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

Contact Person: Patricia Harris
(916) 445-5014

LICENSING COMMITTEE MEETING

Hilton Burbank Airport & Convention Center
2500 Hollywood Way
Burbank, CA 91505-1019
(818) 843-6000

June 15, 2005
9:30 a.m. – 3:30 p.m.
Celebration/Gala Room

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Candy Place at telephone number (916) 445-5014, at least 5 working days prior to the meeting. Opportunities are provided to the public to address the committee on each agenda item. Board members who are not on the committee may also attend and comment.

A.	Call to Order	**9:30 a.m.**
B.	Proposed Statutory Changes to the Licensure and Regulation of Clinics (B&P Code sec. 4180 –4186) and Surgical Clinics (B & P Code sec. 4190-4195)	
C.	Announcement by the National Association of Boards of Pharmacy (NABP) of the Pharmacist Assessment Mechanism (PSAM)	
D.	Announcement by the Accreditation Council for Pharmacy Education (ACPE) that Drug and Device Manufacturers Are No Longer Recognized as ACPE Accredited CE Pharmacy Providers	
E.	Request from Department of Health Services to Update Letter to All Pharmacists Regarding Infusion Services/Suites	
F.	Competency Committee Report -- Licensure of New Pharmacists, Status of New Contract for CPJE Administration and Appointment of New Committee Members	
G.	Development of Proposal for Pharmacist Performing Drug Utilization Review (DUR), Medication Therapy Management, Pharmacist Call Centers and Central Processing of Prescriptions for California Patients	**10:30 a.m.**
Lunch		**12:30 p.m.**
Adjournment		**3:30 p.m.**

Meeting materials will be on the board's Web site by June 8, 2005

AGENDA ITEM B

State of California **Department of Consumer Affairs**

Memorandum

To: **Licensing Committee** **Date: June 7, 2005**

From: Anne Sodergren
Staff Services Manager
Board of Pharmacy

Subject: Recommendation to Revise Clinic Licensing Program

A clinic license issued by the board allows for the purchase of drugs at wholesale and allows for the commingling of dangerous drugs and devices that are then dispensed by authorized prescribers. Without a clinic license, a physician must maintain separate drug stock.

At the March 16, 2005 Licensing Committee Meeting, a draft of proposed language was reviewed and comments elicited from attendees. In addition, written comments were submitted from interested parties unable to attend this meeting. The attached language is a result of the collaborative input received.

Below is a brief description of each of the changes.

Business and Professions Code Section (B & P) 4180

- Changes the records retention from seven years to three years consistent with pharmacy record retention requirement.
- Changes the language to allow the board to change the location of a clinic license without issuing a new clinic license (change of permit).
- Requires the addition or deletion of a member of the Board of Directors of a tax-exempt clinic's non-profit corporation.

B & P 4181

- Removes the requirement to detail the method used to develop the policies and procedures.

B & P 4182

- Requires the consulting pharmacist to certify in writing quarterly if the clinic is operating in compliance with pharmacy law. These certifications shall be retained for three years.
- Changes the meaning of a professional director to include a dentist or podiatrist.
- Requires notification of a change in professional director.

B & P 4190

- Changes the records retention from seven years to three years.
- Changes the language to allow the board to change the location of a clinic license without issuing a new clinic license.
- Requires any change in ownership to be reported to the board.

B & P 4191

- Removes the requirement to detail the method used to develop the policies and procedures.

B & P 4192

- Requires the clinic to retain a consulting pharmacist to review the policies and procedures.
- Requires the consulting pharmacist to certify in writing quarterly if the clinic is operating in compliance with pharmacy law. These certifications shall be retained for three years.
- Defines "professional director."
- Requires notification of a change in professional director.

The proposed language is currently under review. Any written comments received in advance of the meeting will be provided on June 15, 2005.

Article 13- Nonprofit or Free Clinics

4180. (a) (1) Notwithstanding any provision of this chapter, any of the following clinics may purchase drugs at wholesale for administration or dispensing, under the direction of a physician, to patients registered for care at the clinic:

(A) A licensed nonprofit community clinic or free clinic as defined in paragraphs (1) and (2) of subdivision (a) of Section 1204 of the Health and Safety Code.

(B) A primary care clinic owned or operated by a county as referred to in subdivision (b) of Section 1206 of the Health and Safety Code.

(C) A clinic operated by a federally recognized Indian tribe or tribal organization as referred to in subdivision (c) of Section 1206 of the Health and Safety Code.

(D) A clinic operated by a primary care community or free clinic, operated on separate premises from a licensed clinic, and that is open no more than 20 hours per week as referred to in subdivision (h) of Section 1206 of the Health and Safety Code.

(E) A student health center clinic operated by a public institution of higher education as referred to in subdivision (j) of Section 1206 of the Health and Safety Code.

(F) A nonprofit multispecialty clinic as referred to in subdivision (l) of Section 1206 of the Health and Safety Code.

(2) The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of ~~seven~~ three years for inspection by all properly authorized personnel.

(b) No clinic shall be entitled to the benefits of this section until it has obtained a license from the board. ~~Each license shall be issued to a specific clinic and for a specific location.~~ A separate license shall be required for each of the clinic sites owned and operated by a single county, tribe or tribal organization, non-profit corporation or public institution of higher education. A clinic that changes location, shall notify the board of the change of address on a form provided by the board.

(c) The addition or deletion of a member of the Board of Directors of a tax-exempt clinic's non-profit corporation shall be reported to the board within 30 days on a from to be furnished by the Board.

4181. (a) Prior to the issuance of a clinic license authorized under Section 4180, the clinic shall comply with all applicable laws and regulations of the State Department of Health Services relating to the drug distribution service to insure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation occur in a manner that is consistent with the promotion and protection of the health and safety of the public. The policies and procedures to implement the laws and regulations shall be developed and approved by the consulting pharmacist, the professional director, and the clinic administrator.

~~(b) These policies and procedures shall include a written description of the method used in developing and approving them and any revision thereof.~~

(c) The dispensing of drugs in a clinic shall be performed only by a physician, a pharmacist, or other person lawfully authorized to dispense drugs, and only in compliance with all applicable laws and regulations.

4182. (a) Each clinic that makes an application for a license under Section 4180 shall show evidence that the professional director is responsible for the safe, orderly, and lawful provision of pharmacy services. In carrying out the professional director's responsibilities, a consulting pharmacist shall be retained to approve the policies and procedures in conjunction with the professional director and the administrator. In addition, the consulting pharmacist shall be required to visit the clinic regularly and at least quarterly. However, nothing in this section shall prohibit the consulting pharmacist from visiting more than quarterly to review the application of policies and procedures based on the agreement of all the parties approving the policies and procedures.

(b) The consulting pharmacist shall certify in writing ~~least twice a year~~ quarterly that the clinic is, or is not, operating in compliance with the requirements of this article, ~~and the most recent of those written certifications shall be submitted with the annual application for the renewal of a clinic license~~. Each written certification shall be kept on file in the clinic for three years after it is performed and shall include corrective actions recommended if appropriate.

(c) For the purposes of this article, "professional director" means a physician acting in his or her capacity as medical director or dentist or podiatrist acting in his or her capacity as a professional director in a clinic where only dental or podiatric services are provided.

(d) Any person who has obtained a license to conduct a clinic shall notify the board within 30 days of a change in professional director on a form provided by the board.

Article 14 – Surgical Clinics

4190. (a) Notwithstanding any provision of this chapter, a surgical clinic, as defined in paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code may purchase drugs at wholesale for administration or dispensing, under the direction of a physician, to patients registered for care at the clinic, as provided in subdivision (b). The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of ~~seven~~ three years for inspection by all properly authorized personnel.

(b) The drug distribution service of a surgical clinic shall be limited to the use of drugs for administration to the patients of the surgical clinic and to the dispensing of drugs for the control of pain and nausea for patients of the clinic. Drugs shall not be dispensed in an amount greater than that required to meet the patient' s needs for 72 hours. Drugs for administration shall be those drugs directly applied, whether by injection, inhalation, ingestion, or any other means, to the body of a patient for his or her immediate needs.

(c) No surgical clinic shall operate without a license issued by the board nor shall it be entitled to the benefits of this section until it has obtained a license from the board. ~~Each license shall be issued to a specific clinic and for a specific location.~~ A separate license shall be required for each of the premises of any person operating a clinic in more than one location.

(d) Any change in the proposed beneficial ownership interest shall be reported to the board within 30 days thereafter upon a form to be furnished by the board.

4191. (a) Prior to the issuance of a clinic license authorized under this article the clinic shall comply with all applicable laws and regulations of the State Department of Health Services and the board relating to drug distribution to insure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation are carried out in a manner that is consistent with the promotion and protection of the health and safety of the public. ~~These policies and procedures shall include a written description of the method used to develop, approve, and revise those policies and procedures.~~ The policies and procedures to implement the laws and regulations shall be developed and approved by the consulting pharmacist, the professional director, and clinic administrator.

(b) The dispensing of drugs in a clinic that has received a license under this article shall be performed only by a physician, a pharmacist, or other person lawfully authorized to dispense drugs, and only in compliance with all applicable laws and regulations.

4192. Each clinic that makes an application for a license under this article shall show evidence that the professional director is responsible for the safe, orderly, and lawful provision of pharmacy services. In carrying out the professional director's responsibilities, a consulting pharmacist shall be retained to approve the policies and procedures in conjunction with the professional director and the administrator. In addition, the consulting pharmacist shall be required to visit the clinic regularly and at least quarterly. However, nothing in this section shall prohibit the consulting pharmacist from visiting more than quarterly to review the application of policies and procedures based on the agreement of all the parties approving the policies and procedures.

(b) The consulting pharmacist shall certify in writing least quarterly that the clinic is, or is not, operating in compliance with the requirements of this article. Each written certification shall be kept on file in the clinic for three years after it is performed and shall include corrective actions recommended in appropriate.

(c) For the purposes of this article, "professional director" means a physician acting in his or her capacity as medical director or dentist or podiatrist acting in his or her capacity as a professional director in a clinic where only dental or podiatric services are provided.

(d) Any person who has obtained a license to conduct a clinic shall notify the board within 30 days of a change in professional director.

AGENDA ITEM C

News Release

FOR IMMEDIATE RELEASE

May 2, 2005

For more information contact:
Reneeta C. "Rene" Renganathan, Editorial Manager
847/391-4405; custserv@nabp.net

NABP Launches PSAM, Non-Punitive, Knowledge Evaluation Tool for Pharmacists

The National Association of Boards of Pharmacy® (NABP®) is pleased to announce that the Pharmacist Self-Assessment Mechanism™ (PSAM™) is now available. The PSAM is an evaluation tool intended to assist pharmacists in obtaining objective, non-punitive feedback on their knowledge base and is available on the Association's Web site at www.nabp.net.

"Today's escalating complexities of health care delivery systems and the evolving role of the pharmacist as the patients' medication expert make it increasingly important for pharmacists to participate in a formal lifelong learning program," explains NABP President Donna M. Horn. "The PSAM will greatly aid pharmacists as they endeavor to better serve their patients because it provides objective feedback on their knowledge base – an outcome that is often difficult for pharmacists attempting to evaluate themselves."

The PSAM, which is applicable to general pharmacy practitioners in all practice settings, consists of 100 multiple choice questions and is divided into three sections of equal length. Each section can be completed in as little as one hour, but a maximum of three hours per section is allowed. Pharmacists may take all three sections in one sitting, or complete one section at a time, but

(— more —)

once a section is begun it must be completed in its entirety. All three sections must be completed within 30 days of when pharmacists begin the first section. The fee for the PSAM is $75.

To benefit pharmacists and serve as a learning tool, the end of each section offers a feedback loop, which displays each question, the answer selected, the correct answer, a brief rationale, and a reference where more information relating to the topic may be obtained. Upon completion of the PSAM, pharmacists receive a Record of Completion indicating their name and date of completion.

As a non-punitive learning tool, the PSAM does not report scores to any person or group other than the pharmacist utilizing the PSAM. Once they have completed the mechanism, pharmacists will receive a confidential Achievement Report indicating the percentage of questions answered correctly in each of the five content areas as well as the overall percentage of questions answered correctly. The Achievement Report is separate from the Record of Completion and has no identifiers of the test taker.

The PSAM is one part of NABP's Continuing Professional Development (CPD) program, a cyclical process that includes five components: reflecting upon one's practice, conducting a learning needs assessment, developing a learning plan, implementing the learning plan, and evaluating the learning plan outcomes. As a component of CPD, the PSAM facilitates the general pharmacy practitioner's ability to conduct a needs assessment and develop a learning plan.

For more information about the PSAM, contact NABP's Customer Service Department at 847/391-4406 or via e-mail at custserv@nabp.net, or visit the Association's Web site at www.nabp.net.

NABP is the independent, international, and impartial Association that assists its member boards and jurisdictions in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health.

AGENDA ITEM D

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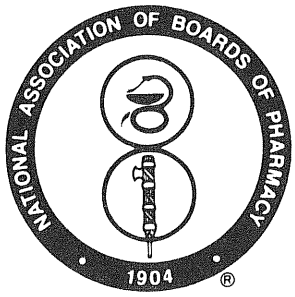

National Association of Boards of Pharmacy

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

TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: Charisse Johnson, Professional Affairs Manager

DATE: March 11, 2005

RE: Drug and Device Manufacturers No Longer Recognized as ACPE-Accredited Providers of Continuing Pharmacy Education

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In a press release issued in February 2004, the Accreditation Council for Pharmacy Education (ACPE) announced that it would no longer recognize pharmaceutical and device manufacturers as ACPE-accredited continuing education (CE) providers. ACPE has accredited certain pharmaceutical and biomedical device manufacturers as continuing education providers which, on paper, have met the ACPE Criteria for Quality and Interpretive Guidelines. However, ACPE, in carrying out its responsibilities to the boards, the profession and the public, must now accredit only those providers who are in compliance with ACPE criteria and the Office of the Inspector General (OIG) Compliance Program Guidance for Pharmaceutical Manufacturers (2003).

The guidance from OIG includes recommended restrictions in regard to CE programs sponsored by manufacturers. A manufacturer that maintains any influence over the subject matter of such programs or the presenters, or provides funding for attendees or other incentives with respect to the attendance of the CE program could potentially be subjected to liability under various federal statutory provisions. While these guidelines provide a safe harbor for manufacturers, strict compliance essentially relegates manufacturers solely to providing unencumbered educational grants to CE providers.

Therefore, after consultation with legal counsel, the ACPE Board of Directors approved the following at its January 2005 meeting:

(1) Commencing February 1, 2005, ACPE will not accept applications from pharmaceutical and biomedical device manufacturers seeking accreditation as providers of continuing education.

(2) Effective July 1, 2005, ACPE will not recognize pharmaceutical and biomedical device manufacturers as accredited providers. (This time frame was chosen to allow the organizations to complete any planned CE programs and permit adequate notice to these providers and pharmacists of ACPE's new policies regarding manufacturers as ACPE-accredited providers.)

Organizations with a commercial interest and any proprietary entity producing health care goods or services, with the exception of nonprofit or government organizations, and non-health care-related companies, will not be eligible for ACPE accreditation status. Furthermore, any organization with a commercial interest will not be able to engage in the co-sponsorship of relationship with an ACPE-accredited provider.

As a result, any statement of credit issued by a pharmaceutical or medical device manufacturer after June 30, 2005, will not be valid evidence of completion of ACPE-accredited CE. Manufacturers and ACPE will both be making efforts to communicate this action to all stakeholders, including pharmacists seeking accredited CE. Manufacturers still retain the ability to provide educational grants to ACPE-accredited providers within the confines of the OIG Guidelines.

ACPE has contacted all the accredited providers, that it knows to be pharmaceutical or medical device manufacturers and informed them directly of the Board's decision. Pharmaceutical or medical device manufacturers that have not been contacted by ACPE need to contact ACPE as soon as possible to ensure compliance with the Board's action.

If you have any questions regarding the above, please contact ACPE Executive Director Peter H. Vlasses, at 312/664-3575 or via e-mail at pvlasses@acpe-accredit.org.

Attachment

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

Accreditation Council for Pharmacy Education

NEWS RELEASE

RECEIVED
FEB 25 2005
By

Accreditation Council for Pharmacy Education (ACPE)
20 North Clark Street, Suite 2500
Chicago, Illinois 60602
United States of America
Tel: (312) 664-3575 Fax: (312) 664-4652
Contact: Peter H. Vlasses: pvlasses@acpe-accredit.org

FOR IMMEDIATE RELEASE
February 4, 2005

DRUG AND DEVICE MANUFACTURERS NO LONGER RECOGNIZED AS ACPE ACCREDITED CONTINUING PHARMACY EDUCATION PROVIDERS

At their January 2005 meeting, the Board of Directors of the Accreditation Council for Pharmacy Education (ACPE) took the following action based on the need for congruence between an Office of the Inspector General Guidance and ACPE Criteria:

1. Commencing February 1, 2005, ACPE will not accept applications from pharmaceutical and biomedical device manufacturers seeking accreditation as providers of continuing education (CE).

2. Effective July 1, 2005, ACPE will not recognize pharmaceutical and biomedical device manufacturers as accredited CE providers and they will not be able to engage in a co-sponsorship relationship with an ACPE-accredited provider.
   (This timeframe was chosen to allow the organizations to complete any planned CE programs and permit adequate notice to these providers and pharmacists of ACPE's new policies regarding manufacturers as CE providers).

As a result, any statement of CE credit issued by a pharmaceutical or medical device manufacturer after June 30, 2005, will not be valid evidence of completion of ACPE accredited CE. Manufacturers and ACPE both will make good faith efforts to communicate this action to all stakeholders, including pharmacists seeking accredited CE. Manufacturers still retain the ability to provide educational grants.

Basis for the Action

Over the past three years, the following guidance documents have been released regarding the role of pharmaceutical and biomedical device industries in CE for health professionals:

a. PhRMA (Pharmaceutical Research and Manufacturers of America) Code of Interactions with Healthcare Professionals (2002)

b. AdvaMed (Advanced Medical Technology Association) Code of Ethics on Interactions with Healthcare Professionals (2004)
c. Updated ACCME (Accreditation Council for Continuing Medical Education) Standards for Commercial Support (2004), and
d. Office of the Inspector General (OIG) Compliance Program Guidance for Pharmaceutical Manufacturers (2003)

The OIG guidance includes Compliance Program Guidance for Pharmaceutical Manufacturers, which provides recommended restrictions regarding CE programs sponsored by manufacturers. This Guidance notes that a manufacturer that maintains any influence over the subject matter of CE programs or the presenters, or provides funding for attendees or other incentives with respect to the attendance of the CE program potentially could be subjected to liability under various federal statutory provisions. While these guidelines provide a safe harbor for manufacturers, strict compliance essentially relegates manufacturers solely to providing unencumbered educational grants to CE providers.

The ACPE Criteria for Quality require the provider to control the content speakers or authors of a CE program. The OIG Guidelines provide that the manufacturer, with regard to continuing education, should have no control over the content or speakers/authors of CE programs. It follows that a manufacturer cannot meet both the ACPE criteria and the OIG Guidelines.

In the past, ACPE has accredited certain pharmaceutical and biomedical device manufacturers as continuing education providers, which, on paper, have met the *ACPE Criteria for Quality and Interpretive Guidelines*. However, ACPE, in carrying out its responsibilities to the boards, the profession and the public, must now accredit only those providers who are in compliance with ACPE criteria and the OIG guidelines.

ACPE is the national agency for accreditation of professional programs in pharmacy and providers of continuing pharmacy education and certificate programs in pharmacy. ACPE is an autonomous and independent agency whose Board of Directors (the decision and policy-making body) includes pharmacy educators, pharmacy practitioners, state board of pharmacy members/executives, and public representation. The ACPE office is located in Chicago, IL.

AGENDA ITEM E

State of California | Department of Consumer Affairs

Memorandum

To: Licensing Committee | Date: June 6, 2005

From: Patricia F. Harris
Executive Officer

Subject: **Infusion Services/Suites**

Attached is a letter that was jointly issued by the Department of Health Services (DHS) and Board of Pharmacy in 1997. The letter addresses whether or not a pharmacist who operates an infusion service or suite where patients receive intravenous drug therapy is exempt from licensure as a primary care clinic. Health and Safety Code section 1206(a) exempts from clinic licensure any place or establishment owned or leased and operated as a clinic or an office by one or more licensed health care practitioners for the practice of their profession within the score of their license.

It was determined that a pharmacist who operates an infusion suite or service and who contracts to provide these services to patients of a health care service plan is functioning under the scope of his or her license as a pharmacist. However, the pharmacist must comply with the protocol requirements set forth in Business and Professions Code section 4052. Since 1997, when the letter was first issued, Business and Professions Code section 4052 was changed.

DHS has requested that the Board of Pharmacy review this 1997 letter to determine if the board's interpretation is still the same and whether or not the letter should be updated. Since the letter was first issued in 1997, Business and Professions Code section 4052 has been changed. Using the board's previous interpretation, under current law, a pharmacist would be authorized to provide the infusion services to a patient of any physician for whom the pharmacist has established a protocol.

STATE OF CALIFORNIA–HEALTH AND WELFARE AGENCY

PETE WILSON, Governor

DEPARTMENT OF HEALTH SERVICES
Licensing and Certification
1800 Third Street, Suite 210
P.O. Box 942732
Sacramento, CA 94234-7320
(916) 445-3054

Carol W.

March 28, 1997

To: All California Licensed Pharmacists

Subject: Infusion Services/Suites

The California Department of Health Services (DHS) and the California State Board of Pharmacy (BOP) wish to clarify an issue that relates to the practice of pharmacy, the operation of a licensed clinic, and the operation of infusion services and infusion suites.

The BOP licenses pharmacists and pharmacies in California. The DHS, Licensing and Certification Program, licenses health facilities and clinics. Recently enacted changes in the pharmacy law, Business and Professions Code Section 4027 and 4052 [4046], have resulted in questions and some confusion among pharmacists in California.

The question of concern is whether a pharmacist, who contracts with a health care service plan and operates an infusion service or suite where patients receive intravenous drug therapy, is exempt from licensing as a primary care clinic.

Health and Safety Code Section 1206(a) exempts from clinic licensure requirements any place or establishment owned or leased and operated as a clinic or an office by one or more licensed health care practitioners for the practice of their profession within the scope of their license.

The BOP has concluded that a pharmacist who operates an infusion suite or service and who contracts to provide these services to patients of a health care service plan is functioning under the scope of his or her license as a pharmacist. Such pharmacists must comply with all the requirements set forth in Sections 4052(a)(5)(A) and 4052(b) [4046(c)(5)(A)] of the Business and Professions Code as it relates to pharmacists' services in a health care service plan.

Pharmacists operating infusion services or suites which do not comply with these requirements would potentially be in violation of Section 1205 of the Health and Safety Code. This law requires that all clinics be licensed by DHS.

Questions concerning the practice of pharmacy should be addressed to the BOP at 400 R Street, Suite 4070, Sacramento, CA 95814.

Questions concerning the operation of a clinic under the Health and Safety Code should be addressed to William Murray, Pharm.D., Chief Pharmaceutical Consultant , Department of Health Services, Licensing and Certification, P.O. Box 942732, Sacramento, CA. 94234-7320.

Note: Sections of the Business and Professions Code shown in brackets [ ] are from California Pharmacy Law 1995. Unbracketed section numbers are from Pharmacy Law revised January 1, 1997.

Margaret DeBow
Deputy Director
Licensing and Certification

Patricia F. Harris
Executive Officer
State Board of Pharmacy

cc: BOP Supervising Inspectors

John Hagerty, Chief
L&C Field Operations Branch

AGENDA ITEM F

State of California **Department of Consumer Affairs**

Memorandum

To: Licensing Committee Date: June 6, 2005

From: Board of Pharmacy

Subject: Report on Pharmacist Licensure Examinations

Report on the Pharmacist Licensure Examinations

The board transitioned to the new examination structure in January 2004 and began administering the California Pharmacist Jurisprudence Exam (CPJE) in March 2004.

The statistics for the board's examination process as of June 6, 2005, are as follows:

3,580 applications have been received to take the California license exams
465 of these are retake applications

1,605 individuals have become licensed as pharmacists since mid-June

2,692 individuals have been made eligible to take the licensure examinations
392 individuals have also been requalified to take the exams (These applicants have failed one of the exams, and had to requalify.)

2,028 individuals have been verified to the NABP as qualified to take the NAPLEX for California including score transfers

2,268 CPJE examinations have been administered

96 regrades of the CPJE have been performed resulting in no change of score

The CPJE's pass rate is 81.5 percent.

AGENDA ITEM G

State of California | Department of Consumer Affairs

Memorandum

To: Licensing Committee | Date: June 3, 2005

From: Patricia F. Harris
Executive Officer

Subject: **Development of Proposal for Pharmacists Performing Drug Utilization Review (DUR), Medication Therapy Management (MTM), Pharmacist Call Centers and Central Processing of Prescriptions for CA Patients**

At the December Licensing Committee meeting, staff prepared an overview of the many issues and questions that the board has received regarding pharmacist's care and the practice of pharmacy for California patients. At the March meeting, the Licensing Committee was provided a document whose purpose was to provide the foundation to begin the discussion on how the board should address these many issues that do not fit the traditional statutory definition of pharmacy and the independent practice of pharmacists as health care professionals.

At this committee meeting, the discussion of the proposal will continue. Interested parties are encouraged to review the proposal and be prepared so that discussion on this proposal will be productive.

The following is a summary of the proposed statutory changes to address the issues that were provided to the Licensing Committee at its last meeting. **(Attachment 1)**

Section 4036 - This change updates the definition of pharmacist.

Section 4037 – This change updates the definition of a pharmacy to include an "intake/dispensing pharmacy", a "prescription processing pharmacy", an "advice/clinical care pharmacy" and "nonresident pharmacy". These pharmacy types are not mutually exclusive. In addition, the definition of pharmacy excludes clinics licensed by the board.

Section 4050 – This change acknowledges that pharmacy is an evolving profession that includes more sophisticated and comprehensive patient care activities.

Section 4051 – This change is to update pharmacy law to accurately reflect pharmacy practice and the functions of a pharmacist. It also requires that a pharmacist who performs cognitive services for California patients be licensed in California. Additionally, it specifies that a pharmacist who authorizes the initiation of a prescription or performs other cognitive services outside a licensed pharmacy must maintain patient records or other patient-specific information used in those activities and the records must be provided to the board upon request.

Section 4052, 4052.1, 4052.2 and 4052.3 – These changes are technical clean up of these statutes to make them easier to read and understand. These sections provide for pharmacists' collaborative practice with a physician pursuant to a protocol. There is no change to the scope of practice for pharmacists, the protocol or the emergency contraception drug therapy requirements.

Section 4112 – This change updates the definition of a nonresident pharmacy to include prescription review, patient consultation drug utilization review, medication therapy management and other cognitive pharmacy services. Requires that the pharmacist-in-charge of a nonresident pharmacy be a California licensed pharmacist. Requires that only a California licensed pharmacist can perform prescription review, consultation, drug utilization review, medication therapy management or other cognitive pharmacy services for California patients.

Section 4113 – This change updates the requirements for the pharmacist-in-charge and clarifies the board authority to deny an application for a pharmacist-in-charge.

Section 4125 – This change requires a pharmacy to include in its quality assurance program not only the documentation of medication errors, but also inappropriate provision of cognitive services such as prescription review, consultation, and drug utilization review or medication therapy management.

Section 4207 – This change includes the board's authority to investigate matters related to the performance or provision of cognitive services.

Section 4306.5 – This change adds to the definition of unprofessional conduct for a pharmacist those acts or omissions that involve the failure to exercise or implement his or her best professional judgment and/or corresponding responsibility with regard to dispensing or furnishing controlled substances, dangerous drugs or dangerous devices and/or with regard to the provision of cognitive services. It also includes the acts or omissions that involve the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function. For pharmacists that practice outside of a licensed pharmacy premise, unprofessional conduct may include acts or omissions that involve the failure to fully maintain and retain appropriate patient-specific information pertaining to the performance of any pharmacy function.

Attachment 2 has the background documents from the last meeting that framed the issues.

Issue 1

This issue addressed the central processing of prescriptions by California licensed pharmacies. In this situation, Pharmacy A sends a prescription electronically or via fax to its other Pharmacy

B for input into its computer system to generate a prescription label. A pharmacist at Pharmacy B reviews and analyzes the prescription, performs drug utilization review and other cognitive activities required to confirm that the prescription is appropriate. The pharmacist at Pharmacy B approves the filling of the prescription and the confirmation is sent to Pharmacy A to fill the prescription and dispense it. A pharmacist at Pharmacy A performs final verification, and dispenses/consults. The assumption is that both these pharmacies have common ownership and electronic prescription files.

In this situation, central processing of a prescription is performed in a licensed California pharmacy that also dispenses prescriptions and the cognitive services are performed by licensed California pharmacists either in the pharmacy or by access to the information pursuant to Business and Professions Code section 4051, subdivision (b).

Appropriate licensed entities and personnel are performing the functions as required and authorized by California pharmacy law. This process is different from the refill and central fill processes authorized by California Code of Regulations, title 16, sections 1707.4 and 1710.

It is the corresponding responsibility of every pharmacist and/or pharmacy filling a prescription to ensure legitimacy, propriety, and accurate dispensing.

The Licensing Committee didn't have an issue with this situation.

Issue 2
In this example, a prescription is sent electronically or via fax to a central facility to process the prescription and perform drug utilization review. This central facility is located in California and California licensed pharmacists are performing the review. This facility doesn't dispense prescription drugs. Once approved, the prescriptions are dispensed by a licensed pharmacy that may or may not have a shared ownership and common electronic prescription files with the central prescription processing facility.

The central processing facility would fit the definition of proposed Business and Professions Code section 4037(a)(2). It would be considered a prescription processing pharmacy.

Issue 3
This scenario is related to a prescription that originates in California. It is sent electronically or via fax to an out-of-state central prescription processing facility. The out-of-state central prescription processing facility inputs the prescription label information and a pharmacist (who may or may not be licensed in California) performs drug utilization review. The prescription is filled and dispensed at a California pharmacy or through a California licensed nonresident pharmacy. Also, within the central prescription process facility, there may be a Call Center, where California patients can talk to a pharmacist and receive pharmacist's services. In some instances, a Call Center may be stand-alone and not part of a central prescription processing facility.

It was noted that the out-of-state central prescription processing facility may or may not be licensed in its resident state as a pharmacy. If it is licensed as a pharmacy in its resident state,

the pharmacy does not meet the definition of a California nonresident pharmacy in that the pharmacy doesn't ship, mail or deliver controlled substances, dangerous drugs, or dangerous devices into California.

The proposal would require that this pharmacy be licensed as a "nonresident pharmacy" and would require that the pharmacist-in-charge and the pharmacists performing drug utilization review and/or any other cognitive pharmacy services for California patients be licensed as well.

Issue 4

The fourth example that was presented was about a database for California pharmacies that is maintained in or through a regional call center located and managed in another state. This regional call center is a licensed pharmacy in that state and is supervised by a licensed pharmacist from that state. It is unknown if this licensed pharmacy also dispenses dangerous drugs, either within its state or to California patients. The database identifies non-preferred drugs. These non-preferred drugs are identified for evaluation and consideration for therapeutic interchange and conversion to the company's preferred drug. The goal is to switch equally effective medications within a class to alternatives that are less costly.

A California licensed pharmacist reviews and approves the therapeutic interchange of a non-preferred drug with that of a preferred drug. Once approved by the California licensed pharmacist, the prescription is faxed to the California physician for approval or rejection. The physician faxes back the approval or denial to the our-of-state regional call center where the database is updated.

For this scenario, the out-of-state pharmacy would be required to be licensed in California as a non-resident pharmacy. The pharmacist-in-charge and any pharmacists performing cognitive services would also be required to be licensed in California.

Issue 5

The last situation is the new provision in the Medicare Modernization Act (MMA) that addresses pharmacists' services within the Medication Therapy Management Programs (MTMP) of the Medicare Act. The drug benefit in Medicare Part D provides reimbursement for pharmacists to provide Medication Therapy Management (MTM) for Medicare beneficiaries. Examples of MTM services are: patient health status assessments; medication "brown bag" reviews; formulating/monitoring/adjusting prescription treatment plans; patient education and training; collaborative drug therapy management; special packaging; refill reminders; and other pharmacist related services.

It was noted in the comments provided by the National Association of Boards of Pharmacy (NABP) to the Centers for Medicare & Medicaid Services on the proposed regulations to implement the MMA, that NABP was not clear on how states will view the provision of MTMP's across state lines.

The proposal amends Business and Professions Code section 4051, updating the authority and responsibility of pharmacists performing functions related to the practice of pharmacy so as to encompass many of the MTM services. The proposal also requires that a pharmacist performing

these functions for California patients be licensed in California. This section of law currently authorizes a pharmacist outside of a licensed pharmacy to provide cognitive services, clinical advice or information and patient consultation.

This attachment has model rules developed by the National Association of Boards of Pharmacy (NAB) and examples from other states on central processing of prescriptions. **(Attachment 3)**

ATTACHMENT 1

Proposed Scope of Practice Revisions – Licensing Committee March 16, 2005

§ 4036. Pharmacist

"Pharmacist" means a natural person to whom a license has been issued by the board, under Section 4200, except as specifically provided otherwise in this chapter. The holder of a valid, unexpired pharmacist license issued by the board is entitled to practice pharmacy as defined by this chapter, within or outside of a licensed pharmacy as authorized by this chapter.

§ 4037. Pharmacy

(a) "Pharmacy" means an area, place, or premises licensed by the board in which the profession of pharmacy is practiced ~~and where prescriptions are compounded~~. The profession of pharmacy may be practiced in diverse settings, including the following:

(1) "Intake/dispensing pharmacy" means an area, place, or premises licensed by the board in which ~~"Pharmacy" includes, but is not limited to, any area, place, or premises described in a license issued by the board wherein~~ controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, ~~manufactured~~, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail by personnel licensed by the board.

(2) "Prescription processing pharmacy" means an area, place, or premises licensed by the board in which personnel licensed by the board engage in and/or supervise drug order/prescription review by performing functions including, but not limited to, data entry, drug utilization review, patient and/or prescriber contact, claims submission and processing, patient profile review, and allergy and drug-interaction review, but in which controlled substances, dangerous drugs, or dangerous devices are not stored, possessed, prepared, derived, compounded, nor repackaged, and from which controlled substances, dangerous drugs, or dangerous devices are not furnished, sold, or dispensed at retail.

(3) "Advice/clinical center pharmacy" means an area, place, or premises licensed by the board in which personnel licensed by the board provide cognitive pharmacy services including, but not limited to, clinical advice or information, telephonic or in-person patient consultation, drug utilization review, and medication therapy management, but in which controlled substances, dangerous drugs, or dangerous devices are not stored, possessed, prepared, derived, compounded, nor repackaged, and from which controlled substances, dangerous drugs, or dangerous devices are not furnished, sold, or dispensed at retail.

(4) "Nonresident pharmacy" means an area, place, or premises licensed by the board that is located outside this state, that ships, mails, or delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state, and/or that performs prescription review, patient consultation, drug utilization review, medication therapy management, or other cognitive pharmacy services for patients in this state. It may be any or all of types (a)(1) to (a)(3).

(b) These pharmacy types are not mutually exclusive.

(c) Unless otherwise specified, whenever the term "pharmacy" is used in this chapter, it shall be deemed to refer to every one of the types in (a)(1) to (a)(4). Unless otherwise specified, each requirement made applicable to any pharmacy by this chapter is applicable to all.

~~(b)~~(d) "Pharmacy" shall not include any area in a facility licensed by the State Department of Health Services where floor supplies, ward supplies, operating room supplies, or emergency room supplies of dangerous drugs or dangerous devices are stored or possessed solely for treatment of patients registered for treatment in the facility or for treatment of patients receiving emergency care in the facility.

(e) "Pharmacy" shall not include any of those clinics listed in Section 4180 or Section 4190.

§ 4050. Professional status

(a) In recognition of and consistent with the decisions of the appellate courts of this state, the Legislature hereby declares the practice of pharmacy to be a profession.

(b) Pharmacy practice is a dynamic patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes. Pharmacy practice is continually evolving to include more sophisticated and comprehensive patient care activities.

§ 4051. ~~Dangerous drugs and devices~~Pharmacy practice

(a) The holder of a valid, unexpired pharmacist license issued by the board is vested with the authority and responsibility to perform the following functions inherent to pharmacy practice:

(1) Interpreting, verifying, and implementing drug orders and prescriptions;
(2) Dispensing pursuant to legitimate drug orders and prescriptions;
(3) Ensuring proper drug storage, documentation, labeling and record-keeping;
(4) Maintaining accurate, complete, and confidential patient profiles and records;
(5) Supervising pharmacy technicians and other ancillary personnel in the pharmacy;
(6) Designing and implementing quality assurance procedures and protocols;
(7) Compounding drug products pursuant to prescription and for prescriber office use;
(8) Maintaining safe, secure, and sanitary conditions in licensed premises;
(9) Performing cognitive services, including drug utilization reviews and management, medication therapy reviews and management, and patient counseling and consultation;
(10) Collaborating with prescribers and other care providers regarding patient care;
(11) Implementing standardized procedures and protocols regarding patient care;
(12) Administering or furnishing drugs or biologicals where permitted by law;
(13) Initiating, adjusting, or implementing patient drug regimens where permitted by law; and
(14) Such other pharmacy functions as are authorized by this chapter.

(~~a~~b) Except as otherwise provided in this chapter, it is unlawful for any person to ~~manufacture~~, compound, furnish, sell, or dispense any dangerous drug or dangerous device, or to dispense or compound any prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist licensed under this chapter.

(c) Except as otherwise provided in this chapter, it is unlawful for any person to perform any prescription review, consultation, drug utilization review, medication therapy management, or other cognitive services for, pertaining to, or at the request of, patients, prescribers, or other care providers in this state, unless he or she is a pharmacist licensed under this chapter.

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

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

(2) The pharmacist has access to prescription records, patient profiles, or other relevant medical information for purposes of cognitive services, patient and clinical consultation, and advice, and appropriately reviews that information before performing any of these functions.~~.~~

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

(4) A pharmacist authorizing the initiation or adjustment of a prescription, providing clinical advice or information or patient consultation outside the premises of a licensed pharmacy shall maintain the patient records or other patient-specific information used in those activities in a readily retrievable form and provide those records to the board upon request. These records or information shall be preserved for a period of at least three years from the date they were relied upon or consulted by for the purposes of performing any such function.

§ 4052. Power to perform procedures and functions; training

(a) Notwithstanding any other provision of law, a pharmacist may:

(1) Furnish a reasonable quantity of compounded ~~medication~~ drug product to a prescriber for office use by the prescriber.

(2) Transmit a valid prescription to another pharmacist.

(3) Administer, orally or topically, drugs and biologicals pursuant to a prescriber's order.

(4) Perform ~~the following~~ procedures or functions in a licensed health care facility as authorized by Section 4052.1. ~~in accordance with policies, procedures, or protocols developed by health professionals, including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:~~

~~(A) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.~~

~~(B) Ordering drug therapy-related laboratory tests.~~

~~(C) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).~~

~~(D) Initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility.~~

(5)~~(A)~~ Perform ~~the following~~ procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, as authorized by Section 4052.2. ~~in accordance, as applicable, with policies, procedures, or protocols of that facility, the home health agency, the licensed clinic, the health care service plan, or that physician, in accordance with subparagraph (C):~~

~~(i) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.~~

~~(ii) Ordering drug therapy-related laboratory tests.~~

~~(iii) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).~~

~~(iv) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the individual patient's treating prescriber, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's treating prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this clause within 24 hours.~~

~~(B) A patient's treating prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.~~

~~(C) The policies, procedures, or protocols referred to in this paragraph shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and, at a minimum, meet all of the following requirements:~~

~~(i) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.~~

~~(ii) Require that the medical records of the patient be available to both the patient's treating prescriber and the pharmacist.~~

~~(iii) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.~~

~~(iv) Except for procedures or functions provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.~~

(6) Manufacture, measure, fit to the patient, or sell and repair dangerous devices or furnish instructions to the patient or the patient's representative concerning the use of those devices.

(7) Provide cognitive services such as drug utilization review, medication therapy management, consultation to patients, and professional information, including clinical or pharmacological information, advice, or consultation, to other health care professionals.

(8)~~(A)~~ Furnish emergency contraception drug therapy ~~in accordance with either of the following~~as authorized by Section 4052.3.~~:~~

(9) Administer immunizations under the supervision of a prescriber.

~~(i) Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.~~

~~(ii) Standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American College of Obstetricians and Gynecologists, the California Pharmacist Association, and other appropriate entities. Both the board and the Medical Board of California shall have authority to ensure compliance with this clause, and both boards are specifically charged with the enforcement of this provision with respect to their respective licensees. Nothing in this clause shall be construed to expand the authority of a pharmacist to prescribe any prescription medication.~~

~~(B) Prior to performing a procedure authorized under this paragraph, a pharmacist shall complete a training program on emergency contraception that consists of at least one hour of approved continuing education on emergency contraception drug therapy.~~

~~(C) A pharmacist, pharmacist's employer, or pharmacist's agent may not directly charge a patient separate consultation fee for emergency contraception drug therapy services initiated pursuant to this paragraph, but may charge an administrative fee not to exceed ten dollars ($10) above the retail cost of the drug. Upon an oral, telephonic, electronic, or written request from a patient or customer, a pharmacist or pharmacist's employee shall disclose the total retail price that a consumer would pay for emergency contraception drug therapy. As used in this subparagraph, total retail price includes providing the consumer with specific information regarding the price of the emergency contraception drugs and the price of the administrative fee charged. This limitation is not intended to interfere with other contractually agreed-upon terms between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health care service plan or insurer. Patients who are insured or covered and receive a pharmacy benefit that covers the cost of emergency contraception shall not be required to pay an administrative fee. These patients shall be required to pay copayments pursuant to the terms and conditions of their coverage. The provisions of this subparagraph shall cease to be operative for dedicated emergency contraception drugs when these drugs are reclassified as over-the-counter products by the federal Food and Drug Administration.~~

~~(D) A pharmacist may not require a patient to provide individually identifiable medical information that is not specified in Section 1707.1 of Title 16 of the California Code of Regulations before initiating emergency contraception drug therapy pursuant to this paragraph.~~

~~(b)(1) Prior to performing any procedure authorized by paragraph (4) of subdivision (a), a pharmacist shall have received appropriate training as prescribed in the policies and procedures of the licensed health care facility.~~

~~(2) Prior to performing any procedure authorized by paragraph (5) of subdivision (a), a pharmacist shall have either (A) successfully completed clinical residency training or (B) demonstrated clinical experience in direct patient care delivery.~~
~~(3) For each emergency contraception drug therapy initiated pursuant to paragraph (8) of subdivision (a), the pharmacist shall provide the recipient of the emergency contraception drugs with a standardized factsheet that includes, but is not limited to, the indications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Health Services, the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. The provisions of this section do not preclude the use of existing publications developed by nationally recognized medical organizations.~~

(b~~c~~) A pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy pursuant to this section shall personally register with the federal Drug Enforcement Administration.

(c~~d~~) Nothing in this section shall affect the requirements of existing law relating to maintaining the confidentiality of medical records.

(d~~e~~) Nothing in this section shall affect the requirements of existing law relating to the licensing of a health care facility.

§ 4052.1. Performance of procedures or functions in a licensed health care facility; requirements

(a) Notwithstanding any other provision of law, a pharmacist may perform the following procedures or functions in a licensed health care facility in accordance with policies, procedures, or protocols developed by health professionals, including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:

(1) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(2) Ordering drug therapy-related laboratory tests.

(3) Administering drugs and biologicals by injection pursuant to a prescriber's order ~~(the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility)~~.

(4) Initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility.

(b) Prior to performing any procedure authorized by this section, a pharmacist shall have received appropriate training as prescribed in the policies and procedures of the licensed health care facility.

§ 4052.2. Performance of procedures or functions authorized by other providers; requirements

(a) Notwithstanding any other provision of law, a pharmacist may perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, in accordance, as applicable, with policies, procedures, or protocols of that facility, the home health agency, the licensed clinic, the health care service plan, or that physician, in accordance with subparagraph (c):

(1) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(2) Ordering drug therapy-related laboratory tests.

(3) Administering drugs and biologicals by injection pursuant to a prescriber's order ~~(the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility)~~.

(4) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the individual patient's treating prescriber, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's treating prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this clause within 24 hours.

(b) A patient's treating prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.

(c) The policies, procedures, or protocols referred to in this paragraph shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and, at a minimum, meet all of the following requirements:

(1) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.

(2) Require that the medical records of the patient be available to both the patient's treating prescriber and the pharmacist.

(3) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.

(4) Except for procedures or functions provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.

(d) Prior to performing any procedure authorized by this section, a pharmacist shall have either (1) successfully completed clinical residency training or (2) demonstrated clinical experience in direct patient care delivery.

§ 4052.3. Furnishing emergency contraception drug therapy; requirements

(a) Notwithstanding any other provision of law, a pharmacist furnish emergency contraception drug therapy in accordance with either of the following:

(1) Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.

(2) Standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American College of Obstetricians and Gynecologists, the California Pharmacist Association, and other appropriate entities. Both the board and the Medical Board of California shall have authority to ensure compliance with this clause, and both boards are specifically charged with the enforcement of this provision with respect to their respective licensees. Nothing in this clause shall be construed to expand the authority of a pharmacist to prescribe any prescription medication.

(b) Prior to performing a procedure authorized under this paragraph, a pharmacist shall complete a training program on emergency contraception that consists of at least one hour of approved continuing education on emergency contraception drug therapy.

(c) A pharmacist, pharmacist's employer, or pharmacist's agent may not directly charge a patient a separate consultation fee for emergency contraception drug therapy services initiated pursuant to this paragraph, but may charge an administrative fee not to exceed ten dollars ($10) above the retail cost of the drug. Upon an oral, telephonic, electronic, or written request from a patient or customer, a pharmacist or pharmacist's employee shall disclose the total retail price that a consumer would pay for emergency contraception drug therapy. As used in this subparagraph, total retail price includes providing the consumer with specific information regarding the price of the emergency contraception drugs and the price of the administrative fee charged. This limitation is not intended to interfere with other contractually agreed-upon terms between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health care service plan or insurer. Patients who are insured or covered and receive a pharmacy benefit that covers the cost of emergency contraception shall not be required to pay an administrative fee. These patients shall be required to pay copayments pursuant to the terms and conditions of their coverage. The provisions of this subparagraph shall cease to be operative for dedicated emergency contraception drugs when these drugs are reclassified as over-the-counter products by the federal Food and Drug Administration.

(d) A pharmacist may not require a patient to provide individually identifiable medical information that is not specified in Section 1707.1 of Title 16 of the California Code of Regulations before initiating emergency contraception drug therapy pursuant to this section.

(e) For each emergency contraception drug therapy initiated pursuant to this section, the pharmacist shall provide the recipient of the emergency contraception drugs with a standardized factsheet that includes, but is not limited to, the indications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Health Services,

the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. The provisions of this section do not preclude the use of existing publications developed by nationally recognized medical organizations.

§ 4052.4~~1~~. Skin puncture

Notwithstanding Section 2038 or any other provision of law, a pharmacist may perform skin puncture in the course of performing routine patient assessment procedures or in the course of performing any procedure authorized under Section 1206.5. For purposes of this section, "routine patient assessment procedures" means: (a) procedures that a patient could, with or without a prescription, perform for himself or herself, or (b) clinical laboratory tests that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Health Care Financing Administration, as authorized by paragraph (11) of subdivision (a) of Section 1206.5. A pharmacist performing these functions shall report the results obtained from a test to the patient and any physician designated by the patient. Any pharmacist who performs the service authorized by this section shall not be in violation of Section 2052.

§ 4110. Licenses; renewal; transfer; temporary permits; fees

(a) No person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the board. A license shall be required for each pharmacy owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a pharmacy in more than one location. The license shall be renewed annually. The board may, by regulation, determine the circumstances under which a license may be transferred.

(b) The board may, at its discretion, issue a temporary permit, when the ownership of a pharmacy is transferred from one person to another, upon the conditions and for any periods of time as the board determines to be in the public interest. A temporary permit fee shall be established by the board at an amount not to exceed the annual fee for renewal of a permit to conduct a pharmacy. When needed to protect public safety, a temporary permit may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary permit was issued by mistake or denies the application for a permanent license or registration, the temporary license or registration shall terminate upon either personal service of the notice of termination upon the permitholder or service by certified mail, return receipt requested, at the permitholder's address of record with the board, whichever comes first. Neither for purposes of retaining a temporary permit nor for purposes of any disciplinary or license denial proceeding before the board shall the temporary permitholder be deemed to have a vested property right or interest in the permit.

§ 4112. Nonresident pharmacies; registration; prerequisites and requirements; fee; application; contact lenses

(a) Any pharmacy located outside this state that ships, mails, or delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state, and/or that performs prescription review, patient consultation, drug utilization review, medication therapy management, or other cognitive pharmacy services for patients in this state, shall be considered a nonresident pharmacy.
(b) All nonresident pharmacies shall register with the board. The board may register a nonresident pharmacy that is organized as a limited liability company in the state in which it is licensed.

(c) A nonresident pharmacy shall disclose to the board the location, names, and titles of (1) its agent for service of process in this state, (2) all principal corporate officers, if any, (3) all general partners, if any, and (4) all pharmacists who are dispensing controlled substances, dangerous drugs, or dangerous devices to residents of this state. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, partner, or pharmacist.

(d) All nonresident pharmacies shall comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section. The nonresident pharmacy shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the pharmacy in compliance with the laws of the state in which it is a resident. As a prerequisite to registering with the board, the nonresident pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.

(e) All nonresident pharmacies shall comply with Section 4113.

(~~e~~f) All nonresident pharmacies shall maintain records of controlled substances, dangerous drugs, or dangerous devices dispensed to patients in this state so that the records are readily retrievable from the records of other drugs dispensed.

(g) Any prescription review, consultation, drug utilization review, medication therapy management, or other cognitive services performed by a nonresident pharmacy for, pertaining to, or at the request of, patients, prescribers, or other care providers in this state, may only be performed by a pharmacist licensed under this chapter.

(~~f~~h) Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. This toll-free telephone number shall be disclosed on a label affixed to each container of drugs dispensed to patients in this state.

(~~g~~i) The board shall adopt regulations that apply the same requirements or standards for oral consultation to a nonresident pharmacy that operates pursuant to this section and ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state, as are applied to an in-state pharmacy that operates pursuant to Section 4037 when the pharmacy ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state . The board shall not adopt any regulations that require face-to-face consultation for a prescription that is shipped, mailed, or delivered to the patient. The regulations adopted pursuant to this subdivision shall not result in any unnecessary delay in patients receiving their medication.

(~~h~~j) The registration fee shall be the fee specified in subdivision (a) of Section 4400.

~~(i) The registration requirements of this section shall apply only to a nonresident pharmacy that ships, mails, or delivers controlled substances, dangerous drugs, and dangerous devices into this state pursuant to a prescription.~~

(~~j~~k) Nothing in this section shall be construed to authorize the dispensing of contact lenses by nonresident pharmacists except as provided by Section 4124.

§ 4113. Pharmacists-in-charge; designation; responsibilities; notifications

(a) Every pharmacy shall designate a pharmacist-in-charge, and shall not operate as a pharmacy without a designated pharmacist-in-charge. ~~and w~~Within 30 days ~~thereof~~of a new or replacement designation, the pharmacy shall ~~notify~~ submit an application for approval of this designation to the board stating in writing ~~of~~ the identity and license number of ~~that~~ the designated pharmacist-in-charge, ~~pharmacist~~ and the date he or she was designated. The designated pharmacist-in-charge must have a valid, unexpired pharmacist license issued by the board. Where a designated pharmacist-in-charge has been denied a license, had a license revoked, suspended, or placed on probation, or is the subject of an ongoing board investigation into possible unprofessional conduct, the board may prospectively refuse or retroactively withdraw its approval of the designation and require that the pharmacy designate another pharmacist-in-charge.

(b) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

(c) Every pharmacy shall notify the board within 30 days of the date when a pharmacist ceases to be a pharmacist-in-charge. This duty is separate from and additional to that stated in subpart (a).

§ 4120. Nonresident pharmacies; registration; application forms; legislative intent

(a) A nonresident pharmacy shall not sell or distribute dangerous drugs or dangerous devices in this state through any person or media other than a wholesaler who has obtained a license pursuant to this chapter or through a selling or distribution outlet that is licensed as a wholesaler pursuant to this chapter without registering as a nonresident pharmacy.

(b) Applications for a nonresident pharmacy registration shall be made on a form furnished by the board. The board may require any information as the board deems reasonably necessary to carry out the purposes of this section.

(c) Each application to conduct a nonresident pharmacy shall specify the type or types of pharmacy for which the application is submitted, pursuant to Section 4037.

(~~c~~d) The Legislature, by enacting this section, does not intend a license issued to any nonresident pharmacy pursuant to this section to change or affect the tax liability imposed by Chapter 3 (commencing with Section 23501) of Part 11 of Division 2 of the Revenue and Taxation Code on any nonresident pharmacy.

(~~d~~e) The Legislature, by enacting this section, does not intend a license issued to any nonresident pharmacy pursuant to this section to serve as any evidence that the nonresident pharmacy is doing business within this state.

§ 4122. Consumer information; posting or written receipts; prices

(a) In every pharmacy there shall be prominently posted in a place conspicuous to and readable by prescription drug consumers a notice provided by the board concerning the availability of prescription price information, the possibility of generic drug product selection, and the type of services provided by pharmacies. The format and wording of the notice shall be adopted by the board by regulation. A written receipt that contains the required information on the notice may be provided to consumers as an alternative to posting the notice in the pharmacy.

(b) A pharmacist, or a pharmacist's employee, shall give the current retail price for any drug sold at the pharmacy upon request from a consumer, however that request is communicated to the pharmacist or employee.

(c) If a requester requests price information on more than five prescription drugs and does not have valid prescriptions for all of the drugs for which price information is requested, a pharmacist may require the requester to meet any or all of the following requirements:

(1) The request shall be in writing.

(2) The pharmacist shall respond to the written request within a reasonable period of time. A reasonable period of time is deemed to be 10 days, or the time period stated in the written request, whichever is later.

(3) A pharmacy may charge a reasonable fee for each price quotation, as long as the requester is informed that there will be a fee charged.

(4) No pharmacy shall be required to respond to more than three requests as described in this subdivision from any one person or entity in a six-month period.

(d) This section shall not apply to a nonresident pharmacy, or to a pharmacy that is located in a licensed hospital and that is accessible only to hospital medical staff and personnel.

(e) Notwithstanding any other provision of this section, no pharmacy shall be required to do any of the following:

(1) Provide the price of any controlled substance in response to a telephone request.

(2) Respond to a request from a competitor.

(3) Respond to a request from an out-of-state requester.

§ 4125. Quality assurance program

(a) Every pharmacy shall establish a quality assurance program that shall, at a minimum, document medication errors and/or inappropriate provision of cognitive services such as prescription review, consultation, drug utilization review, or medication therapy management attributable, in whole or in part, to the pharmacy or its personnel. The purpose of the quality assurance program shall be to assess errors that occur in the pharmacy in dispensing or furnishing prescription medications, or providing cognitive services, so that the pharmacy may take appropriate action to prevent a recurrence.

(b) Records generated for and maintained as a component of a pharmacy's ongoing quality assurance program shall be considered peer review documents and not subject to discovery in any arbitration, civil, or other proceeding, except as provided hereafter. That privilege shall not prevent review of a pharmacy's quality assurance program and records maintained as part of that system by the board as necessary to protect the public health and safety or if fraud is alleged by a government agency with jurisdiction over the pharmacy. Nothing in this section shall be construed to prohibit a patient from accessing his or her own prescription records. Nothing in this section shall affect the discoverability of any records not solely generated for and maintained as a component of a pharmacy's ongoing quality assurance program.

~~(c) This section shall become operative on January 1, 2002.~~

§ 4201. Contents of applications; fees; powers of license holders

(a) Each application to conduct a pharmacy, wholesaler, or veterinary food-animal drug retailer, shall be made on a form furnished by the board, and shall state the name, address, usual occupation, and professional qualifications, if any, of the applicant. If the applicant is other than a natural person, the application shall state the information as to each person beneficially interested therein.

(b) Each application to conduct a pharmacy shall specify the type or types of pharmacy for which the application is submitted, pursuant to Section 4037.

(~~b~~c) As used in this section, and subject to subdivision (~~c~~d), the term "person beneficially interested" means and includes:

(1) If the applicant is a partnership or other unincorporated association, each partner or member.

(2) If the applicant is a corporation, each of its officers, directors, and stockholders, provided that no natural person shall be deemed to be beneficially interested in a nonprofit corporation.

(3) If the applicant is a limited liability company, each officer, manager, or member.

(~~c~~d) In any case where the applicant is a partnership or other unincorporated association, is a limited liability company, or is a corporation, and where the number of partners, members, or stockholders, as the case may be, exceeds five, the application shall so state, and shall further state the information required by subdivision (a) as to each of the five partners, members, or stockholders who own the five largest interests in the applicant entity. Upon request by the executive officer, the applicant shall furnish the board with the information required by subdivision (a) as to partners, members, or stockholders not named in the application, or shall refer the board to an appropriate source of that information.

(~~d~~e) The application shall contain a statement to the effect that the applicant has not been convicted of a felony and has not violated any of the provisions of this chapter. If the applicant cannot make this statement, the application shall contain a statement of the violation, if any, or reasons which will prevent the applicant from being able to comply with the requirements with respect to the statement.

(~~e~~f) Upon the approval of the application by the board and payment of the fee required by this chapter for each pharmacy, wholesaler, or veterinary food-animal drug retailer, the executive officer of the board shall issue a license to conduct a pharmacy, wholesaler, or veterinary food-animal drug retailer, if all of the provisions of this chapter have been complied with.

(~~f~~g) Notwithstanding any other provision of law, the pharmacy license shall authorize the holder to conduct a pharmacy. The license shall be renewed annually and shall not be transferable.

(~~g~~h) Notwithstanding any other provision of law, the wholesale license shall authorize the holder to wholesale dangerous drugs and dangerous devices. The license shall be renewed annually and shall not be transferable.

(~~h~~i) Notwithstanding any other provision of law, the veterinary food-animal drug retailer license shall authorize the holder thereof to conduct a veterinary food-animal drug retailer and to sell and dispense veterinary food-animal drugs as defined in Section 4042.

(~~i~~j) For licenses referred to in subdivisions (~~f~~g), (~~g~~h), and (~~h~~i), any change in the proposed beneficial ownership interest shall be reported to the board within 30 days thereafter upon a form to be furnished by the board.

~~(j) This section shall become operative on July 1, 2001.~~

§ 4207. Investigations; limitations; requests for additional information

(a) Upon receipt of an application for a license and the applicable fee, the board shall make a thorough investigation to determine whether the applicant is qualified for the license being sought. The board shall also determine whether this article has been complied with, and shall investigate all matters directly related to the issuance of the license that may affect the public welfare.

(b) The board shall not investigate matters connected with the operation of a premises other than those matters solely related to the furnishing of dangerous drugs or dangerous devices, or to the performance or provision of cognitive services, that might adversely affect the public welfare.

(c) The board shall deny an application for a license if the applicant does not qualify for the license being sought.

(d) Notwithstanding any other provision of law, the board may request any information it deems necessary to complete the application investigation required by this section, and a request for information that the board deems necessary in carrying out this section in any application or related form devised by the board shall not be required to be adopted by regulation pursuant to the Administrative Procedures Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code).

§ 4306.5. Acts or omissions constituting unprofessional conduct

(a) Unprofessional conduct for a pharmacist may include:

(1) ~~a~~Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board;

(2) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment and/or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices and/or with regard to the provision of cognitive services;

(3) Acts or omissions that involve, in whole or in part, the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function.

(b) For pharmacists who practice outside of a pharmacy premises, unprofessional conduct may include acts or omissions that involve, in whole or in part, the failure to fully maintain and retain appropriate patient-specific information pertaining to the performance of any pharmacy function.

ATTACHMENT 2

ISSUE 1
Central Processing of Prescriptions by California Licensed Pharmacies

Scenario: Pharmacy A sends a prescription electronically or via fax to its other Pharmacy B for input into its computer system to generate a prescription label. A pharmacist at Pharmacy B reviews and analyzes the prescription, performs drug utilization review and other cognitive activities required to confirm that the prescription is appropriate. The pharmacist at Pharmacy B approves the filling of the prescription and the confirmation is sent to Pharmacy A to fill the prescription and dispense it. A pharmacist at Pharmacy A performs final verification, and dispenses/consults. The assumption is that both these pharmacies have common ownership and electronic prescription files.

Discussion:
Under this scenario, central processing of a prescription is performed in a licensed California pharmacy that also dispenses prescriptions and the cognitive services are performed by licensed California pharmacists either in the pharmacy or by access to the information pursuant to Business and Professions Code section 4051, subdivision (b).

Appropriate licensed entities and personnel are performing the functions as required and authorized by California pharmacy law. This process is different from the refill and central fill processes authorized by California Code of Regulations, title 16, sections 1707.4 and 1710.

It is the corresponding responsibility of every pharmacist and/or pharmacy filling a prescription to ensure legitimacy, propriety, and accurate dispensing.

ISSUE 2
California Central Prescription Processing Facility

Scenario: A prescription is sent electronically or via fax to a central facility to process the prescription and perform drug utilization review. This central facility is located in California and California licensed pharmacists are performing the review. This facility doesn't dispense prescription drugs. Once approved, the prescriptions are dispensed by a licensed pharmacy that may or may not have a shared ownership and common electronic prescription files with the central prescription processing facility.

Discussion:
Business and Professions Code section 4071.1 authorizes a pharmacist to electronically enter a prescription or order into a pharmacy or hospital's computer from any location outside of the pharmacy or hospital with the permission of the pharmacy or hospital.

California Code of Regulations, title 16, section 1793.7 authorizes a pharmacy to employ a non-licensed individual (clerk-typist) to enter prescription information into a computer system, generate a prescription label and to receive and request refill information. These functions must be performed under the direction of a pharmacist.

At least one central prescription processing facility in California has been licensed as a pharmacy. The reason for licensure as a pharmacy is two-fold. First, the prescriptions are faxed to the facility for central processing. Because there is a fax copy of the prescription, it has been reasoned that the facility must be licensed as a pharmacy to accept the faxed prescription document. (Cal. Code Regs., tit. 16, section 1717, subd. (e)). It can be argued that Business and Professions Code section 4051, subdivision (b)(2) authorizes the pharmacist to have access to the prescription, patient profile or other relevant medical information. This section doesn't require that this information be electronic only. However, does this central facility have the authority to maintain the faxed copy of the prescription record once it has been processed and the pharmacist has approved it for filling? Does the pharmacist? What happens to the faxed prescription document? What are the record-keeping requirements for each prescription recipient?

The second reason that this facility is licensed as a pharmacy is so that it can employ non-licensed pharmacy personnel to process prescriptions as authorized by California Code of Regulations, title 16, section 1793.7.

However, this central prescription processing facility doesn't dispense prescription drugs, so the question is raised whether this central facility is appropriately licensed as a "pharmacy." California pharmacy law defines a "pharmacy" in part as "an area, place, or premises licensed by the board in which the profession of pharmacy is practiced and where prescriptions are compounded." (Bus. & Prof. Code, § 4037, subd. (a)). This definition also states that a pharmacy includes, but is not limited to, "any area, place, or premises described in a license issued by the board wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail." (*Ibid.*). Possession, storage, and sale of dangerous drugs or devices is therefore a central part, though not an explicitly necessary part, of the definition of a California "pharmacy."

California pharmacy law does not specifically define the scope of practice for the profession of pharmacy. That scope of practice has been defined in other sources. For instance, the National Association of Boards of Pharmacy in its *Model Act* defines the "Practice of Pharmacy" as: the interpretation, evaluation, and implementation of Medical orders; the Dispensing of Prescription Drug Orders; participation in Drug and Device selection; Drug Administration; Drug Regimen Reviews, the Practice of Telepharmacy within and across state lines; Drug or Drug-Related research; the provision of Patient Counseling and the provision of those acts or services necessary to provide Pharmaceutical Care in all areas of patient care, including Primary Care and Collaborative Pharmacy Practice; and the responsibility for Compounding and Labeling of Drugs and Devices (except Labeling by a Manufacturer, repackager, or Distributor of Non-Prescription Drugs and commercially packaged Legend Drugs and Devices), proper and safe storage of Drugs and Devices and maintenance of proper records for them.

The issue before the Licensing Committee is whether or not the Board of Pharmacy

should license a "central prescription processing facility" located in California that does not dispense prescription drugs or devices as a "pharmacy."

Business and Professions Code section 4051, subdivision (b), provides that a pharmacist may perform cognitive services outside of a pharmacy as long as the pharmacist has access to the records. For discussion purposes, the committee may want to consider amending this section to require that the pharmacist in the central processing facility who is performing these services outside the pharmacy maintain the patient records or other patient specific information used in these activities in a readily retrievable form and provide those records to the board upon request. This would include all faxed prescription documents and other records. The proposal would require the pharmacist to maintain patient records similar to that of a prescriber and the patient records may be different than the patient profile maintained by the pharmacy.

The committee may also want to seek clarification from counsel as to whether the law needs to be amended to allow a pharmacist to use a "non-licensed" individual to assist in the processing of prescriptions at a central location.

Another alternative for consideration would be to develop a special license category for the central prescription processing center that is not designated as a "pharmacy," and therefore the facility isn't given the authority to compound, purchase, store, or dispense prescription drugs and devices.

ISSUE 3
Central Prescription Processing Facility and/or Call Center Located Outside of California

Scenario: A prescription originates in California. It is sent electronically or via fax to an out-of-state central prescription processing facility. The out-of-state central prescription processing facility inputs the prescription label information and a pharmacist (who may or may not be licensed in California) performs drug utilization review. The prescription is filled and dispensed at a California pharmacy or through a California licensed nonresident pharmacy. Also, within the central prescription process facility, there may be a Call Center, where California patients can talk to a pharmacist and receive pharmacist's services. In some instances, a Call Center may be stand-alone and not part of a central prescription processing facility.

Discussion:
The out-of-state central prescription processing facility may or may not be licensed in its resident state as a pharmacy. If it is licensed as a pharmacy in its resident state, the pharmacy does not meet the definition of a California nonresident pharmacy in that the pharmacy doesn't ship, mail or deliver controlled substances, dangerous drugs, or dangerous devices into California.

Therefore, does an out-of-state central prescription processing facility have the authority to process prescriptions for California patients? Is this authority increased if the review process is performed or overseen by a pharmacist licensed in California? Does a non-California licensed pharmacist have the authority to perform drug utilization review and/or other pharmacist's services for California patients? Also, what authority or ability does the Board of Pharmacy have to protect the public if the out-of-state pharmacist is unprofessional in providing pharmacist's care to California patients? What would be the record-keeping requirements for each prescription recipient?

Under current law, a California licensed nonresident pharmacy may perform all these services for California patients without requiring California licensure for the pharmacist.

The Call Center may be required to be registered with the Telephone Medical Advice Services Bureau (Bus. & Prof. Code, § 4999 et. seq.).

ISSUE 4
Out-of-State Regional Call Center Database – Therapeutic Interchange

Scenario: A database for California pharmacies is maintained in or through a regional call center located and managed in another state. This regional call center is a licensed pharmacy in that state and is supervised by a licensed pharmacist from that state. It is unknown if this licensed pharmacy also dispenses dangerous drugs, either within its state or to California patients. The database identifies non-preferred drugs. These non-preferred drugs are identified for evaluation and consideration for therapeutic interchange and conversion to the company's preferred drug. The goal is to switch equally effective medications within a class to alternatives that are less costly.

A California licensed pharmacist reviews and approves the therapeutic interchange of a non-preferred drug with that of a preferred drug. Once approved by the California licensed pharmacist, the prescription is faxed to the California physician for approval or rejection. The physician faxes back the approval or denial to the our-of-state regional call center where the database is updated.

Discussion

While the regional call center is licensed as a pharmacy in its domestic state, it doesn't appear to meet the definition of a California nonresident pharmacy (e.g., it does not ship, mail or deliver drugs into California). Based on the information provided, it is a California licensed pharmacist who makes the determination whether or not a therapeutic interchange is appropriate for the California patient and if so, then the California prescriber is contacted to approve the change. Can a pharmacy not licensed in California, such as this regional call center (e.g., licensed in Texas) maintain and make use of a pharmacy database for California patients?

The Call Center may be required to be registered with the Telephone Medical Advice Services Bureau (Bus. & Prof. Code, § 4999 et. seq.).

ISSUE 5
Medication Therapy Management Programs Across State Lines

Consistent with the above scenarios, there is a provision in the Medicare Modernization Act (MMA) that addresses pharmacists' services within the Medication Therapy Management Programs (MTMP) of the Medicare Act. The drug benefit in Medicare Part D provides reimbursement for pharmacists to provide Medication Therapy Management (MTM) for Medicare beneficiaries. Examples of MTM services are: patient health status assessments, medication "brown bag" reviews, formulating/monitoring/adjusting prescription treatment plans, patient education and training, collaborative drug therapy management, special packaging, refill reminders and other pharmacist related services.

Discussion
As pointed out in the comments provided by NABP to the Centers for Medicare & Medicaid Services on the proposed regulations to implement the MMA, NABP was not clear on how states will view the provision of MTMP's across state lines. Similar to the situations presented above, California needs to decide how it wishes to address pharmacists not licensed in California providing MTM to California patients.

Another possible issue is whether California should alter, expand or refine its scope of practice and/or provisions dealing with collaborative practice/medication management to respond to the MMA and the existence of the MTM reimbursement protocols. As noted above, for example, the definition of "pharmacy" in the NABP *Model Act* addresses the propriety of collaborative practice and provision of drug management services explicitly.

SUMMARY

Issues for Consideration by the Licensing Committee

1. **Are any issues raised by inter-network pharmacy prescription processing?**

2. **How should a central processing prescription facility located in California that doesn't dispense prescription drugs or devices be regulated?**

    - **Should the facility be licensed as a pharmacy?**
    - **Should the facility be licensed as a "central processing prescription facility"?**
    - **Should such a facility be allowed?**
    - **Should the facility not be licensed, but require that the pharmacist maintain patient records for cognitive services? Should the pharmacist be allowed to use non-licensed personnel to assist in**

the processing of prescriptions as is currently authorized in a licensed (dispensing) pharmacy?

- **What are the record keeping requirements for each prescription recipient? Are the prescriptions being transmitted twice? First to the local pharmacy then to the central processing facility and then back to the dispensing pharmacy.**

3. **How should a central prescription processing facility located outside of California that processes prescriptions for California patients but doesn't dispense prescription drugs to California patients be regulated?**

    - **Should the facility be licensed as a nonresident pharmacy?**
    - **Should the facility be licensed as a nonresident "central processing prescription facility"?**
    - **Should an out-of-state facility be allowed to process prescriptions for California patients?**
    - **What are the record keeping requirements for each prescription recipient? Are the prescriptions being transmitted twice? First to the local pharmacy then to the central processing facility and then back to the dispensing pharmacy.**

4. **Can a pharmacist not licensed in California perform cognitive services (Medication Therapy Management) for California patients?**

    - **Can a pharmacist not licensed in California perform such services in a facility licensed in California as a nonresident pharmacy?**
    - **Should the pharmacist be licensed in California to perform such services for California patients?**

5. **Can an out-of-state pharmacy or call center (not licensed in California) maintain a central pharmacy database for California pharmacies and/or California patients? Who would have access to this database for California patients?**