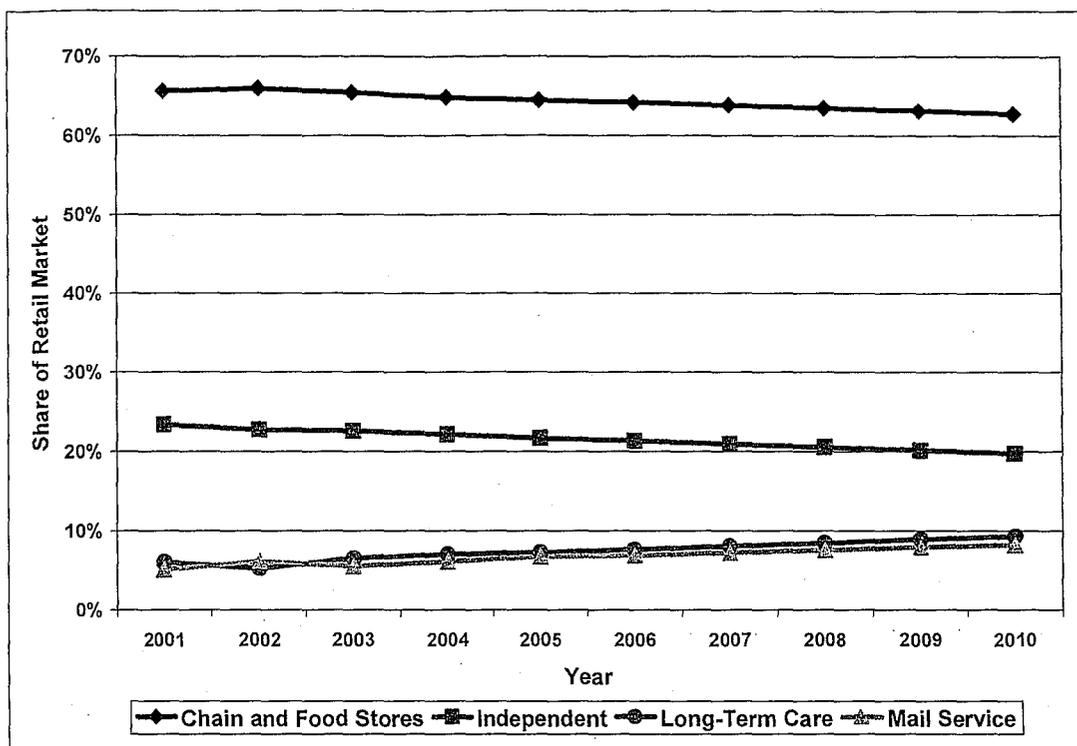
A linear trend using 2001 through 2005 data extrapolated to 2010 was modeled; it was assumed that market shares remain at their 2010 levels through 2030.

Importation of prescription products from Canada and other countries, ordered mostly through mail and courier services, accounted for less than 1 percent of total pharmacy sales in the United States in 2003.³⁴ IMS Health reports that cross-border importation of medications from Canadian Internet pharmacies declined by 23 percent between 2004 and 2005 (as measured by total sales volume in U.S. dollars), and that “importation is no longer as significant a market issue as it was two years ago.”³⁵

³⁴ U.S. Department of Health and Human Services Task Force on Drug Importation. *Report on Prescription Drug Importation*. December 2004. Posted at <http://www.hhs.gov/importtaskforce/Report1220.pdf>. Accessed March 2007. Estimates based on IMS Health data.

³⁵ IMS Health press release dated February 22, 2006.

Exhibit 33. Trend in Share of Total Dispensed Retail Prescriptions



Source: IMS Health National Prescription AuditTMPlus data for 2001 to 2005, shown with linear trend through 2010.

2. Role of the Pharmacist and Productivity Trends

Demand for pharmacists is derived largely from the demand for pharmaceuticals. For each prescription generated, pharmacists spend time dispensing the medication and counseling and educating the patient. Pharmacists also have administrative responsibilities, some of which are related to patient volume (e.g., ordering bulk medications). Pharmacists in some settings might be involved in research and other activities not directly related to patient care.

While historically the role of pharmacists has focused on dispensing, pharmacists report a desire to have greater involvement in patient education, counseling, and disease management.^{36, 37} According to the 2004 National Pharmacist Workforce Survey, pharmacists currently spend half their time dispensing medication and one-third in counseling and drug use management—but

³⁶ Knapp, DA. Professionally Determined Need for Pharmacy Services in 2002. *American Journal of Pharmaceutical Education*. Vol 66 (Winter 2002): 421-429.

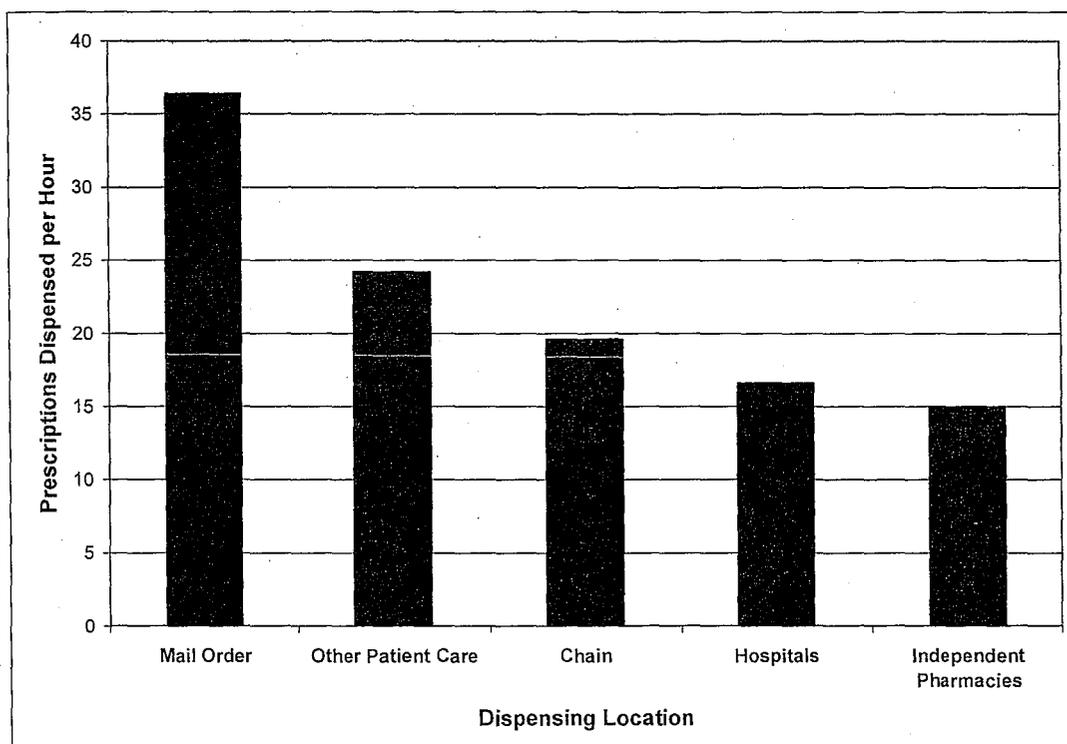
³⁷ Nester TM, Hale LS. Effectiveness of a pharmacist-acquired medication history in promoting patient safety. *American Journal of Health-System Pharmacy*. 2002;59(22):2221-2225. This study found that pharmacists were more likely to identify non-prescription medications and herbal preparations, discrepancies in previously documented allergy information, and inconsistencies and mistakes in patients' self reported medication histories than other health care professionals. The authors recommend pharmacists taking medication histories whenever possible.

they would like these proportions to be reversed.³⁸ Advances in pharmacology contribute to a need for pharmacists to interact more with patients. Drug therapy is becoming more complex, and pharmacists are often more knowledgeable than the prescribing physician regarding the possible drug interactions and side effects associated with new pharmaceuticals.

For a given level of pharmaceuticals demanded, the demand for pharmacists is dependant on the number of prescriptions filled per pharmacist—taking into account the amount of time per prescription spent dispensing, providing counseling/education, and other activities. The greater the average time spent per patient to fill a prescription, the larger the number of pharmacists required to serve a given population.

The use of automation and technology, pharmacy technicians, and other potentially productivity-enhancing activities varies by dispensing setting. In addition, the degree to which pharmacists are engaged in non-dispensing activities (e.g., consultation, management, research, etc.) varies by dispensing setting. Consequently, the average number of prescriptions dispensed per hour per pharmacist varies by dispensing setting with mail order pharmacies reporting the highest rate and independent pharmacists reporting the lowest rate (*Exhibit 34*).

Exhibit 34. Average Prescriptions Dispensed per Hour

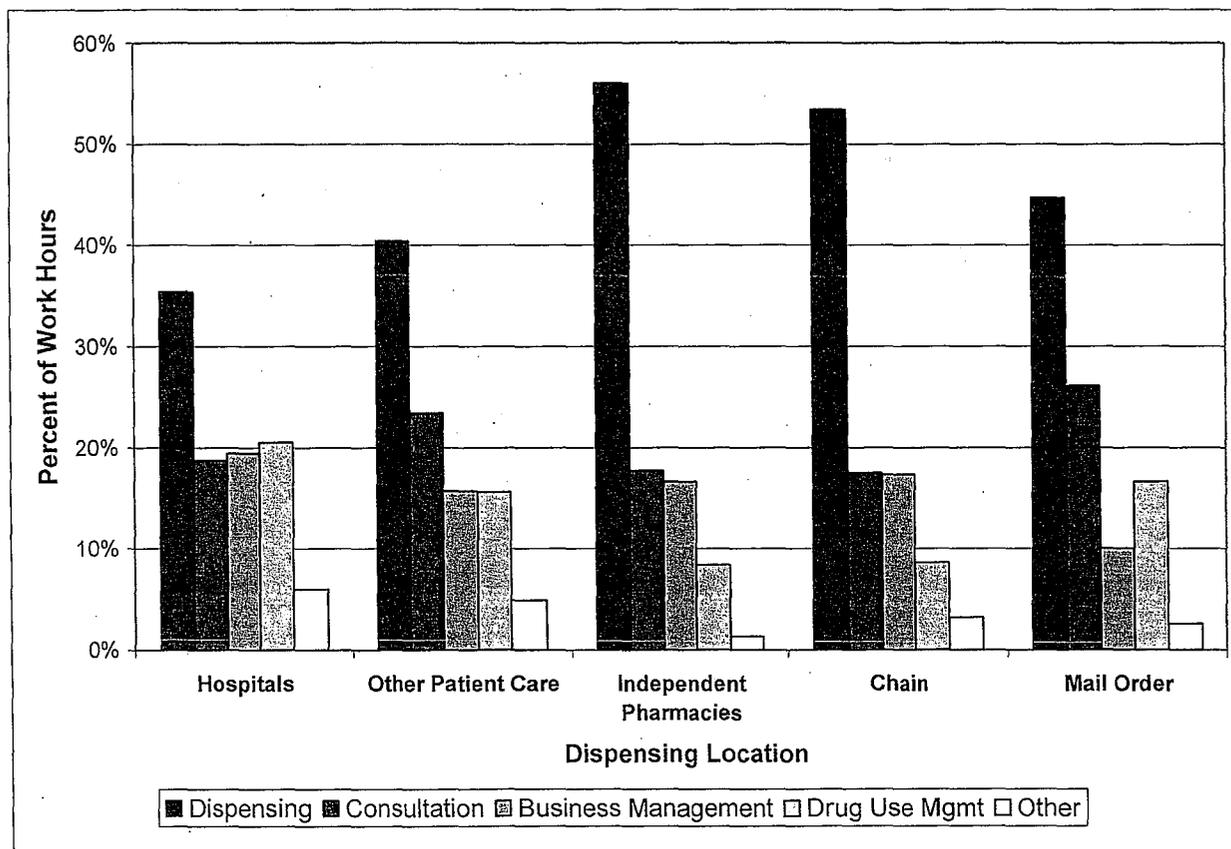


Source: 2004 NPWS analysis.

³⁸ Mott DA, Doucette WR, Gaither CA, et al. *Final Report of the National Sample Survey of the Pharmacist workforce to Determine Contemporary Demographic and Practice Characteristics*. Alexandria, VA: Pharmacy Manpower Project, Inc.; 2005.

Part of the variation in average number of prescriptions dispensed per hour is explained by how pharmacists allocate their time (*Exhibit 35*). Pharmacists in hospitals, for example, spend less time dispensing and more time in drug use management and other activities (e.g., research) compared to pharmacists in other settings. Independent pharmacies report the lowest rate of prescription dispensing per hour, yet have the largest portion of pharmacist time allocated to dispensing activities. This highlights the disparities across settings in ability to use labor-saving technologies, with automation more likely to occur in settings with high prescription volume. Mail order pharmacies, on the other hand, have the highest allocation of time to consultation and yet have the highest average number of prescriptions dispensed per hour.

Exhibit 35. Average Time Allocation Across Activities



Source: 2004 NPWS analysis.

3. Technological Advances

Technologies in use in pharmacies include automated systems for managing work flow, for receiving prescription orders, and for dispensing medications. Workflow management systems often incorporate automated checks for errors or possible drug interactions. Orders can be received using fax machines, interactive voice response systems, or over the Internet. The process of filling prescriptions can be automated to varying degrees, from counter top pill counting devices through robotic systems that count pills, fill bottles, and apply labels.

While the degree to which each type of technology is currently being used varies by setting, the vast majority of pharmacies currently use some type of automated order processing and some type of automated dispensing technology. According to a recent survey of community pharmacies in 18 metropolitan statistical areas of the United States, over 85 percent possessed at least one type of automated prescription processing technology.³⁹ The most common technology was the counter top pill counting device (62 percent). In a 2003 study, all four of the national retail chains surveyed, 85 percent of the regional chains, 73 percent of the independent pharmacies, and 92 percent of the hospitals surveyed had some kind of automated pill-counting system.⁴⁰

Many hospitals and high volume pharmacies employ costlier robotic dispensing systems. In a 2005 national hospital survey, 15 percent of hospitals used a robotic distribution system, with 40 percent of larger hospitals (those with over 400 staffed beds) using robots. The use of robots in hospitals has been steadily increasing, with only 4.5 percent of hospitals using robots in 1999, and 7.8 percent in 2002.⁴¹

Nearly all community pharmacies employ some type of automated telecommunication system for processing orders, with 85 percent using more than one source. Over 85 percent of community pharmacies have fax machines available, and 83 percent offered automated phone systems to process refills. While electronic prescribing has been slow to reach critical mass among health care providers, 65 percent of community pharmacies report Internet availability to process refill orders (Skrepnek, 2006).

Automation has the potential to both increase productivity and reduce errors. A number of before-and-after observational studies have been conducted at retail pharmacies, showing reductions in time spent dispensing medications on the order of 10 to 15 percent. Differences in pharmacist productivity across settings and the corresponding differences in use of technology would also point to productivity gains through technology. However, some studies have shown that automation increases numbers of prescriptions dispensed per pharmacist, but does not increase counseling rates or patient satisfaction.⁴²

Electronic-prescribing (or “e-prescribing”) offers the potential for moderate improvements in pharmacist productivity. A recent study measured the time to process new prescriptions (n=400) and renewed prescriptions (n=400) using four prescription submission methods: e-prescription, walk-in by the patient, phone-in by the health provider, and fax-in by the health provider.⁴³ This study found that the amount of pharmacist time needed to process a new prescription was lower for e-prescribing versus other prescription submission methods, but renewed prescriptions walk-in required less processing time than other forms of submission (*Exhibit 36*). NACDS reports

³⁹ Skrepnek GH, Workload and Availability of Technology in Metropolitan Community Pharmacies, *Journal of the American Pharmacists Association*, 2006; 46(2): 154-160.

⁴⁰ The Thompsen Group Inc., *Market Survey of Pharmacy Technology and Automation in Retail and Outpatient Pharmacy*, published online in *Retail Pharmacy Management* in November/December 2003.

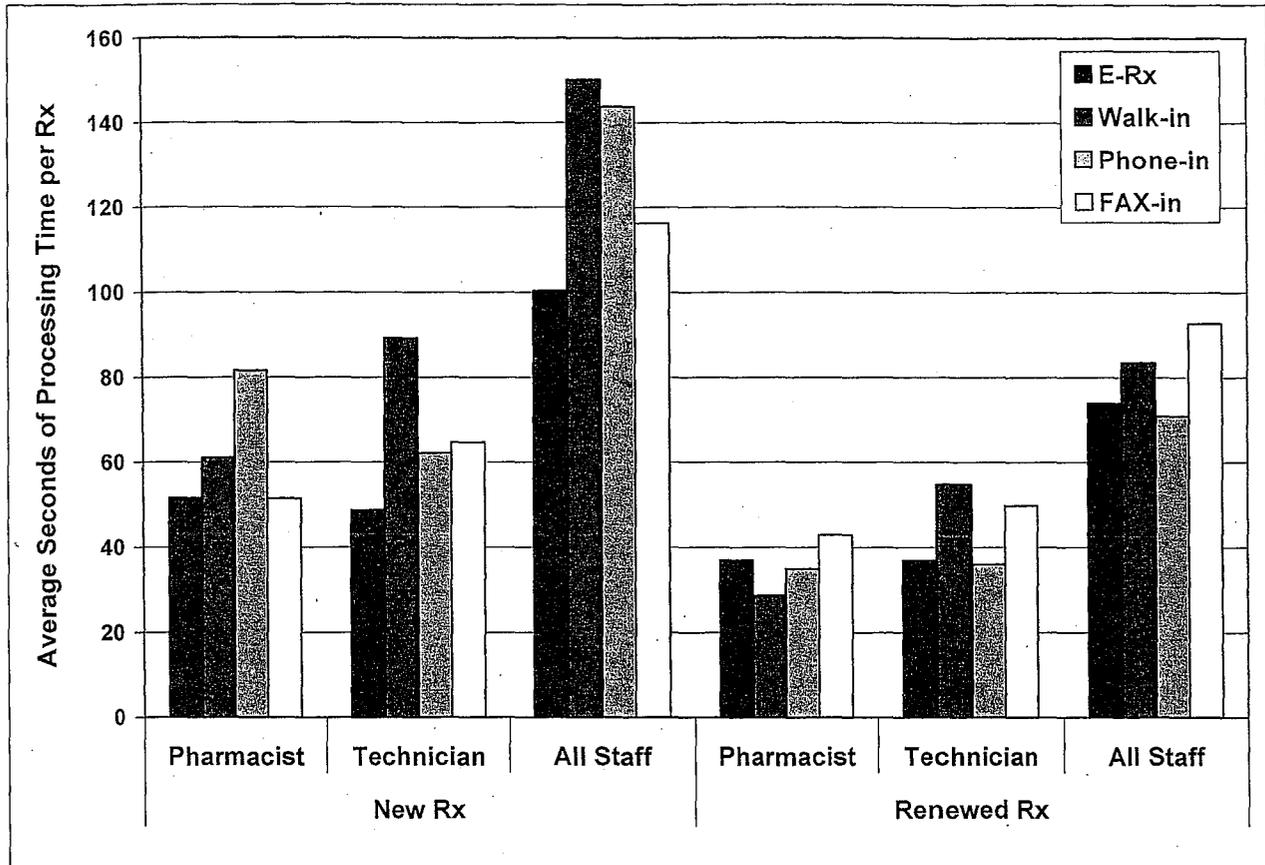
⁴¹ Pedersen CA, ASHP National Survey of Pharmacy Practice in Hospital Settings: Dispensing and Administration – 2005, *American Journal of Health-System Pharmacy*, 2006; 63(4):327-45.

⁴² Angelo LB, Impact of Community Pharmacy Automation on Workflow, Workload, and Patient Interaction, *Journal of the American Pharmacists Association*, 2005; 45:138-144.

⁴³ Rupp MT. E-Prescribing: The value Proposition. *America's Pharmacist*, 2005, 23-25.

that less than 1 percent of prescriptions written by doctors in 2004 were delivered via e-prescription. As of June 2005, 49 States allowed e-prescribing.⁴⁴

Exhibit 36. Differences in Rx Processing Time by Prescription Submission Method



Source: Rupp MT. April 2005. E-Prescribing: The value Proposition. *America's Pharmacist*.⁴⁵

The technology exists, and is already in use in some settings, to automate the majority of the dispensing process, from the transfer of the prescription, through automated checking for errors or harmful interactions, through robotic pill counting, bottle filling, and labeling, to delivery to the patient. Overseen by pharmacists and implemented by properly trained and certified pharmacy technicians, full implementation of technology would allow the pharmacist's role to be primarily one of supervision, patient and provider counseling, and medication management. Barriers to this practice model are technology investment and maintenance costs, reimbursement mechanisms for pharmacists' time, and the need for greater integration of pharmacists into the patient care team.

Robotic systems can cost upwards of \$200,000 per installation, making them cost-effective only in high volume pharmacies. Most insurance programs pay pharmacists only for drug dispensing services. There is still a lack of widespread recognition on the part of physicians, other

⁴⁴ NACDS 2005 Chain Pharmacy Industry Profile. E-prescribing is not addressed in Nebraska's regulations, and e-prescribing is prohibited in the District of Columbia.

⁴⁵ <http://www.surescripts.com/pdf/PharmacyROIDocument.pdf>. Accessed March 2007.

providers, and general public, on the use of pharmacists as the primary patient care resource for medication issues.

There is some evidence that these barriers are beginning to erode, particularly with regard to reimbursement for non-dispensing activities. The Medicare part D benefit plan requires medication therapy management services, which may be delivered by a pharmacist, for specific enrollees. It remains to be seen whether medication management will become widespread as a benefit in private drug insurance plans, and whether the profession will be successful in marketing the benefits of its expertise.

D. Future Pharmacist Requirements

Using the PhSRM, a range of future requirements for pharmacists under alternate assumptions based on numbers of prescriptions (RXs) per capita was projected:

A low Rx/capita growth scenario assumes that current patterns of pharmaceutical use and dispensing will continue into the future, incorporating the following trends:

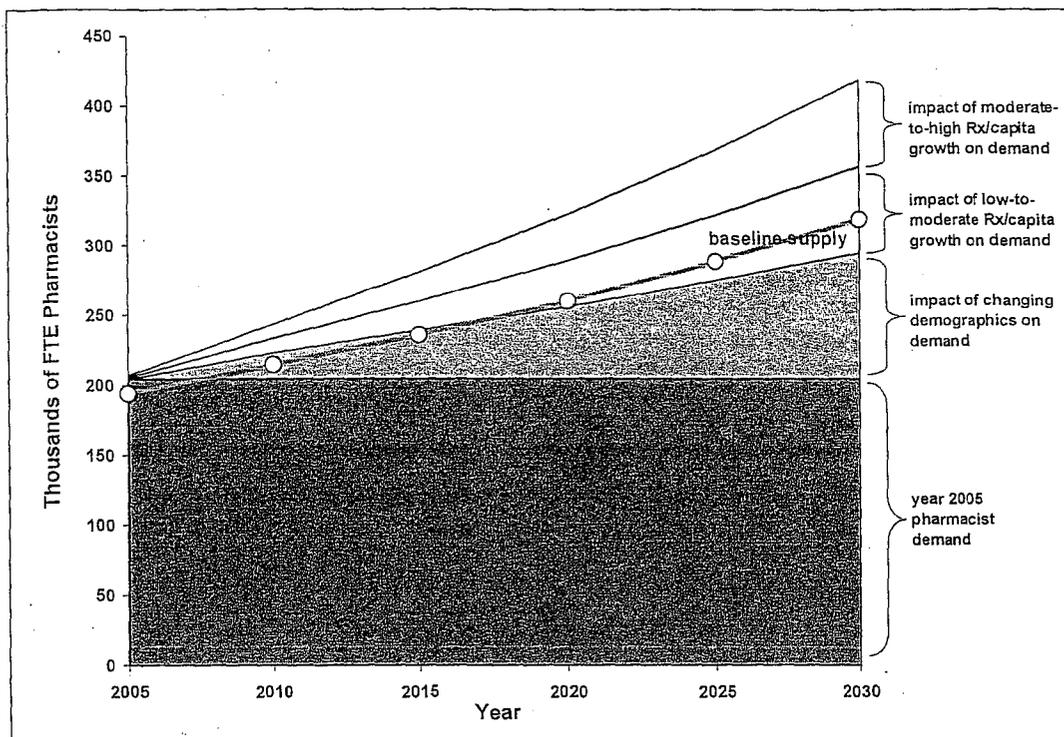
- A growing and aging population will consume more pharmaceuticals,
- No growth in prescriptions written per physician visit (controlling for age and health care delivery setting),
- Improvements in the efficiency of dispensing pharmaceuticals due to technological innovations will be offset by increases in the proportion of pharmacist time spent counseling patients, and
- The proportion of retail pharmaceuticals dispensed from mail order and nursing-home based pharmacies will rise slightly.

A high Rx/capita growth scenario is based on the above scenario, but assumes that prescriptions written per physician visit will increase over time as new medications become available (in addition to increased Rx/capita due to an aging population). The assumed annual rate of growth is the average increase in prescriptions dispensed per physician visit over the period 1995 to 2004, with the increase in per capita use of pharmaceuticals varying by age group and outpatient setting (office visit, emergency visit, hospital outpatient visit). (Prescriptions dispensed per hospital admission is modeled the same for each demand scenario, using pharmacist-to-inpatient day ratios that remain over time for each age group).

A moderate Rx/capita growth scenario takes the midpoint between the low and high Rx/capita growth scenarios, which is equivalent to an annual growth in prescriptions written per physician visit that is half the annual 1995 to 2004 average increase.

Under the low Rx/capita, moderate growth, and high growth scenarios, annual growth in demand for pharmacists between 2005 and 2020 is, respectively, 1.4 percent, 2.3 percent and 2.9 percent (*Exhibit 37*). Between 2005 and 2020, the growth and aging of the population will increase demand for pharmacists from 204,300 to 255,700 (a 51,400 increase). Moderate growth in Rx/capita will likely increase demand by an additional 33,100 pharmacists, bringing the total demand in 2020 to 288,800. High growth in Rx/capita could increase demand by an additional 33,100 pharmacists, bringing the total demand to 321,900.

Exhibit 37. Components of Growth in Pharmacist Requirements

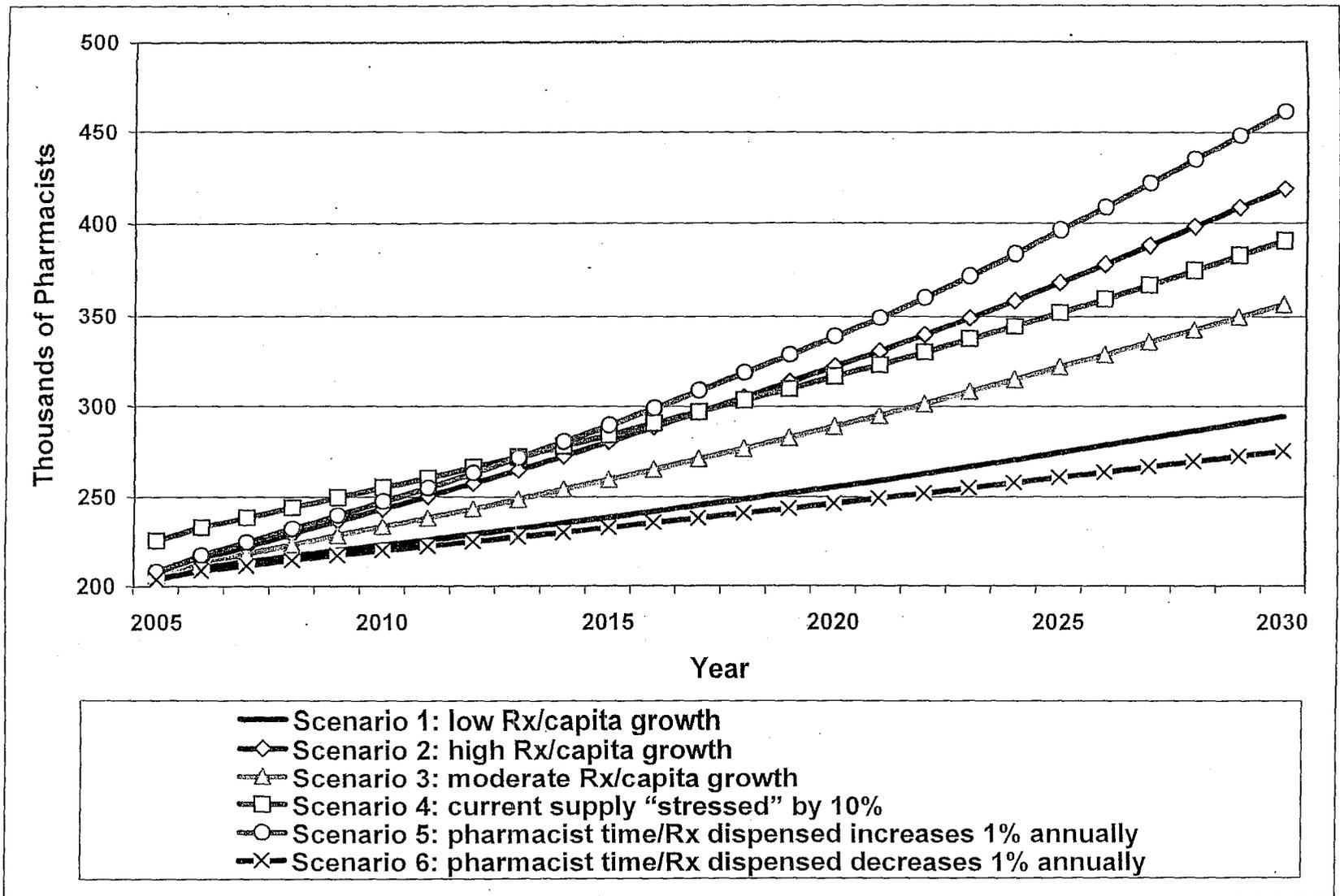


Source: Projections from the PhSRM.

- In addition to the above three scenarios for Future Pharmacist Requirements, which assumed different rates of growth in prescriptions per capita, three additional scenarios were modeled in order to test the sensitivity of the projections to alternate assumptions regarding hours worked by pharmacists and their productivity. Results are presented in *Exhibits 38* and *39*.
- **The current pharmacy system is stressed, with pharmacists working approximately 10 percent more hours per week than is desirable.** This scenario starts with the moderate growth scenario but assumes that base year demand is equal to vacancies plus 1.1 times base year FTE supply. Under this scenario the shortfall of pharmacists in the base year is 29,500 (10,400 actual vacancies plus an additional 19,100 FTE pharmacist positions filled by pharmacists working more hours than is desirable).
- **The amount of pharmacist time needed per prescription increases by 1 percent per year** (compounding to a 28 percent increase by 2030) reflecting pharmacists spending more time counseling patients to reflect a greater role of pharmacists in patient care and the increasing complexity of new drugs. This scenario starts with the moderate growth scenario but incorporates this increase in pharmacist time spent per prescription.
- **The amount of pharmacist time needed per prescription decreases by 1 percent per year** (compounding to a 22 percent decrease by 2030) reflecting productivity gains from the adoption of new technologies and increased use of pharmacy technicians.

Note that a combination of the latter two scenarios is largely offsetting; productivity gains from improved technology and use of pharmacy technicians could allow pharmacists to spend more time providing counseling to patients without affecting overall pharmacist requirements.

Exhibit 38. Projected Pharmacist Requirements Under Alternate Scenarios



Source: Projections from the PhSRM.

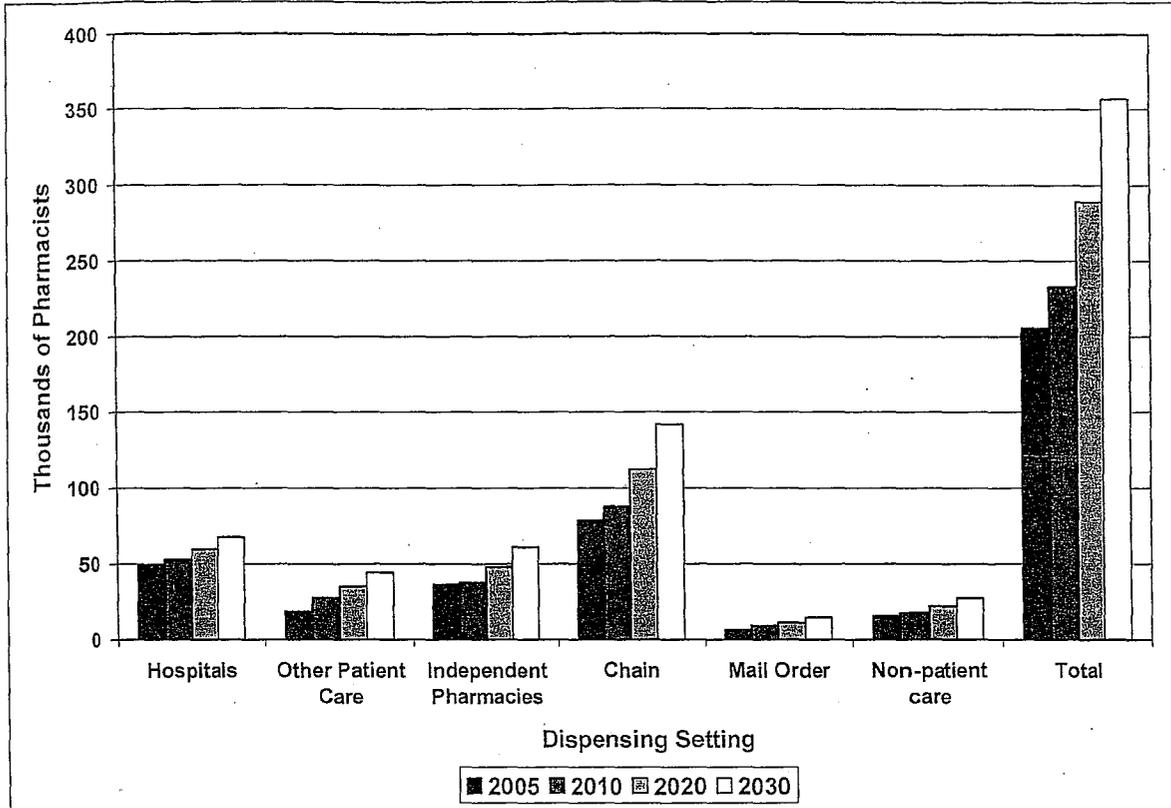
Exhibit 39. Projected FTE Pharmacist Requirements

Year	Scenario 1	Scenario 2	Scenario 3	Scenario 4	Scenario 5	Scenario 6
	Low Rx/capita growth	High Rx/capita growth	Moderate Rx/capita growth	Current supply "stressed" by 10%	Pharmacist time per prescription dispensed increases 1% annually	Pharmacist time per prescription dispensed decreases 1% annually
2004	201,600	201,600	201,600	220,700	201,600	201,600
2005	204,300	206,800	205,500	225,000	207,700	203,500
2006	210,000	215,200	212,500	232,700	216,800	208,400
2007	213,200	221,900	217,600	238,200	224,300	211,100
2008	216,600	229,000	222,900	244,000	231,900	214,200
2009	219,700	236,300	228,100	249,700	239,700	216,900
2010	223,000	243,400	233,200	255,300	247,700	219,700
2011	225,900	250,500	238,200	260,800	255,200	222,000
2012	228,900	257,600	243,400	266,500	263,600	224,900
2013	232,300	265,200	248,700	272,300	272,000	227,500
2014	235,500	272,800	254,200	278,300	280,700	230,100
2015	238,800	280,700	259,800	284,400	289,700	232,900
2016	242,100	288,600	265,400	290,600	299,000	235,500
2017	245,500	296,800	271,100	296,800	308,500	238,100
2018	248,700	304,900	276,900	303,200	318,400	240,900
2019	252,300	313,300	282,700	309,500	328,300	243,500
2020	255,700	321,900	288,800	316,200	338,500	246,300
2021	259,200	330,500	294,800	322,800	349,000	249,100
2022	263,000	339,700	301,300	329,900	360,500	252,000
2023	266,800	349,000	308,000	337,200	372,200	255,000
2024	270,700	358,600	314,600	344,400	383,900	257,800
2025	274,800	368,500	321,600	352,100	396,400	261,100
2026	278,700	378,400	328,400	359,500	408,900	263,900
2027	282,700	388,200	335,600	367,400	421,800	266,900
2028	286,700	398,400	342,500	375,000	434,900	269,800
2029	290,400	408,600	349,600	382,800	448,300	272,600
2030	294,500	418,800	356,700	390,500	462,000	275,300

Source: Projections from the PhSRM.

As illustrated using the moderate Rx/capita growth scenario projections, chain retailers will continue to employ the majority of pharmacists, followed by hospitals, independent pharmacies, other patient care setting employers, non-patient care employers, and mail order pharmacies (*Exhibits 40*).

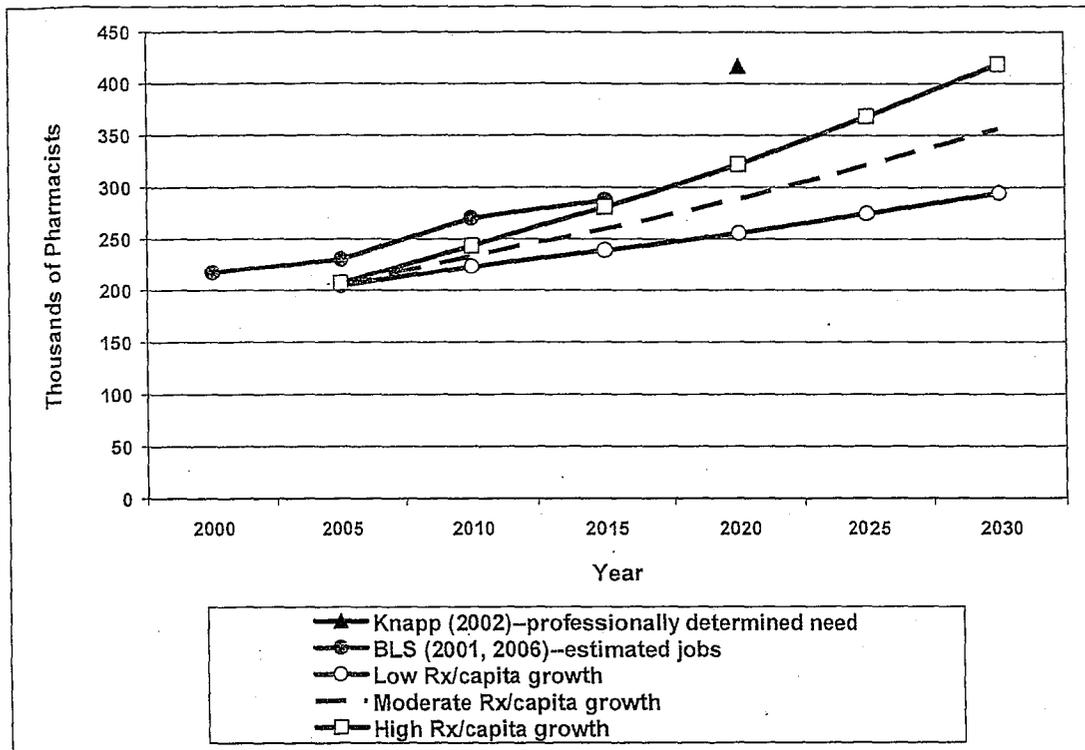
Exhibit 40. Projected Requirements by Dispensing Location: Moderate Rx/Capita Growth Scenario



Source: Projections from the PhSRM.

Few pharmacist requirements projections have been published, and the projections that have been published are not directly comparable (*Exhibit 41*). BLS (2001) estimates there were 217,000 pharmacist jobs in 2000 and projected 270,000 jobs in 2010. BLS (2006) estimates there were 230,000 pharmacist jobs in 2004 and projects 287,000 jobs in 2014. FTE positions and number of jobs are not equivalent, with some pharmacists working part-time jobs. Knapp (2002) reports that a conference attended by approximately two dozen pharmacy workforce experts concluded that by 2020 there would be an estimated need for 417,000 FTE pharmacists. This estimate assumes that in the future there will be a greatly increased need for pharmacists to provide primary services—a more than five-fold increase from the estimated 30,000 FTE pharmacists providing primary services in 2001 to 165,000 FTEs by 2020. Similarly, there would be a more than seven-fold increase in the number of FTE pharmacists providing secondary/tertiary services (130,000 FTEs in 2020 compared to 18,000 FTEs in 2001). The needs-based estimate reported by Kapp envisions a very different role for pharmacists in the future compared to the demand-based projections presented in this report.

Exhibit 41. Comparison of Pharmacist Requirements Projections



Source: Projections from the PhSRM.

IV. CURRENT AND FUTURE ADEQUACY OF PHARMACIST SUPPLY

The Bureau of Labor Statistics defines a shortage in a market economy as a situation “when the demand for workers for a particular occupation is greater than the supply of workers who are qualified, available, and willing to do that job.” While this report looks at the current shortfall of pharmacists, the focus of this study is to assess the future adequacy of supply taking into consideration key trends in supply and demand determinants.

While there is evidence of a current national shortage of pharmacists, the size of the shortage seems to have declined in recent years. A 2004 study by the American Society of Health-System Pharmacists reports that 5 percent of hospitals’ budgeted pharmacist positions were vacant—a decline from 8.9 percent in 2000.⁴⁶ A July 2004 survey by the National Association of Chain Drug Stores (NACDS) Foundation found that chain store pharmacies reported approximately 4,000 vacancies (a vacancy rate of 5 percent).⁴⁷ Combining information from different sources, it was estimated that in 2004 (the base year for the projection model) there were an estimated 10,400 unfilled FTE positions across all settings that employ pharmacists, or a vacancy rate of approximately 5 percent.⁴⁸

The Pharmacy Manpower Project, sponsored by a consortium of organizations interested in collecting, analyzing, and disseminating data on the adequacy of pharmacist supply, developed the Aggregate Demand Index (ADI) to track the level of employer difficulty in hiring pharmacists over time and across States. The ADI suggests that in March 2007 most employers across the Nation were experiencing some difficulty in filling open positions, with the level of difficulty down slightly from March 2006. Among the 50 States plus the District of Columbia, the ADI suggests that 46 States are experiencing some difficulty filling open positions, three States (Alabama, Kentucky and California) report significant difficulty filling open positions, and two States (Rhode Island and Vermont) report that supply seems to be in balance with demand in their State.⁴⁹ No States reported having an excess supply of pharmacists.

The shortfall of pharmacists has contributed to rising earnings for pharmacists, with an analysis of BLS data finding that average salaries for pharmacists have risen about 6 percent per year over the past several years. The median compensation for pharmacists in the United States is approximately \$100,000.⁵⁰ Rising compensation levels have the following short term impacts on supply: (1) some inactive pharmacists are drawn back into the labor force, (2) some pharmacists work more hours (e.g., working full time instead of part time, or working multiple jobs), (3) some pharmacists work fewer hours (e.g., finding that their pay is adequate working just one full time job and no longer needing to work multiple jobs), and (4) some pharmacists delay retirement. In the longer term, interest in pharmacy as a profession rises and more people enroll in schools of pharmacy. Rising salaries also depress demand for pharmacists, with some pharmacies reducing hours rather than pay higher labor costs, and some pharmacies investing in

⁴⁶ 2004 and 2005 Annual Pharmacy Staffing Survey Results. Available at <http://www.ashp.org>. Accessed March 2007.

⁴⁷ NACDS Foundation July 2004 Chain Pharmacy Employment Survey Results. Available at <http://www.nacds.org>. Accessed March 2007.

⁴⁸ Some economists might argue that a 5 percent vacancy rate does not reflect a shortfall, but rather reflects normal turnover and the normal time lag between when a position becomes available and when it is filled.

⁴⁹ Available at <http://www.pharmacymanpower.com>. Accessed March 2007.

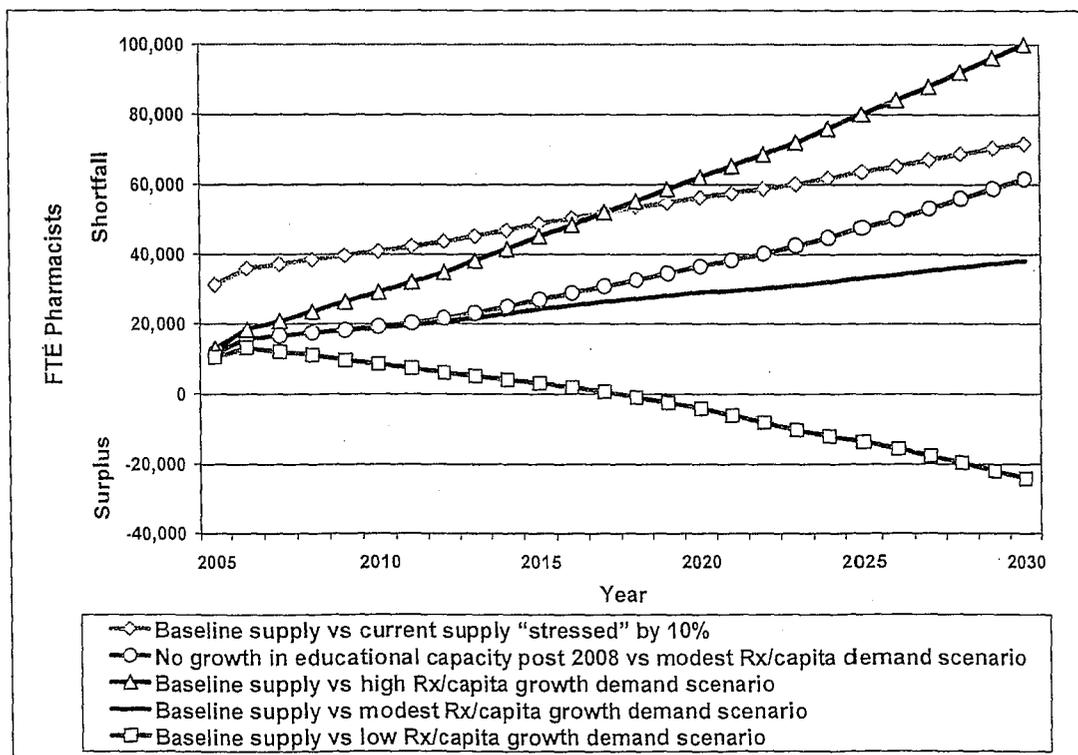
⁵⁰ Salary and benefits information obtained from <http://www.salary.com>. Accessed March 2007.

equipment and non-pharmacist labor (e.g., technicians) to increase the productivity of their existing pharmacists.

Political and regulatory forces also influence the adequacy of pharmacist supply. The National Association of Boards of Pharmacy (NABP) conducts an annual Survey of Pharmacy Law documenting the laws, rules, and regulations that govern pharmacy in each State, the District of Columbia, and Puerto Rico. Comparing the 2000-01 Survey of Pharmacy Law to the 2006 edition, eleven States, or 20 percent, have increased or eliminated the maximum allowable ratio of pharmacist technicians to pharmacists in ambulatory care settings. Between 2000 and 2006, the number of States allowing technicians to compound medications for dispensing increased from 39 to 48, and the number of States allowing technicians to call physician offices for refill authorization increased from 34 to 40. Since HRSA's 2000 *Report to Congress - The Pharmacist Workforce: A Study of the Supply and Demand for Pharmacists*, the number of pharmacy technicians employed has increased significantly. BLS reports a nearly 40 percent increase in numbers of pharmacy technicians, from about 191,000 in 2000 to nearly 267,000 in 2005. BLS figures on pharmacists over this same time period show an 8 percent increase.

Comparison of the baseline supply and demand projections produced for this report suggests that the future supply will be adequate only when combining an optimistic supply scenario with a conservative demand scenario (*Exhibits 42 and 43*). Growth in supply is sufficient to serve the projected demand of a growing and aging population only if per capita consumption of pharmaceuticals remains at current levels. Per capita consumption is likely to grow, however, as new medical advances increase the types of diseases that can be treated and new preventive medicines are discovered.

Exhibit 42. Pharmacist Shortfall under Alternate Scenarios



Source: Projections from the PhSRM.

Exhibit 43. FTE Shortfall Projections

Demand Scenario:	Likely Scenario				Shortfall Under Alternate Scenarios			
	Supply Scenario:	Moderate Rx/capita Growth	Shortfall		High Rx/capita Growth	Low Rx/capita Growth	Moderate Rx/capita Growth	Moderate Rx/capita Growth with Current System Stressed by 10%
			Baseline		Baseline	Baseline	No Growth in Educational Capacity Post 2008	Baseline
2004	191,200	201,600	10,400	5%	10,400	10,400	10,400	29,500
2005	193,900	205,500	11,600	6%	12,900	10,400	11,600	31,100
2006	196,900	212,500	15,600	7%	18,300	13,100	15,600	35,800
2007	201,200	217,600	16,400	8%	20,700	12,000	16,400	37,000
2008	205,600	222,900	17,300	8%	23,400	11,000	17,300	38,400
2009	210,100	228,100	18,000	8%	26,200	9,600	18,100	39,600
2010	214,400	233,200	18,800	8%	29,000	8,600	19,100	40,900
2011	218,600	238,200	19,600	8%	31,900	7,300	20,200	42,200
2012	222,900	243,400	20,500	8%	34,700	6,000	21,500	43,600
2013	227,200	248,700	21,500	9%	38,000	5,100	23,000	45,100
2014	231,500	254,200	22,700	9%	41,300	4,000	24,800	46,800
2015	235,700	259,800	24,100	9%	45,000	3,100	26,800	48,700
2016	240,300	265,400	25,100	9%	48,300	1,800	28,700	50,300
2017	244,900	271,100	26,200	10%	51,900	600	30,600	51,900
2018	249,800	276,900	27,100	10%	55,100	-1,100	32,400	53,400
2019	254,800	282,700	27,900	10%	58,500	-2,500	34,300	54,700
2020	259,900	288,800	28,900	10%	62,000	-4,200	36,400	56,300
2021	265,400	294,800	29,400	10%	65,100	-6,200	38,100	57,400
2022	271,200	301,300	30,100	10%	68,500	-8,200	40,100	58,700
2023	277,100	308,000	30,900	10%	71,900	-10,300	42,300	60,100
2024	282,800	314,600	31,800	10%	75,800	-12,100	44,600	61,600
2025	288,500	321,600	33,100	10%	80,000	-13,700	47,500	63,600
2026	294,400	328,400	34,000	10%	84,000	-15,700	50,000	65,100
2027	300,400	335,600	35,200	10%	87,800	-17,700	53,000	67,000
2028	306,400	342,500	36,100	11%	92,000	-19,700	55,800	68,600
2029	312,500	349,600	37,100	11%	96,100	-22,100	58,600	70,300
2030	318,800	356,700	37,900	11%	100,000	-24,300	61,500	71,700

Source: Projections from the PhSRM.

V. CONCLUSIONS

This study looked at the trends in pharmacist supply and demand determinants to assess the current and future adequacy of supply. These trends include changes in technology, distance and distributive learning models, growth and aging of the population, expansion of the Nation's pharmacy school capacity, and other developments (e.g., creation of the Medicare Part D Program) that have occurred since HRSA's 2000 *Report to Congress - The Pharmacist Workforce: A Study of the Supply and Demand for Pharmacists*. This section contains a summary of key findings and their implications, as well as the study strengths, limitations, and areas for future research.

A. Summary of Key Findings and Implications

Pharmacies across the Nation continue to experience some difficulty in filling vacancies, but the severity of the shortfall appears to have diminished somewhat since HRSA's 2000 Report to Congress. Several factors help explain the improvement in adequacy of supply.

- The Nation has increased its supply of pharmacy technicians and has increased the scope of practice of these technicians. As the technician-to-pharmacist ratio increases, however, the Nation cannot continue to rely on producing more technicians to reduce the shortfall of pharmacists.
- Rising wages for pharmacists has both provided an incentive for pharmacists to remain in the workforce and for pharmacies to scale back their hiring needs.
- Improved technology continues to make pharmacists more productive.

In response to high pharmacist vacancy rates, rising pay, and concerns over a growing shortfall, the Nation's educational capacity has expanded and an increasing number of people have chosen pharmacy as a career. The Nation's educational capacity has expanded through the opening of new schools, as well as increased enrollment at existing schools. The number of colleges and schools of pharmacy with accredited professional degree programs rose from 82 in 2000 to 92 by 2005. AACP predicts that 110 programs will be open by Fall 2010. The number of graduates from pharmacy schools has increased from 7,300 in 2000 to 9,100 in 2005. The use of distance learning models in pharmacy education has expanded since the 2000 Report to Congress, and has contributed to the growth in existing training programs. Raising the minimum education level (to a Pharm.D) for new pharmacists does not appear to have reduced the desirability of pharmacy as a career. The Nation's ability to continue expanding its educational capacity is threatened by a potential shortfall of faculty, with a large proportion of faculty nearing retirement and wages for faculty falling behind the wages for pharmacists in retail settings.

The projections suggest that only when combining an optimistic supply scenario with a conservative demand scenario will future supply be adequate to meet the needs of a growing and aging population. However, under most scenarios modeled, supply will be insufficient to meet the needs of a population caused by growth in per capita consumption of pharmaceuticals.

The demand projections assume that the role of pharmacists will remain largely unchanged over the projection horizon. With the Pharm.D now the minimum educational requirement for entry into the workforce, new pharmacists have greater ability than do earlier cohorts to take on

increasing responsibilities in patient management and counseling. Participants at a 2002 conference discussed the number of pharmacists that would be needed to deliver high-quality care under a scenario where pharmacists play a larger role in patient care management. These participants concluded that an estimated 417,000 pharmacists would be needed by 2020 (approximately 128,000 more than calculated under our moderate Rx/capita growth demand scenario), which when compared to our baseline supply projections suggests a shortfall of approximately 157,000 pharmacists in 2020.⁵¹ An expanded role for pharmacists can occur only if a reimbursement mechanism is instituted to pay pharmacists for such services. The Medicare Modernization Act of 2003 has opened the door for pharmacists to receive reimbursement for medication therapy management services for a select number of high-drug-utilization Medicare beneficiaries.⁵²

Women constitute a growing proportion of active pharmacists. Currently, half of all active pharmacists are women. By 2020, approximately 62 percent of active pharmacists will be women. Female pharmacists tend to work fewer hours per year than their male colleagues, so FTE supply will grow at a slightly lower rate than active supply.

Racial minorities continue to be underrepresented in the pharmacist workforce. In the 2000 Census, 25 percent of the U.S. population indicated they are in a racial minority group, while only 18 percent of individuals self-identified as pharmacists indicated they are in a racial minority group.

The role of pharmacists in the future is closely linked to the adequacy of supply. Pharmaceuticals are becoming more complex, and with a growing elderly population an increasing number of patients take multiple medications. Consequently, the demand for counseling and education by pharmacists continues to rise. The baseline demand projections presented in this report assume that pharmacists will spend an increasing proportion of their time providing counseling and educating patients. Such a shift in work activities will be made possible by rising pharmacist productivity made possible through greater use of pharmacy technicians and improved technology that reduces the time per prescription spent dispensing and performing administrative duties.

This study focused on the national adequacy of pharmacist supply, although geographic inequities exist in access to pharmacist services. Consequently, there continues to be a role for programs such as the National Health Service Corps Chiropractor and Pharmacist Loan Repayment Demonstration that uses financial aid as a means to recruit and retain pharmacists in hard-to-employ settings such as rural areas, low-income urban areas, and select Federal institutions such as prisons.

B. Study Strengths, Limitations, and Areas for Future Research

The findings of this study reflect an extensive review of the literature, empirical analysis, and discussions with area experts. The major strengths of this study include the following:

⁵¹ Knapp, David A. Professionally Determined Need for Pharmacy Services in 2002. *American Journal of Pharmaceutical Education*. Vol 66 (Winter 2002): 421-429.

⁵² DaVanzo J, Dobson A, Koenig L, and Book R. *Medication Therapy Management Services: A Critical Review*. Report prepared by The Lewin Group for the American Pharmacist Association. May 2005.

- The pharmacist supply and demand projections come from a workforce model developed based on a wide body of literature regarding the important components of pharmacist supply and demand, as well as empirical research that reflects current trends in supply and demand determinants.
- The supply projections reflect the recent surge in enrollment and graduations from schools of pharmacy. This surge is largely in response to the current shortfall of pharmacists (with the resulting rise in wages and job opportunities) and previous studies that suggested the shortfall of pharmacists would continue to grow. Other components of the supply model have also been updated (e.g., retirement and workforce participation patterns).
- This study quantifies the projected future demand for pharmacists, whereas most previous work provides only a qualitative assessment of future demand.
- The Pharmacist Supply and Requirements Model was designed so that frequent updates of supply and demand projections could be made to quickly analyze the implications of changes in supply and demand determinants, as well as analyze the implications of policy decisions affecting supply or demand.

The major limitations of this study include the following:

- The base year demand for pharmacists is only an estimate, with demand defined as FTE employment plus FTE vacancies. If the current system is overstretched such that pharmacists are working more hours than is desirable (either from a quality of services perspective or a quality of life perspective), then this definition of current demand might underestimate true demand for pharmacists. Underestimates of demand in the base year are extrapolated into the future.
- There is substantial uncertainty regarding changes in some demand determinants—especially regarding technological growth (e.g., advances in biotechnology), growth in the number and role of pharmacy technicians, and the future role of pharmacists.
- The demand projections are highly sensitive to growth in per capita consumption of pharmaceuticals. A range of demand estimates were projected to reflect this sensitivity.

Important areas for future research to improve our understanding of the current and projected future adequacy of pharmacist supply include:

- The potential impact of new technology on pharmacist productivity,
- The potential impact of advances in biotechnology on individualized drug therapy and the resulting demand for pharmacists,
- Whether lifestyle changes are leading to patterns of fewer hours worked per pharmacist per year—irrespective of trends in demographics (age and gender) of the pharmacist workforce,
- The changing role of pharmacists, and
- The degree to which pharmacy technicians offset the demand for pharmacists and the limits of such substitution before quality is compromised.

As attributed to Mark Twain, “making predictions is risky business, especially when it involves the future.” Over time, trends in pharmacist supply and demand determinants can change. In addition to the uncertainties regarding technological advances, changes in government policies and programs and changes in insurer approaches to managing prescription drug costs can affect demand for pharmacists.

On the supply side, the number of new graduates might deviate from projected levels if a shortage of faculty threatens the Nation’s ability to train new pharmacists. Furthermore, work patterns can change toward the desire to work fewer hours, and retirement patterns can change. These uncertainties mean that the accuracy of the supply and demand projections will diminish as the projection horizon increases. This uncertainty highlights the need to update the projections every few years to reflect changes in policies and trends.

The overall finding of this study is that the Nation appears to have responded to both the current shortfall of pharmacists and predictions of a growing shortfall. Market forces (e.g., higher wages) and political forces (e.g., increased scope of practice for pharmacy technicians) have helped reduce the shortfall of pharmacists. Still, the increase in supply will only be sufficient to keep pace with rising demand due to changing demographics. If a faculty shortfall at schools of pharmacy prevents the planned expansion in the capacity of schools to graduate new pharmacists, or if per capita consumption of pharmaceuticals continues to increase, then the current shortfall of pharmacists could worsen. Likewise, technological improvements that increase pharmacist productivity and efforts to control growth in consumption of pharmaceuticals could slow the growth in demand for pharmacists to dispense medications, thus increasing the likelihood that pharmacists can play a larger role in counseling patients and providing care management.

FPGEE Advisory



custserv@nabp.net
12/17/2008 11:15 AM

To
cc
bcc
Subject NABP to Launch New Computerized FPGEE at April 2009 Administration

Licensing

FOR IMMEDIATE RELEASE

December 17, 2008

For more information contact:

Larissa Doucette, Communications Manager

847/391-4405; custserv@nabp.net

**NABP to Launch New Computerized FPGEE at
April 2009 Administration**

As advancements in secure testing technology continue, the National Association of Boards of Pharmacy® (NABP®) is pleased to announce the launch of the new computerized Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®). Set to replace the paper-and-pencil examination, the first computerized administration of the FPGEE will be on April 14, 2009.

The computerized FPGEE will continue to be administered one day in the spring and one day in the fall; however, instead of limiting the available testing locations to three sites, applicants will be able to choose from more than 200 Pearson VUE testing sites located within the continental United States. In addition, it is anticipated that applicants will be able to schedule their test sites electronically 48 to 72 hours after having been accepted to take the FPGEE.

The FPGEE is the third computerized examination to be administered by NABP, after the North American Pharmacist Licensure Examination® (NAPLEX®) and Multistate Pharmacy Jurisprudence Examination® (MPJE®). NABP test vendor, Pearson VUE, will administer the computerized FPGEE as it does with the NAPLEX and the MPJE. Demonstrating a record of solid customer service combined with a secure and consistent test center network, Pearson VUE is committed to providing a reliable and professional testing environment for applicants on behalf of NABP.

The FPGEE is one component of the Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) certification process. In addition to passing the examination, FPGEC applicants must have their educational and licensure institutions submit documents that present their educational backgrounds and licensure and/or registration to practice pharmacy. Applicants must also pass the Test of English as a Foreign Language™ (TOEFL®) and the Test of Spoken English™ (TSE®), or the TOEFL Internet-based Test (iBT). The FPGEC Certificate allows foreign graduates to partially fulfill eligibility requirements for licensure in the 50 United States and the District of Columbia where the certification is recognized.

To prepare for the FPGEE, NABP recommends that applicants take the Pre-FPGEE®, the official FPGEE practice examination written and developed by NABP. This practice examination is designed to help familiarize applicants with the FPGEE by exhibiting the types of questions provided on the actual examination as well as providing a score estimate.

Additional information on the FPGEE as well as the Pre-FPGEE is available in the Examination Programs section on the NABP Web site at www.nabp.net.

NABP is the independent, international, and impartial Association that assists its member boards and jurisdictions

Pharmacy Access Partnership Request



PACIFIC INSTITUTE FOR WOMEN'S HEALTH



December 5, 2008

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

RE: Collaborative Protocol Practice Pilot - Pharmacy Access to Hormonal Contraception

Dear Ms. Herold,

Pharmacy Access Partnership, a center of the non-profit Pacific Institute for Women's Health has been at the forefront of advancing pharmacy access to emergency contraception (EC) in California and nationally and sees this model as plausible for other hormonal contraception (HC) methods namely, oral contraceptives, the contraceptive patch and vaginal ring. Our goal is to increase capacity for contraceptive access at the pharmacy to better meet women's healthcare needs.

Research shows widespread interest and support among consumers and pharmacists nationally and, even more so, in California for pharmacists to work under a collaborative protocol to provide HC directly to eligible women who meet the screening criteria. To that end, over the last few years, Pharmacy Access Partnership has been working with a group of high-level experts and interested stakeholders to explore the potential for developing a pharmacy access to HC model in California, building upon the successes and lessons learned from a pharmacist-initiated provision of HC pilot study in Washington State.

In collaboration with the University of Southern California, School of Pharmacy and the University of California, San Francisco, Department of Obstetrics and Gynecology, Pharmacy Access Partnership is seeking to set up a collaborative practice pilot that would allow pharmacists in a community pharmacy practicing under a protocol with a physician to provide limited supplies (up to one year) of oral contraceptives, contraceptive patches and vaginal rings, to women who present at the pharmacy and meet the screening requirements (based on the World Health Organization 2000 guidelines, category 1 and 2). We understand that, as we did with EC, we might have to ultimately change law in California for pharmacists to work under collaborative protocol to provide pharmacy access to hormonal contraceptives. However, a pilot to explore the feasibility and acceptability of such a model would be possible under state regulations (§1706.5 Experimental Programs1) with approval and a waiver from the CA State Board of Pharmacy. In our efforts to investigate an innovative practice in pharmacy, we respectfully request the CA State Board of Pharmacy to allow this pilot to use a protocol similar to pharmacist immunization services whereby a protocol between a pharmacist and physician permits the application of the protocol for qualifying women who want to get hormonal contraception from the pharmacist directly for a set period of time. We are seeking a waiver for the "prior diagnosis" portion of the protocol; since a request for hormonal contraception does not require a "diagnosis," the need for a prior relationship between provider and patient is not relevant.

Attached please find a brief pilot overview entitled "*Healthcare Within Reach: Pharmacies as Viable Points of Access - Piloting Pharmacy Access to Hormonal Contraception in California.*" Please let us

Pharmacy Access Partnership, A center of the Pacific Institute for Women's Health
614 Grand Avenue, Suite 324 ~ Oakland, CA ~ 94610 ~ Tel 510-272-0150 ~ Fax 510-272-0285
www.pharmacyaccess.org ~ www.piwh.org

know if you have further questions or need additional information. Feel free to contact us at slandau@piwh.org and kbesin@usc.edu or 818-884-8228. Thank you in advance for your consideration and we look forward to hearing back from you as soon as possible to discuss next steps.

Respectfully,



Sharon Landau, MPH
Director, Pharmacy Access Partnership



Kathy Besinque, PharmD
Associate Professor, USC School of Pharmacy

Enclosures

¹ §1706.5 Experimental Programs: In order to enable any accredited school of pharmacy recognized by the Board to experiment with new and innovative methods for drug handling, teaching, research, or to develop new and better methods or concepts involving the ethical practice of pharmacy, the Board enacts the following:

- a) The application of particular provisions of the Pharmacy Rules and Regulations contained in Title 16, California Administrative Code, Chapter 17, may be waived as to an accredited school of pharmacy recognized by the Board if the Dean of said school has filed with the Board an experimental plan or program which specifies the particular provisions to be waived, and which has been approved by the Board.
- b) Any plan or program approved by the Board shall have: definite time limitations; progress reports which shall be filed as required by the Board.
- c) The Board may rescind approval and terminate said plan or program at its discretion, at any time it may deem the public interest is not fully protected; nor shall any such plan or program be approved by the Board if such proposal might jeopardize public health or welfare or conflict with provisions of Chapter 9, Div. 2, Business and Professions Code.

Licensure



Healthcare Within Reach: Pharmacies as Viable Points of Access -
Piloting Pharmacy Access to Hormonal Contraception in California
Pharmacy Access Partnership, Center of the Pacific Institute for Women's Health
University of Southern California, School of Pharmacy
University of California, San Francisco, Department of Obstetrics and Gynecology
December 5, 2008

Why Pilot Pharmacy Access to Hormonal Contraception:

Pharmacy Access Partnership, a center of the non-profit Pacific Institute for Women's Health has been at the forefront of advancing pharmacist initiated prescriptions for emergency contraception (EC) under collaborative protocol in California and sees this model as plausible for other hormonal contraception (HC) methods namely, oral contraceptives, the contraceptive patch and vaginal ring. Our goal is to increase capacity at the pharmacy to better meet women's healthcare needs and improve individual patient and community health overall.

Broadening access to reproductive healthcare services is essential to reduce the incidence of unintended pregnancy in the United States, which is among the highest in the world for developed countries.ⁱ A leading cause of unintended pregnancy is poor utilization of effective methods of contraception, and as such nearly half of unintended pregnancies end in abortion. Research shows that women face substantial barriers obtaining their birth control. A national survey of women at risk for pregnancy published in *Contraception*, December 2006, showed that one in four women experience problems obtaining a prescription for hormonal contraception, refilling a prescription, or getting additional supplies when they need them. This number is even higher in California with a third of women (37%) saying they had problems getting their HC. Obstacles included long waits to get an appointment, inconvenient physician/clinic office hours, costly physician office appointments, difficulty to get time off from work or school and not wanting to get a pelvic exam.

Streamlining access to HC may help reduce the rate of unplanned pregnancy. Pharmacies are widely distributed and provide convenient access to health services during evening and weekend hours when other healthcare services are closed. Direct access to HC from pharmacists has the potential to expand access, increase adherence, reduce unintended pregnancies in California and serve as a feasible model for other states.

There is documented interest and support among women for direct access to HC from the pharmacist.ⁱⁱ In fact, three-quarters of the California women surveyed say they would use pharmacy access to HC, including three in ten California women not using any contraception who would begin a hormonal method if they could obtain it directly from a pharmacist. This highlights a significant role for pharmacists to play in expanding access to HC and suggests that the pharmacy is an important site to invest in for sexual health education, screening, and supplies.

Although pelvic examinations are cited by women as access barriers to HC, research shows that a Papanicolaou (Pap) smear and pelvic examination are not medically necessary to assess appropriate candidacy for hormonal contraception.^{iii,iv,v,vi} In fact, the American College of Obstetricians and Gynecologists, the World Health Organization, the US Food and Drug Administration and Planned Parenthood Federation of America have all published guidelines or recommendations stating that a Pap smear and pelvic examination are not necessary prerequisites to prescribing hormonal contraception and that these exams are no longer required annually for many women.^{vii,viii,ix} In practice, Planned Parenthood affiliates in California and nationally offer the HOPE program (Hormonal Options without Pelvic Exam) to women seeking hormonal contraceptives. These changed guidelines and successful programs also open the door for pharmacy-based initiation of hormonal contraception.

A precedent exists for pharmacists initiating prescriptions and provision of hormonal contraceptives. In addition to California, eight states currently allow pharmacists to provide pharmacy access to EC for all women, regardless of age, and ten other states have introduced similar legislation in the last few years.^x A pilot project in Washington State of pharmacist-initiated HC, including oral contraceptives, the patch and ring, has also demonstrated patient and pharmacist satisfaction with pharmacist delivered services. Between 2002 and 2004, 26 pharmacists working in eight pharmacies in Seattle, Washington, served approximately 200 women with pharmacy-based access to HC as part of the Direct Access Study, funded by National Institute of Child Health and Human Development. The study found that the majority of women who sought hormonal contraception directly from the pharmacist did so because the pharmacy was a convenient point of access and/or they did not have a regular provider.^{xi}

The question remains whether the direct pharmacy access to HC model could be adapted and implemented in community pharmacies outside of Washington State. According to a 2005 national survey conducted in collaboration with the American Pharmacists Association, the majority of pharmacists (85%) are interested in providing HC pharmacy access, with interest even higher in California. (Study scheduled for publication in the *Journal of the American Pharmacists Association* in early 2009.) As such, California is well-positioned to initiate a pharmacy access to HC pilot program and lead the nation in creating paradigm shifts in contraceptive access for women. Moreover, since research shows that California pharmacists provide pharmacy access to EC more than any other clinical services, they are primed to offer women even greater timely access to contraceptive services. We believe this is a prime opportunity to model system change in policy and practice that would promote and facilitate collaborative partnerships between the pharmacy, medical, reproductive health and public health communities overall.

Pilot Program Overview:

The University of Southern California (USC) School of Pharmacy in collaboration with Pharmacy Access Partnership and the University of California San Francisco (UCSF) Department of Obstetrics and Gynecology are seeking to develop and implement a pilot program with the goal and purpose of increasing access to hormonal contraception by providing a new, additional point of healthcare delivery at the pharmacy. Our objective is to explore the feasibility and acceptability of pharmacy access to HC among consumers, providers and payers. We are not interested in replacing routine gynecological care or to imply that the pharmacy is a better point of service delivery. Our study hypothesis is that utilizing pharmacists and pharmacies as initial providers for hormonal contraception increases access without posing additional risks to patients or pharmacists.

Under a demonstration pilot in California, the targeted patient population would include both new and current users of hormonal contraception. A woman aged 15-55 would be able to walk into a participating community pharmacy with a pharmacist specially trained in hormonal contraceptive management, working under collaborative protocol with a physician. The patient would indicate her interest in getting a prescription for oral contraceptives, the contraceptive patch or vaginal ring. Patients also presenting to the pharmacy for EC would be informed of the pilot and availability of pharmacy-based access to ongoing hormonal contraception. A patient would then complete a screening form (adapted from a validated screening form used in Washington State and reviewed by the Pharmacy Access Partnership's HC Workgroup and the CA Board of Pharmacy) and pilot consent form. The pharmacist would review these forms to assess whether the patient was an appropriate candidate based on established pilot program protocols and guidelines (consistent with the World Health Organization 2000 guidelines, category 1 & 2). The pharmacist would then counsel the patient as necessary on method selection and use, provide a prescription, initiate up to three months supply and/or make any appropriate referrals. Pharmacists would be encouraged to work closely with the physician signing their collaborative protocol and make referrals as necessary. For those women without regular providers, pharmacists can play a critical role in linking women to vital care. Pharmacists can encourage women to obtain physical exams or other clinical services as well as

provide information about providers and state funded insurance programs for low-income clients. Upon a follow up revisit and screening check-in, pharmacists may authorize and provide pilot participating women a refill supply for up to one year.

Patient screening forms would also include questions to help evaluate patient acceptability. As part of participation in the pilot, patients would consent to complete one-week, six-month and 12-month interviews (to be further determined in evaluation plan) to assess patient satisfaction with pharmacy-based services, clinical services utilization and contraceptive compliance. Participating pharmacists' satisfaction and acceptability will also be assessed on a quarterly basis through a mailed questionnaire or phone interview. These pharmacy survey tools will be adapted from those used in Washington and will be reviewed by the HC workgroup as well as the California Board of Pharmacy and the USC's Institutional Review Board. All survey instruments related to the evaluation methodology, design, distribution, and data analysis will be conducted in collaboration with USC School of Pharmacy faculty and UCSF Department of Obstetrics and Gynecology faculty. We will collaborate on the evaluation of participants' contraceptive access and continuation with Dr. Diana Foster, a faculty member in the department of UCSF Obstetrics and Gynecology and an expert in the evaluation of reproductive health programs.

We have identified and been in conversation with both chain and independent pharmacies receptive to participating in our pilot program. We expect to recruit a total of at least 10 pharmacies in urban and suburban areas in the Los Angeles area, the San Francisco Bay area, and the central coast (San Luis Obispo) to participate in the pilot demonstration. We would like at least three of these pharmacies to be pharmacies serving as a site for residency programs with colleges of pharmacy so that student pharmacists are also exposed to the program. We have also identified and gained support from two Planned Parenthood Medical Directors who have expressed interest in serving as physician signatories for collaborative protocols in the pilot. We will utilize our strong relations with the California Pharmacists Association, Planned Parenthood Affiliates of California, and the American College of Obstetrics and Gynecologists District IX to assist with recruitment and promotion of the pilot. We will work with a statistician to determine the appropriate sample size of women necessary to produce results that may be generalized to a larger population.

We will collaborate with USC School of Pharmacy faculty Dr. Kathy Besinque and Planned Parenthood Medical Directors to conduct a live training for participating pharmacists on contraceptive management and pilot protocols and procedures. The training curriculum will be adapted and updated from training conducted in Washington State. After the pilot duration, we will work with the California Pharmacists Association to provide contraceptive management training to pharmacists statewide at the annual CPhA conference, online and/or other appropriate venues. We will also make our training materials and curriculum available to interested stakeholders for use in other states. We will also leverage our collaboration with University of California, San Francisco School of Pharmacy faculty and students who recently conducted statewide research on student pharmacists' interest and readiness to participate in HC pharmacy access programs, and to determine additional training they might require. These findings will inform our efforts to successfully integrate reproductive health service related training needs in school of pharmacy curriculum and ensure that future pharmacists statewide are prepared to meet women's reproductive health needs.

We will develop culturally and linguistically appropriate educational and promotional materials to inform the public about the HC pilot. These materials will be strategically distributed in pharmacies, conferences, events, and other appropriate venues to maximize reach to women of reproductive age.

As California, and our nation, grapples with a dynamic and stressed healthcare system, it is important that we put in place systemic policy changes that will make a difference in how consumers access quality and affordable reproductive healthcare that gives them more control over their choices. We believe pharmacy access to hormonal contraception has real potential for making a difference in access to reproductive healthcare and improved health outcomes for women.

-
- ⁱ Jones EF, Forrest JD, Henshaw SK, Silverman J, Torres A. Unintended pregnancy, contraceptive practice and family planning services in developed countries. *Family Planning Perspectives*, 1988; 20:53-5,58-67
- ⁱⁱ Landau SC, Parker MT, Taylor-McGhee B. Birth control within reach: a national survey on women's attitudes toward and interest in pharmacy access to hormonal contraception. *Contraception*, 2006; 74:463-470.
- ⁱⁱⁱ Leeman, L. Medical barriers to effective contraception. *Obstetrics and Gynecology Clinics of North America*, 2007;34:1 Pages 19-29
- ^{iv} Harper C, Balistreri E, Boggess J, Leon K, Darney, P. Provision of hormonal contraceptives without a mandatory pelvic examination: the First Stop demonstration project. *Fam Plann Perspect* 2001; 33:13-8.
- ^v Scott A, Glasier AF. Are routine breast and pelvic examinations necessary for women starting combined oral contraception? *Hum Reproduc Update* 2004;10: 449-52.
- ^{vi} Stewart FH, Harper CC, Ellertson CE, Grimes DA, Sawaya GF, Trussell J. Clinical breast and pelvic examination requirements for hormonal contraception: Current practice vs evidence. *JAMA* 2001;285(17):2232-9.
- ^{vii} World Health Organization (WHO). Improving access to quality care in family planning: medical eligibility criteria for initiating and continuing use of contraceptive methods. Geneva7 WHO; 1996.
- ^{viii} American College of Obstetricians and Gynecologists. Cervical Cytology Screening. ACOG Practice Bulletin No. 45. Washington, DC: ACOG; 2003. *Int J Gynaecol Obstet*. Nov 2003;83(2):237-247.
- ^{ix} US Food and Drug Administration. Labeling guidance text for combination oral contraceptives, prescribing information, physician labeling; 1994. Available at: <http://www.fda.gov/ohrms/dockets/dailys/04/may04/050604/050604.htm> [accessed July 14, 2006].
- ^x Pharmacy Access Partnership. Legislation. 2007. Available at: www.go2ec.org/Legislation.htm, accessed October 25, 2007.
- ^{xi} Personal communication. Solmaz Shotorbani, University of Washington April 8, 2005 and Jacqueline Gardner, University of Washington, Department of Pharmacy, May 21, 2007.

Summary of Licensing Committee Meeting held on March 24, 2009



California State Board of Pharmacy

1625 N. Market Blvd., N219, Sacramento, CA 95834

Phone (916) 574-7900

Fax (916) 574-8618

www.pharmacy.ca.gov

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

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

DATE: March 24, 2009

LOCATION: First Floor Hearing Room
Department of Consumer Affairs
Sacramento, CA 95834

**BOARD MEMBERS
PRESENT:**

Stanley C. Weisser, RPh, Acting Chair
James Burgard, Public Member
Susan L. Ravnan, PharmD
Kenneth Schell, PharmD

**STAFF
PRESENT:**

Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Kristy Schieldge, DCA Staff Counsel
Tessa Fraga, Staff Analyst

Call to Order

Chair Weisser called the meeting to order at 10:04 a.m.

1. Emergency and Disaster Response Planning: EMS Authority Looking for Pharmacists and Other Health Care Volunteers

Chair Weisser provided that the Emergency Medical Services Authority (EMSA) has notified the board and other agencies that it is seeking service providers in three areas:

1. Maintenance of state-owned disaster readiness equipment and state-run warehouses
2. Management and deployment of licensed medical and support personnel for disaster response
3. Development and implementation of disaster response training program.

Chair Weisser explained that the intent is to identify if services are available to the State of California to provide a "turnkey" California Medical Assistance Team (CAL-MAT) program with readiness and response capabilities for disaster medical assistance personnel and equipment.

Chair Weisser indicated that EMSA may subsequently issue either a Request for Proposal (RFP), or an Invitation for Bid (IFB), or both, for various services to begin as early as July 1, 2009.

2. Review of the Professional Competency Statement for Pharmacy

Chair Weisser provided that the competency statement for pharmacy was created in 1969 when clinical pharmacy was under creation and there was no definition of what a pharmacist does. This statement was used by the board in part for what we use the CPJE content outline for: to develop test questions for the licensure examinations. This was used to construct exams prior to the advent of job analyses and content outlines which have been in use since the late 1980s.

Chair Weisser directed the committee to evaluate this statement with the following questions:

1. Does the board need the competency statement? Why?
2. If yes, does it need revision?

Committee Discussion:

Susan Ravnar indicated that the statement may still serve some benefit.

Kenneth Schell provided that the statement does not seem to be relevant in its current location. He indicated that the statement may be a better fit in an alternative location. Dr. Schell stated that the statement could be reevaluated and possibly included on the board's website.

James Burgard commented that the statement is misplaced and seems to be more of a mission statement. He provided that the document is outdated and is not worth revising.

Kristy Schieldge, DCA Staff Counsel, expressed concern regarding the accuracy of the statement. She also provided that the statement may be constraining when trying to set standards of practice for a dynamic profession.

Motion: To remove the competency statement from the pharmacy lawbook and to discontinue its use.

M/S: JB/KS

Support: 4 Oppose: 0

3. National Association of Boards of Pharmacy's and Accreditation Council for Pharmacy Education's Confirmation of Appropriate Content for Continuing Education Provider Coursework

Chair Weisser provided that on March 12, 2009, the ACPE sent a letter advising all state boards of pharmacy with independent approval authority for continuing education to ensure that pharmacists receive balanced and independent continuing education.

Chair Weisser provided the following from this letter:

It has come to the attention of the Accreditation Council for Pharmacy Education (ACPE) and the National Association of Boards of Pharmacy (NABP) that some individual state-based continuing pharmacy education (CPE) approval processes of non-ACPE CPE that awards credit towards pharmacist relicensure has occurred for content that was commercial in nature (e.g. promotional talks, advisory board slides, pharmaceutical company speakers, etc.)

The ACPE advises that non-accredited CPE activities should be screened to ensure the aspects of the Office of Inspector General (OIG) and Standards for Commercial Support (SCS) guidance are maintained. Without the appropriate screening, state board approval processes could mistakenly allow credit for promotional materials and undermine the accreditation process, as well impact the pharmacist who received relicensure credit for those activities. ACPE and NABP acknowledge the need for independent state board approval processes to permit pharmacists to meet their individual continuing education and learning needs. However, during these times of heightened investigation and evaluation of educational influence for commercial gain, it is paramount that the state boards with independent approval processes implement safeguards to ensure their pharmacists receive balanced and independent education that is applied towards relicensure requirements.

Chair Weisser indicated that the Pharmacy Foundation of California, which is one of two approvers of pharmacist CE in California, has been advised.

4. Request for Board Recognition of a School of Pharmacy with Precandidate Status with the Accreditation Council for Pharmacy Education Pursuant to 16 CCR § 1719 – Jefferson School of Pharmacy, Philadelphia, PA

Chair Weisser provided that current regulation, Title 16 CCR §1719, states that a "recognized school of pharmacy" means a school accredited, or granted candidate status by the Accreditation Council for Pharmacy Education (ACPE).

Chair Weisser stated that Jefferson School of Pharmacy (JSP), Philadelphia, PA was granted Pre-Candidate status by the ACPE during its January 2008 meeting and the first class of students was admitted in the Fall of 2008. JSP is undergoing review by the ACPE during 2008/09 Review Period for advancement to Candidate accreditation status. Recently, the Jefferson School of Pharmacy requested board recognition of its program for purposes of issuing intern pharmacist licenses to students attending their program, but who may spend some time and work in CA.

Committee Discussion:

Ms. Herold provided that new schools of pharmacy are emerging throughout the US to meet the demand for pharmacists. She indicated that board staff has worked closely with ACPE to ensure proper accreditation standards for these schools.

Dr. Schell expressed concern regarding the requirement for two 15-week semesters during the first three years of the PharmD program and requested that board staff seek clarification.

Chair Weisser sought clarification regarding the board's authority under Title 16.

Ms. Schieldge responded that the board does have the authority to recognize and provide accreditation. She suggested that the board remain consistent and possibly define criteria for recognition within regulation.

Motion: To recognize the Jefferson School of Pharmacy, Philadelphia, PA, with its precandidate status with the Accreditation Council for Pharmacy Education for purposes of issuing intern permits as authorized in Business and Professions Code § 4208.

M/S: JB/KS

Support: 4 Oppose: 0

5. Assembly Bill 418 (Emmerson): Pharmacy Technician Qualifications

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

Chair Weisser provided a summary of events since that time including that on December 4, 2008, CSHP sponsored another stakeholder meeting. Discussion at this meeting revealed that there is still disagreement within industry about what and if there is a problem with the current existing pharmacy technician qualifications requirements as well as whether the draft legislative proposal correctly addresses the minimum qualifications. At that time, CSHP indicated that they may move forward with their legislative proposal, but scale back the requirements to apply to only pharmacy technicians working in the inpatient setting.

Chair Weisser also discussed AB 418 (Emmerson), which was introduced on February 23, 2009. Chair Weisser stated that this legislation will change the minimum qualifications for licensure as a pharmacy technician as well as require 20 hours of continuing education each renewal cycle.

Chair Weisser stated that existing law authorizes the board to issue a pharmacy technician license to an individual if that individual is a high school graduate or possesses a general educational development certificate equivalent and has either obtained a specified

associate's degree, completed a specified course of training, graduated from a specified school of pharmacy, or is certified by the Pharmacy Technician Certification Board.

Chair Weisser indicated that the bill would authorize the board to issue a pharmacy technician license to an individual if that individual is a high school graduate or possesses a general educational development certificate equivalent, passes a pharmacy technician examination recognized by the National Organization for Competency Assurance and approved by the board, and has either obtained a specified associate's degree, completed a course of training offered by a specified accredited program, or graduated from a specified school of pharmacy.

Chair Weisser provided that the bill identifies an effective date of January 1, 2011, and will also require a pharmacy technician to successfully complete 20 hours of approved courses of continuing pharmacy education (CE) during the 2-years preceding an application for renewal and exempts this requirement for the first renewal cycle. The bill also specifies the form and subject matter content for these CE courses and provides that a pharmacy technician license that is not renewed within 3-years after expiration may not be renewed and shall be canceled at the end of a 3-year period.

Chair Weisser explained that in its current form, the bill would automatically prohibit any application with a felony drug or pharmacy related conviction from seeking licensure. Board staff consulted with staff counsel, who expressed concern that the bill in its current form could constitute a de facto ban from licensure for those with a specified criminal background.

Chair Weisser provided that the bill author's intent is that the technician exam and the completion of an approved continuing education will better protect California consumers.

Committee Discussion:

Ms. Herold explained that the bill would have a fiscal and workload impact on the board.

Chair Weisser sought clarification regarding the legal requirements.

Ms. Schieldge explained that a testing requirement being added prohibits anyone with a felony conviction from taking the exam. She added that under current law, pharmacists can retain their license with a conviction deemed not to be substantially related to the profession or by demonstrating satisfactory rehabilitation. Ms. Schieldge provided that technicians will not have the same opportunity under the new bill.

Bob Ratcliff, Supervising Inspector, sought clarification on the status of technicians who do not complete CE.

Ms. Herold responded that the technician will go into inactive status.

Public Comment:

Bryce Docherty, representing CSHP, reported that CSHP has addressed some of the major philosophical issues with the bill. He added that the bill has some technical issues that will

be addressed. Mr. Docherty provided that the bill is heavily supported and will be heard in the Assembly Business and Professions Committee on March 31, 2009.

Lynn Rolston, representing California Pharmacists Association (CPhA), provided that the bill conforms with CPhA policy. She expressed concern regarding the bill's short timeline and the board's staffing and workload.

Ms. Herold responded that she does anticipate staffing to be an issue. She asked Ms. Schiedge to clarify if regulations will need to be developed to fulfill Section 4202 (a) within Section 3 of the bill.

Ms. Schiedge responded that a regulation is needed.

Discussion continued regarding requirements and necessary regulations.

Mr. Docherty provided that there will be implementation issues. He added that the implementation date is flexible in order to ensure that the process is effective.

Lorie Rice, representing the UCSF School of Pharmacy, expressed concern regarding accrediting bodies having the ability to provide continuing education. Ms. Rice questioned if this was the intent.

Mr. Docherty provided that the intent is to approve an entity to accredit training programs. He indicated that it is the responsibility of the pharmacist technician to obtain continuing education credits in a manner consistent with the bill's requirements.

Ms. Rice suggested that a provision be drafted to address the potential conflict of interest of the approving agency also providing CE.

Chair Weisser provided that the Legislation/Regulation Committee will be discussing this issue at a future meeting.

There was no addition committee or public comment.

6. ExCPT Examination For Pharmacy Technicians

Chair Weisser provided that Business and Professions Code Section 4202 specifies the requirements for licensure as a pharmacist technician in California. Specifically, an applicant must either be a high school graduate or possess a general education certificate equivalent as well as satisfy one of four qualification methods:

1. Possess an associate's degree in pharmacy technology.
2. Complete a course of training specified by the board in regulation.
3. Graduate from a school of pharmacy recognized by the board.
4. Be certified by the Pharmacy Technician Certification Board (PTCB).

Chair Weisser stated that in September 2006, this committee discussed this Exam for the Certification of Pharmacy Technicians (ExCPT). At that time, the board directed a review of the exam to determine if it is job-related. The ExCPT exam is a computer-based test used

to assess the knowledge of pharmacist technicians and is accredited by the National Commission for Certifying Agencies. The examination is accepted by several states as a qualifying method for licensure. The exam is being offered in all 50 states and there are currently 42 test sites available in California. Chair Weisser indicated that because of staffing changes with the Department's Office of Examination Resources as well as legislative proposals which would alter the licensing requirements for pharmacy technicians, this action was tabled.

More recently, board staff met with the Chief Executive Officer at her request to discuss the exam and provided technical input on the process for California law to allow use of this exam as one of the qualification methods for licensure, including an assessment of the exam for job-relatedness as well as a statutory change to B&PC 4202(a)(4).

Chair Weisser highlighted that AB 418 (Emmerson) would alter the requirements for licensure. In its current form, the bill would make the necessary statutory changes to allow the use of the ExCPT in addition to any other exam that is accredited, as specified. If this bill does not pass, as the board so chooses, the board would need to sponsor legislation to allow for the use of this exam.

Chair Weisser also discussed that the board would need an assessment of the examination for compliance with Section 139 of the Business and Professions Code and that board staff recommend that a similar assessment be conducted on the PTCB.

Committee Discussion:

Ms. Herold advised the committee not to take action on this item until more information is gathered.

Ms. Weisser indicated that the committee will not act on this issue at this time.

There was no additional committee discussion.

7. Issue Statement on Pharmacy Workforce Shortage by the California Hospital Association Workforce Committee, December 1, 2008

Chair Weisser provided that in mid-2008, the California Hospital Association (CHA) established a coalition to develop and implement strategic solutions to the shortage of non-nursing allied health professionals. This coalition was comprised of workforce committees, an advisory council and four workgroups. Board executive staff was invited to participate on the pharmacy services workgroup.

Chair Weisser referenced the issue statement provided and stated that the CHA report concludes that, although there has been an increase in the number of pharmacists educated within California over the prior few years, there continues to be a gap in the number of pharmacists that California will need.

Discussion indicated that it appears that the CHA used somewhat dated data regarding the number of pharmacists graduated. A footnote in CHA's report provided board statistics

showing that in fiscal year 2007-08, 2,061 applicants took the board's examination. Of these, 890 were graduates of California schools of pharmacy. Also, in fiscal year 2007-08, a total of 1,385 pharmacists were licensed.

Committee Discussion:

Dr. Ravnan questioned if data is available regarding licensees who have stayed in California to practice and was advised that it is not.

Public Comment:

David Smith expressed concern regarding possible errors and information provided in the report.

Ms. Herold offered to relay Mr. Smith's remarks to the CHA.

There was no additional committee or public comment.

8. US Department of Health and Human Services, Health Resources and Services Administration's Report: *The Adequacy of Pharmacist Supply: 2004-2030*

Chair Weisser stated that the board was provided with a copy of a Health and Human Services Agency report entitled: *The Adequacy of Pharmacist Supply 2004-2030*. This report presents a slightly less dire picture of the supply of future pharmacists than the California Hospital Association's Report; however both predict continued shortages of needed pharmacists.

Chair Weisser highlighted the conclusions from the report, as follows:

- The supply of pharmacists is growing significantly faster than was previously projected.
- The demand for pharmacists continues to grow.
- There is currently a moderate shortfall of pharmacists.
- The future supply of pharmacists is projected to grow at a rate similar to the projected growth in demand from changing demographics.
- Supply and demand are projected with a level of uncertainty. Only under an optimistic supply projection combined with a conservative demand projection is future supply adequate to meet demand.

9. Experiences of an Employer Recruiting Foreign-Trained Pharmacists for Work in the United States

Chair Weisser indicated that documentation of workforce shortages continues to emerge. With a limited number of pharmacy schools in the US and a rising demand for pharmacist services, one potential recruitment source are foreign-trained pharmacists. As recently as the November 2008 Pact Summit, the Department of Consumer Affairs encouraged all attendees to consider foreign-trained professionals to address shortages.

Chair Weisser summarized the requirements for licensure, indicating such individuals must be certified by the Foreign Pharmacy Graduate Examination Committee (FPGEC) before applying for a license in California. The certification process through the FPGEC includes passing the Foreign Pharmacy Graduate Equivalency Examination (FPGEE); passing the Test of Spoken English (TSE) and Test of English as a Foreign Language (TOEFL) or iBT TOEFL; and evaluation by the FPGEC of educational curriculum and foreign licensure requirements of each applicant.

In addition, the board is required by law to collect a social security number prior to the issuance of any license.

Presentation to the Committee:

Alan Pope and Kim Guggiana (Safeway):

Mr. Pope provided information regarding Safeway's foreign-trained pharmacist program to combat pharmacist shortages and to fill positions in less desirable areas. He indicated that the program recruits its participants primarily online from India, the Philippines, South Africa, Korea, and Canada. Mr. Pope explained that the program offers assistance to its participants including legal counsel, paid relocation expenses, intern hours, guidance with the visa process, and help with obtaining a position after receiving a license.

Ms. Guggiana provided that the program is faced with several challenges including the number of available visas and costly wage requirements.

Ms. Guggiana indicated that the foreign-trained pharmacists have practiced in their country of origin. She added that despite Safeway's efforts to advertise and employ locally, there are many positions that are still not filled in less desirable areas.

Committee Discussion:

Chair Weisser sought clarification on the number of foreign graduates that have participated in the program and the retention rate.

Ms. Guggiana indicated that Safeway has brought 30-40 foreign graduates into California. She added that the program's retention rate is great and that most participants leave due to family needs, not to work for the competitor.

Chair Weisser asked how the program addresses language issues with its participants.

Mr. Pope provided that the applicants undergo a thorough hiring process. He added that the hires have performed exceptionally well.

Ms. Herold questioned if applicants are encountering any obstacles when obtaining a social security card.

Ms. Guggiana provided that it usually takes 2-4 weeks to obtain a social security card.

Discussion continued regarding the visa and social security card process.

Mr. Burgard commended Mr. Pope and Ms. Guggiana for their presentation.

Public Comment:

David Smith expressed concern regarding the cost per hire, retention rate, and applicant certification.

There was no additional committee or public comment.

10. Pharmacy Access Partnership's Request to Establish a Hormonal Contraception Pilot in Pharmacies

Chair Weisser provided that the Pharmacy Access Partnership is seeking to provide patients with greater pharmacy access to hormonal contraception. To establish support for this practice, they propose a study under the aegis of the board.

The Pharmacy Access Partnership proposes a pilot to establish practice protocols where physicians and pharmacists would collaborate in writing protocols to allow pharmacists in a community pharmacy to provide limited supplies (up to one year) of oral contraceptives, contraceptive patches and vaginal rings, to women who come into the pharmacy and meet the screening criteria. If the pilot is successful, they propose seeking statutory authority to allow such programs permanently.

The request is based on 16 CCR § 1706.5 which allows the board to waive specified provisions of regulations (Title 16) to an accredited school of pharmacy recognized by the board for purposes of an experimental plan or program. However, the board does not have the authority to waive statute (laws enacted by the Legislative).

Presentation to the Committee:

Sharon Landau (Pharmacy Access Partnership) and Belle Taylor-McGhee (Pacific Institute for Women's Health):

Ms. Landau provided that the Pharmacy Access Partnership has been working with a group of high-level experts and interested stakeholders to explore the potential for developing a pharmacy access hormonal contraception model in California, building upon the successes and lessons learned from a pharmacist-initiated provision of a hormonal contraception pilot in Washington State. The goal is to increase capacity for contraceptive access at the pharmacy to better meet women's healthcare needs.

Ms. Landau indicated that the Pharmacy Access Partnership is requesting the board to allow this pilot to use a protocol similar to pharmacist immunization services whereby a protocol between a pharmacist and a physician permits the application of the protocol for qualifying women who want to get hormonal contraception from the pharmacist directly for a set period of time. She provided that the Pharmacy Access Partnership is seeking a waiver for the "prior diagnosis" portion of such a protocol. Further, she stated that since a request

for hormonal contraception does not require a "diagnosis," the need for a prior relationship between a provider and patient is not relevant.

Ms. Taylor-McGhee provided that recent action to lift restrictions on Medicare Plan B and access to emergency contraceptives increases the need to expand and ensure access to contraception overall.

Committee Discussion:

Dr. Ravnan sought clarification on the standards of care.

Ms. Landau responded that the standards of care have changed. She provided that healthy women require a pelvic exam every 2-3 years. Mrs. Landau indicated that the program receives support from a collaboration of medical physicians.

Dr. Schell questioned if the Medical Board has been approached to participate in the program.

Ms. Landau responded that the partnership has not specifically approached the Medical Board. She added that they are working with organized medicine and various physicians.

Ms. Schieldge provided that the board can not implement the proposal through regulation and indicated that a statutory amendment is required.

Ms. Herold suggested that the Pharmacy Access Partnership implement a patient specific protocol. She also recommended that they discuss their program with potential authors of pharmacy-related bills.

Public Comment:

Ms. Rice sought clarification on whether a pilot program can be implemented under the jurisdiction of a research study with a university. She stated that the pilot program is a great opportunity to expand the scope of practice and increase women's access to emergency contraception.

Ms. Herold responded that authority is required.

Dr. Schell provided that the support of the Medical Board will increase the likelihood of implementing a pilot program.

There was no additional committee or public comment.

11. Competency Committee Report

Chair Weisser provided that the Competency Committee workgroups have met earlier this year and focused on examination development and item writing and additional workgroup meetings are scheduled throughout the year.

Chair Weisser stated that the committee will also begin to develop a job survey to be used to complete an occupational analysis with the board's contracted psychometric firm. Pursuant to Business and Professions Code section 139, the board is required to complete an occupational analysis periodically which serves as the basis for the examination. It is anticipated that distributing the survey to a random sample of pharmacists will begin before the end of year. The information learned from this survey will determine if changes are necessary to the content outline of the CPJE.

12. Public Comment for Items Not on the Agenda

David Smith expressed concern regarding new graduates and PIC qualifications. He also suggested that the board address the licensure process to ensure a more timely and effective procedure.

There was no additional public comment.

The meeting was adjourned at 11:42 p.m.

THIRD QUARTERLY REPORT ON LICENSING COMMITTEE GOALS FOR 2008/09

LICENSING COMMITTEE

Goal 2: Ensure the qualifications of licensees.

Outcome: Qualified licensees

Objective 2.1	Issue licenses within three working days of a completed application by June 30, 2011.								
Measure:	Percentage of licenses issued within three 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)	462	337	293		20	9	15	
	Pharmacist (initial licensing)	507	512	245		4	2	3	
	Pharmacy Intern	702	643	314		11	10	14	
	Pharmacy Technician	2198	1837	2184		26	29	38	
	Pharmacies	110	583	79		19	15	30	
	Non-Resident Pharmacy	23	26	19		24	20	30	
	Wholesaler	26	12	13		20	17	30	
	Veterinary Drug Retailers	1	1	0		14	0	0	
	Designated Representative	115	112	97		30	17	15	
	Out-of-state distributors	21	29	22		25	17	30	
	Clinics	27	18	21		32	30	30	
	Hypodermic Needle & Syringe Distributors	8	7	8		14	5	15	
	Sterile Compounding	15	12	12		14	14	15	
	Change of Permit	235	264	291		U/A	U/A	156	
Pharmacist in Charge	246	445	355		26	26	28		
Designated Representative in Charge	5	12	8		34	38	29		
Discontinuance of Business	13	81	94		21	86	46		

2. Process 100 percent of all deficiency documents within five work days of receipt.

	Average Days to process deficiency:			
	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist (exam applications)	7	7	7	
Pharmacist (initial licensing)	7	7	7	
Pharmacy Intern	8	8	8	
Pharmacy Technician	8	10	10	
Pharmacies	15	14	21	
Non-Resident Pharmacy	20	17	17	
Wholesaler	14	14	14	
Veterinary Drug Retailers	14	0	0	
Designated Representative	10	14	7	
Out-of-state distributors	14	14	14	
Clinics	15	14	15	
Hypodermic Needle & Syringe	14	14	7	

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

	Average Days to Determine to Deny/Issue License:			
	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist (exam applications)	1	1	1	
Pharmacist (initial licensing)	1	1	1	
Pharmacy Intern	1	1	1	
Pharmacy Technician	5	5	5	
Pharmacies	10	5	3	
Non-Resident Pharmacy	5	5	5	
Wholesaler	5	3	5	
Veterinary Drug Retailers	3	0	0	
Designated Representative	2	2	2	
Out-of-state distributors	5	3	5	
Clinics	5	5	2	
Hypodermic Needle & Syringe	3	2	2	

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	526	504	241	
Pharmacy Intern	652	651	248	
Pharmacy Technician	2,008	1,695	1,577	
Pharmacies	121	542	61	
Non-Resident Pharmacy	16	27	20	
Wholesaler	14	9	5	
Veterinary Drug Retailers	0	0	4	
Designated Representative	97	126	93	
Out-of-state distributors	13	18	25	
Clinics	28	9	13	
Hypodermic Needle & Syringe	4	7	3	
Sterile Compounding	17	27	10	

5. Withdrawn licenses to applicants not meeting board requirements.

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacy Technician	0	0	70	
Pharmacies	0	1	1	
Non-Resident Pharmacy	0	1	7	
Clinics	0	0	44	
Sterile Compounding	0	0	0	
Designated Representative	0	5	0	
Hypodermic Needle & Syringe	0	0	1	
Out-of-state distributors	0	5	6	
Wholesaler	0	1	2	
Veterinary Drug Retailers	0	0	2	

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

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacy Technician	8	11	26	
Pharmacies	0	0	0	
Non-Resident Pharmacy	0	0	0	
Clinics	0	0	0	
Sterile Compounding	0	0	0	
Designated Representative	1	0	0	
Hypodermic Needle & Syringe	0	0	0	
Out-of-state distributors	0	0	0	
Wholesaler	0	0	0	

7. Responding to e-mail status requests and inquiries to designated e-mail addresses.

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist/Pharmacist Intern	1,055*	901	1,012	
Pharmacy Technicians	747*	876**	1,176	
Site licenses (pharmacy, clinics)	625	695	840	
Site licenses (wholesalers, nonresident pharmacies)	516	1056	667	
Pharmacist in Charge	***	91	***	
Renewals	238	210	427	

8. Responding to telephone status request and inquiries.

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist/Pharmacist Intern	94*	101**	109	
Pharmacy Technicians	69*	67	140	
Site licenses (pharmacy, clinics)	76	103	141	
Site licenses (wholesalers, nonresident pharmacies)	126	155	243	
Pharmacist in Charge	***	12	***	
Renewals	12	U/A	38	

* E-mail and voicemail status requests for pharmacist, pharmacist intern and pharmacy technician were suspended from 8/8/08-9/8/08 to allow board staff time to focus on processing applications and issuing licenses. E-mail status requests for pharmacist, pharmacist intern and pharmacy technician were suspended from 10/2/08 to 10/20/08 to allow board staff time to focus on processing applications and issuing licenses.

** E-mail/Voicemail on hold 10/4/08 - 10/20/08

*** Included in sites (PHY, CLN)

Objective 2.2	Cashier 100 percent of all revenue received within two working days of receipt by June 30, 2011.																																																																																
Measure:	Percentage of revenue cashiered application within 2 working days.																																																																																
Tasks:	<table border="1"> <thead> <tr> <th data-bbox="370 367 597 409"></th> <th colspan="4" data-bbox="597 367 1128 409">Revenue Received:</th> <th colspan="4" data-bbox="1128 367 1497 409">Average Days to Process:</th> </tr> <tr> <th data-bbox="370 409 597 451"></th> <th data-bbox="597 409 727 451">Qtr 1</th> <th data-bbox="727 409 857 451">Qtr 2</th> <th data-bbox="857 409 987 451">Qtr 3</th> <th data-bbox="987 409 1128 451">Qtr 4</th> <th data-bbox="1128 409 1226 451">Qtr 1</th> <th data-bbox="1226 409 1323 451">Qtr 2</th> <th data-bbox="1323 409 1421 451">Qtr 3</th> <th data-bbox="1421 409 1497 451">Qtr 4</th> </tr> </thead> <tbody> <tr> <td data-bbox="370 451 597 493">Applications</td> <td data-bbox="597 451 727 493">471,599</td> <td data-bbox="727 451 857 493">668,139</td> <td data-bbox="857 451 987 493">360,965</td> <td data-bbox="987 451 1128 493"></td> <td data-bbox="1128 451 1226 493">2-3</td> <td data-bbox="1226 451 1323 493">2-3</td> <td data-bbox="1323 451 1421 493">2-3</td> <td data-bbox="1421 451 1497 493"></td> </tr> <tr> <td data-bbox="370 493 597 535">Renewals</td> <td data-bbox="597 493 727 535">2,297,253</td> <td data-bbox="727 493 857 535">1,529,994</td> <td data-bbox="857 493 987 535">1,962,244</td> <td data-bbox="987 493 1128 535"></td> <td data-bbox="1128 493 1226 535">2-3</td> <td data-bbox="1226 493 1323 535">2-3</td> <td data-bbox="1323 493 1421 535">2-3</td> <td data-bbox="1421 493 1497 535"></td> </tr> <tr> <td data-bbox="370 535 597 577">Cite and Fine</td> <td data-bbox="597 535 727 577">359,300</td> <td data-bbox="727 535 857 577">247,225</td> <td data-bbox="857 535 987 577">210,163</td> <td data-bbox="987 535 1128 577"></td> <td data-bbox="1128 535 1226 577">2-3</td> <td data-bbox="1226 535 1323 577">2-3</td> <td data-bbox="1323 535 1421 577">2-3</td> <td data-bbox="1421 535 1497 577"></td> </tr> <tr> <td data-bbox="370 577 597 661">Probation/ Cost Recovery</td> <td data-bbox="597 577 727 661">23,397</td> <td data-bbox="727 577 857 661">47,193</td> <td data-bbox="857 577 987 661">22,751</td> <td data-bbox="987 577 1128 661"></td> <td data-bbox="1128 577 1226 661">2-3</td> <td data-bbox="1226 577 1323 661">2-3</td> <td data-bbox="1323 577 1421 661">2-3</td> <td data-bbox="1421 577 1497 661"></td> </tr> <tr> <td data-bbox="370 661 597 724">Request for Information/ License Verification</td> <td data-bbox="597 661 727 724">3,390</td> <td data-bbox="727 661 857 724">4,750</td> <td data-bbox="857 661 987 724">3,520</td> <td data-bbox="987 661 1128 724"></td> <td data-bbox="1128 661 1226 724">2-3</td> <td data-bbox="1226 661 1323 724">2-3</td> <td data-bbox="1323 661 1421 724">2-3</td> <td data-bbox="1421 661 1497 724"></td> </tr> <tr> <td data-bbox="370 724 597 766">Fingerprint Fee</td> <td data-bbox="597 724 727 766">17,208</td> <td data-bbox="727 724 857 766">17,529</td> <td data-bbox="857 724 987 766">20,623</td> <td data-bbox="987 724 1128 766"></td> <td data-bbox="1128 724 1226 766">2-3</td> <td data-bbox="1226 724 1323 766">2-3</td> <td data-bbox="1323 724 1421 766">2-3</td> <td data-bbox="1421 724 1497 766"></td> </tr> </tbody> </table>										Revenue Received:				Average Days to Process:					Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Applications	471,599	668,139	360,965		2-3	2-3	2-3		Renewals	2,297,253	1,529,994	1,962,244		2-3	2-3	2-3		Cite and Fine	359,300	247,225	210,163		2-3	2-3	2-3		Probation/ Cost Recovery	23,397	47,193	22,751		2-3	2-3	2-3		Request for Information/ License Verification	3,390	4,750	3,520		2-3	2-3	2-3		Fingerprint Fee	17,208	17,529	20,623		2-3	2-3	2-3	
	Revenue Received:				Average Days to Process:																																																																												
	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4																																																																									
Applications	471,599	668,139	360,965		2-3	2-3	2-3																																																																										
Renewals	2,297,253	1,529,994	1,962,244		2-3	2-3	2-3																																																																										
Cite and Fine	359,300	247,225	210,163		2-3	2-3	2-3																																																																										
Probation/ Cost Recovery	23,397	47,193	22,751		2-3	2-3	2-3																																																																										
Request for Information/ License Verification	3,390	4,750	3,520		2-3	2-3	2-3																																																																										
Fingerprint Fee	17,208	17,529	20,623		2-3	2-3	2-3																																																																										

Objective 2.3	Update 100 percent of all information changes to licensing records within five working days by June 30, 2011.																																																					
Measure:	Percentage of licensing records changes within five working days.																																																					
Tasks:	<table border="1"> <thead> <tr> <th rowspan="2"></th> <th colspan="4">Requests Received:</th> <th colspan="4">Average Days to Process:</th> </tr> <tr> <th>Qtr 1</th> <th>Qtr 2</th> <th>Qtr 3</th> <th>Qtr 4</th> <th>Qtr 1</th> <th>Qtr 2</th> <th>Qtr 3</th> <th>Qtr 4</th> </tr> </thead> <tbody> <tr> <td>Address/Name Changes</td> <td>1,922</td> <td>1,446</td> <td>1,436</td> <td></td> <td>2</td> <td>3</td> <td>3</td> <td></td> </tr> <tr> <td>Discontinuance of Businesses</td> <td>13</td> <td>81</td> <td>94</td> <td></td> <td>21</td> <td>86</td> <td>46</td> <td></td> </tr> <tr> <td>Off-site Storage Applications (approved)</td> <td>18</td> <td>41</td> <td>32</td> <td></td> <td>30</td> <td>30</td> <td>120</td> <td></td> </tr> <tr> <td>Transfer of Intern Hours to Other States</td> <td>28</td> <td>31</td> <td>37</td> <td></td> <td>30</td> <td>30</td> <td>30</td> <td></td> </tr> </tbody> </table>		Requests Received:				Average Days to Process:				Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Address/Name Changes	1,922	1,446	1,436		2	3	3		Discontinuance of Businesses	13	81	94		21	86	46		Off-site Storage Applications (approved)	18	41	32		30	30	120		Transfer of Intern Hours to Other States	28	31	37		30	30	30	
	Requests Received:				Average Days to Process:																																																	
	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4																																														
Address/Name Changes	1,922	1,446	1,436		2	3	3																																															
Discontinuance of Businesses	13	81	94		21	86	46																																															
Off-site Storage Applications (approved)	18	41	32		30	30	120																																															
Transfer of Intern Hours to Other States	28	31	37		30	30	30																																															

Objective 2.4	Implement at least 25 changes to improve licensing decisions by June 30, 2011.
Measure:	Number of implemented changes.
Tasks:	<ol style="list-style-type: none"> <li data-bbox="370 218 1487 285">1. Determine why 26 states do not allow the use of a CA license as the basis for transfer of pharmacist license to that state. <i>Jan. 2007:</i> Survey of some states indicate misunderstanding of why California cannot accept NAPLEX scores earned before January 1, 2004. Educational efforts, on a state by state basis, initiated. <i>March 2007:</i> Pennsylvania agrees to accept California NAPLEX scores. <i>May 2007:</i> At National Association of Boards of Pharmacy meeting several states agree to reconsider their position against accepting California scores. <li data-bbox="370 516 1414 548">2. Evaluate the drug distribution system of clinics and their appropriate licensure. <li data-bbox="370 554 1471 585">3. Work with the Department of Corrections on the licensure of pharmacies in prisons. <i>June 2007:</i> Meet with the Department of Corrections Receiver to discuss possible regulatory structures for drug dispensing and distribution within correctional facilities. <i>Oct. 2008:</i> Board staff meet with Department of Corrections staff to develop regulatory structure for prisons. <i>Dec. 2008:</i> Met with receiver for correctional facilities to discuss regulatory structure. <li data-bbox="370 816 1479 919">4. Work with local and state officials on emergency preparedness and planning for pandemic and disasters. Planning to include the storage and distribution of drugs to assure patient access and safety. <i>Sept. 2006:</i> Committee hears presentation by DHS on emergency preparedness. <i>Oct. 2006:</i> Presentation by Orange County and L.A. emergency response staff at NABP District 7 & 8 meeting. Board meeting has presentation by DHS and board develops policy statement for licensees in responding to declared emergencies. <i>Jan. 2007:</i> Board publishes disaster response policy statement. <i>Feb. & March 2007:</i> Board attends seven-day DHS-hosted training session on SURGE emergency response as part of the state's disaster response. <i>April - June 2007:</i> Board continues to participate in SURGE planning activities and in a joint public/private partnership project envisioned by the Governor. <i>June 2007:</i> Board staff aids in contract evaluation to select a consultant to provide pre-emergency registration of health care providers. <i>Sept. 2007:</i> Board attends Rough & Ready Demonstration in Orange County. <i>Oct. 2007:</i> Board considers legislative proposal to license mobile pharmacies for deployment during declared disasters. Staff resume attendance at ESAR VHPs meeting of EMSA. Board activates disaster response policy to allow rapid response to patients affected by California wild fires. Use of subscriber alerts proves effective in conveying board messages to licensees in effected areas. <i>Dec. 2007:</i> Committee hears presentations on emergency preparedness by California Department of Public Health, L.A. County and Orange County emergency response offices. Focus continues on getting pharmacists prescreened and registered for disaster response. Discussion also includes lessons learned during California wild fires, ESAR-VHPS, renamed California medical volunteers, readied for widespread promotion by January 1, 2008 by EMSA.

	<p>Oct. 2008: <i>Licensing Committee reviews a revised request from San Diego County for an exemption of first responders and families. The Committee directs board staff send a letter to San Diego County expressing concerns and requesting attendance at a future committee meeting. Committee was advised ESAR-VHPS was renamed to Disaster Healthcare Volunteers of California.</i></p> <p>Jan. 2009: <i>Board hears presentation from San Diego County on proposal. Board staff offer an alternative solution, which is acceptable to San Diego County.</i></p> <p>5. Evaluate the need to issue a provisional license to pharmacy technician trainees.</p> <p>6. Evaluate use of a second pharmacy technician certification examination (ExCPT) as a possible qualifying route for registration of technicians.</p> <p>Sept. 2006: <i>Committee hears presentation on ExCPT exam approved for certification of technicians by five states. Committee directs staff to evaluate exam for possible use in California.</i></p> <p>Dec. 2006: <i>DCA recruiting for Chief of Examination Resources Office; review postponed. Additional methods to accomplish review considered.</i></p> <p>March 2007: <i>DCA recruiting for Chief of Examination Resources Office; review postponed. Additional methods to accomplish review considered.</i></p> <p>May 2007: <i>Board seeks private contractor to evaluate both ExCPT and PTCB exams for job validity.</i></p> <p>Sept. 2007: <i>Board required to check with other state agencies to ensure that state-employed PhD psychometricians are not able to perform this review before the board can contract for services. Committee recommends delay until CSHP and CPhA complete their review of pharmacy technician training and knowledge.</i></p> <p>Oct. 2007: <i>Board postpones work on this topic until CSHP and CPhA complete their review.</i></p> <p>March 2009: <i>Board executive staff meet with the executive director of the ExCPT exam.</i></p> <p>7. Review requirements for qualifications of pharmacy technicians with stakeholders</p> <p>4th Qtr. 07/08: <i>Future work on the training of technicians will occur as joint activities of the pharmacist associations. Legislation to require an exam and continuing education for pharmacy technicians is dropped (AB 1947) Board participates in CSHP sponsored stake holder meeting.</i></p> <p>2nd Qtr. 08/09: <i>Executive officer participates in a meeting with CPhA and CSHP to provide technical advice on proposed legislation to be introduced next year. Attend CSHP sponsored stakeholder meeting.</i></p> <p>3rd Qtr. 08/09: <i>Senate Bill 418 introduced to add new requirements for technicians.</i></p>
--	--

8. **Implement the Department of Consumer Affairs Applicant Tracking System to facilitate implementation of I-Licensing system, allowing online renewal of licenses by 2008.**
 - July 2006: Board executive officer becomes executive sponsor of program.*
 - Nov. 2006: Board completes system identification of parameters for each licensing program.*
 - Dec. 2006-Jan. 2007: Preparatory work and pilots completed; Board Staff initiates transfer to ATS system as sole platform for applicant tracking for all licensing programs.*
 - 3rd Qtr 08/09: Request for Proposal for I-Licensing system modified to contain revised parameters. Staff changes in the Office of Information Services cause additional delay in moving the project forward.*
9. **Participate with California's Schools of Pharmacy in reviewing basic level experiences required of intern pharmacists, in accordance with new ACPE standards.**
 - 3rd Qtr 06/07: Board attends 3 day-long working sessions convened by California's schools of pharmacy to develop list of skills students should possess by end of basic intern level experience (about 300 hours).*
 - Oct. 2007: Board considers basic internship competencies developed under the program and develops letter of support.*
 - Oct. 2008: California Pharmacy Council meets to discuss Intern requirements.*
10. **Implement new test administration requirements for the CPJE.**
 - March 2007: Board advised about new exam vendor for CPJE effective June 1, 2007. Board notifies all CPJE eligible candidates of pending change, advises California schools of pharmacy graduating students and applicants in general.*
 - June 2007: Shift to new exam vendor, PSI, takes place. New Candidates Guide is printed and distributed. Some transition issues to new vendor exist and are being worked on.*
 - Oct. 2007: Transition efforts to PSI continue.*
 - 2nd Qtr. 07/08: Transition efforts to PSI continue.*
 - 3rd Qtr. 07/08: New security procedures put in place and corresponding revisions to the Candidates' Guide are published and released.*
 - 3rd Qtr. 08/09: Board participates in three ACPE reviews of the schools of pharmacy at USC, Touro and California Northstate.*
11. **Participate in ACPE reviews of California Schools of Pharmacy.**
 - Oct. 2007: Board participates in review of California Northstate College of Pharmacy.*
 - Jan. 2008: Board participates in review of UCSF.*
 - March 2008: Board participates in review of Touro.*
12. **Initiate Review of Veterinary Food Animal Drug Retailer Designated Representative Training.**
 - Sept. 2007: Licensing Committee initiates review of training requirements for Designated Representatives and notes problems with unavailability 40-hour course specified in board regulations.*
 - Oct. 2007: Board evaluates options for training of designated representatives.*
 - Sept. 2008: Licensing Committee hears testimony regarding program.*
13. **Convene Committee to evaluate drug distribution within hospitals.**
 - 2nd Qtr. 08/09: Executive Officer presents information at CSHP Seminar on failure of the recall system to remove Heparin from nearly 20% of California hospitals months after recall.*
 - 3rd Qtr. 08/09: Board establishes subcommittee to initiate review.*
 - March 2009: First meeting convened.*