



California State Board of Pharmacy

400 R Street, Suite 4070, Sacramento, CA 95814

Phone (916) 445-5014

Fax (916) 327-6308

www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

ARNOLD SCHWARZENEGGER, GOVERNOR

LICENSING COMMITTEE

Hilton Burbank Airport & Convention Center

2500 Hollywood Way

Burbank, CA 91505-1019

(818) 843-6000

December 1, 2004

1:30 p.m. – 4:00 p.m.

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 1:30 p.m.

- B. Recommendation from the Workgroup on Compounding
General Compounding Proposal – Proposed Statutory and Regulatory Changes

- C. Development of Proposal for Pharmacist Performing Drug Utilization Review
(DUR), Medication Therapy Management, Pharmacist Call Centers and Central
Processing of Prescriptions for California Patients

- D. Presentation by the Long Term Care Management Council on Proposed Certification
Program (This presentation has been cancelled.)

- E. Status on the Licensing of Pharmacists in California

- F. Implementation of AB 2682 (Chapter 887) Regarding the Licensure of Wholesalers
and NonResident Wholesalers

Adjournment

4:00 p.m.

Meeting materials will be on the board's Web site by November 24, 2004

AGENDA ITEM B

Memorandum

To: Licensing Committee

Date: November 23, 2004

From: Patricia Harris  Executive Officer
Board of Pharmacy

Subject: Recommendation from the Workgroup on Compounding –
General Compounding Proposal – Proposed Statutory and Regulatory Changes

The Workgroup on Compounding was initially formed in part to respond to a request from the Department of Health Services – Food and Drug Branch to identify the criteria used by the board to determine when a compounding pharmacy should be considered a manufacturer. The goal was to work with the compounding profession to respond to this request as well as identify and address “gaps” in pharmacy law related to pharmacy compounding. At each workgroup meeting, there have been over 30 participants that have provided valuable input into the process.

At the last meeting, Supervising Inspector Dennis Ming and Chief of Legislation Paul Riches presented a concept draft to regulate general compounding by pharmacies. This proposal was discussed and comments were requested. Based on the discussion and the comments that were provided, proposed statutory and regulatory amendments were drafted for the workgroup’s review. The Workgroup on Compounding will be meeting for the last time prior to this Licensing Committee meeting for final review and discussion of the proposal. However, the workgroup members will have the opportunity to address any concerns regarding the proposal to this committee and ultimately to the board.

The proposal that is being recommended for the Licensing Committee’s consideration includes a definition of compounding, which currently is not defined in pharmacy law. It requires that the pharmacist have a professional relationship with both the prescriber and the patient. The proposal also addresses the issues of central fill (where a pharmacy may contract with another pharmacy to compound non-sterile drug products pursuant to a prescription), record keeping requirements, labeling, quality assurance requirements for the compounding process and the compounded drug, and requirements for facilities and equipment. The proposal also specifies that the chemicals, drug products and components must be used and stored according to official United States Pharmacopoeia compendia specifications. There was also discussion regarding the compounding of OTC products and whether a prescription is required. It is the board’s position that a prescription is required whenever a pharmacy compounds a drug product. A drug product is defined broadly enough to include OTC compounding. For clarification purposes, this requirement may be added to the proposal.

At the last meeting there was considerable discussion regarding the relative roles of the Board of Pharmacy, the federal Food and Drug Administration and its California counterpart(s). As stated previously, one of the initial requests from DHS was for the board to identify the criteria it uses to determine when a compounding pharmacy would be considered a manufacturer. While one of the workgroup subcommittees updated the list of factors that the board developed many years ago, board counsel explained that the proposed “factors” for distinguishing compounding from manufacturing would at best be considered “guidelines,” and as such, do not have the force of law. Absent adoption by regulation, they may also be underground regulations.

Further, counsel advised that the Board of Pharmacy regulates the practice of pharmacy, which includes compounding. It is, however, ultimately within the authority of the federal and state FDA to license and regulate manufacturers and it is within their purview to determine when an entity must be licensed as a manufacturer.

While compounding is included in the definition of manufacturing, a pharmacy that engages in compounding is not required to be registered as a manufacturer so long as the compounding is done within the pharmacy practice (upon prescription from a practitioner for a patient who is under the care of that practitioner).

The Board of Pharmacy’s priority mandate is to protect the public and this mandate extends to the compounding of prescription drugs. The proposal provides the regulation necessary to guarantee that those pharmacies that compound prescription drugs meet specific standards to assure patient safety.



California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814-6237
Phone (916) 445-5014
Fax (916) 327-6308
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
Arnold Schwarzenegger, GOVERNOR

**LICENSING COMMITTEE
WORKGROUP ON COMPOUNDING**

Ken Schell, Pharm.D.
John Tilley, R.Ph.

**December 1, 2004
10:00 a.m. – 12 noon**

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

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 days prior to the meeting.

A. Call to Order 10:00 a.m.

B. Introductions and Meeting Format

C. Discussion of Compounding Issues and Recommendation to Licensing Committee

- General Compounding Proposal – Proposed Statutory and Regulatory Changes

Adjournment 12 noon

Meeting materials will be on the board's Web site by November 24, 2004.

Section 4019.5 of the Business and Professions Code is added to read:

“Compounding” means any the following activities occurring in a pharmacy:

- (1) Altering the dosage form or delivery system of a drug.
- (2) Altering the strength of a drug.
- (3) Combining active ingredients.
- (4) Preparing a drug from bulk chemicals.

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

4033. (a) ~~“Manufacturer”~~ “Manufacture” means and includes the preparation, derivation, production, compounding or repackaging of every person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufactures a drug or device compounded in a pharmacy, on the immediate premises where the drug or device is sold to the ultimate consumer.

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

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

Section 4037 of the Business and Professions Code is amended to read:

4037. (a) “Pharmacy” means an area, place, or premises licensed by the board in which the profession of pharmacy is practiced and where dangerous drugs and dangerous devices are stored. prescriptions are compounded.—“Pharmacy” includes, but is not limited to, any area, place, or premises ~~described in a licensed~~ 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.~~

(b) “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.

Section 4051 of the Business and Professions Code is amended to read:

4051. (a) 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 under this chapter.

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

- (1) The clinical advice or information or patient consultation is provided to a health care professional or to a patient.
- (2) The pharmacist has access to prescription, patient profile, or other relevant medical information for purposes of patient and clinical consultation and advice.
- (3) Access to the information described in paragraph (2) is secure from unauthorized access and use.

Section 4123 of the Business and Professions Code is amended to read:

~~4123. Any pharmacy that contracts to compound a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy shall report that contractual arrangement to the board. That information shall be reported by the pharmacy performing the compounding services within 30 days of commencing that compounding.~~

Notwithstanding any other provision of law, a pharmacist may:

- (a) Compound a drug pursuant to a prescription, for delivery to another pharmacy for the purpose of delivering or administering the drug to the patient named in the prescription, provided that the drug is not compounded prior to receipt of the prescription.
- (b) Repackage a drug previously dispensed for the patient at the request of the patient or the patient's agent.

§1716.1. Compounding Unapproved Drugs for Prescriber Office Use.

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

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

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

§1716.2. Record Requirements—Compounding for Future Furnishing.

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

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

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

Article 4.5 General Compounding

§1735. Definitions

- (a) “Integrity” means the drug will retain its effectiveness until the beyond use date noted on the label.
- (b) “Quality” means the drug is free of any contaminants and only contains those active ingredients indicated on the label.
- (c) “Strength” means the amount of active ingredient in each unit of the drug.

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

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

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

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

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

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

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

§1735.1. Requirements

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

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

(1) Active ingredients to be used.

(2) Inactive ingredients to be used.

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

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

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

(6) Beyond use dating requirements.

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

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

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

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

¹ Moved from 1716.1

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

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

(i) A pharmacy may compound drugs in quantities larger than required for immediate dispensing or for prescriber office use.

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

§1735.2. Records

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

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

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

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

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

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

§1735.3. Labeling

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

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

(c) Drugs compounded into unit of use containers shall be labeled with the name of the active component, concentration or strength, volume or weight, and a beyond use date.

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

§1735.4. Policies and Procedures

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

(b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge, who shall document the date when the annual review is completed.

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

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

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

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

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

§1735.5. Facilities and Equipment

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

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

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

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

§1735.6. Training of Staff, Patient and Caregiver

(a) Pharmacies shall maintain written documentation that pharmacy personnel have the skills and training required to correctly perform their assigned responsibilities relating to compounding.

(b) The training of pharmacy personnel shall be documented and retained as part of an annual on-going competency evaluation process for pharmacy personnel involved in compounding.

(c) Pharmacy personnel assigned compounding duties shall demonstrate knowledge about the processes and procedures used to compound drug drugs prior to compounding any drug.

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

§1735.7. Quality Assurance

(a) Pharmacies shall provide written documentation of the development of and adherence to a quality assurance plan.

(b) The quality assurance plan shall include verification, monitoring, and review of the adequacy of the compounding process and shall include documentation of that review by the assigned personnel to demonstrate the compounded drug meets the specified criteria of strength and quality.

(c) As part of the quality assurance plan, all qualitative/quantitative analysis reports for compounded drug drugs shall be retained and collated with the compounding record and master formula.

(d) The quality assurance plan shall also include a written process that describes and documents the action taken when a compounded drug fails to meet the minimum standards for quality, strength and integrity.

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

AGENDA ITEM C

Memorandum

To: Licensing Committee

Date: November 24, 2004

From: Patricia F. Harris 
Executive Officer

Subject: Development of Proposal for Pharmacist Performing DUR, Medication Management Therapy, Pharmacist Call Centers, and Central Processing of Prescriptions for California Patients

I prepared the attached document to provide you with an overview on the many issues and questions that the board has received regarding pharmacist's care and the practice of pharmacy for California patients.

The purpose of this document is to provide the foundation to begin the discussion on how the board should address these many issues that don't fit the traditional statutory definition of pharmacy and the independent practice of pharmacists as health care providers.

The background materials are copies of the various correspondence that the board has received.

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

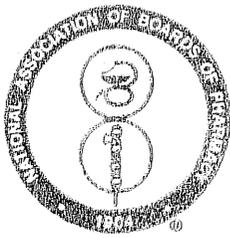
- 1. Are any issues raised by inter-network pharmacy prescription processing?**

- 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?**

BACKGROUND MATERIALS



NABP 100 YEARS

1904 BUILDING A REGULATORY 2004
FOUNDATION FOR PATIENT SAFETY

RECEIVED BY
BOARD OF PHARMACY
2004 OCT 12 AM 10:11

TO: EXECUTIVE OFFICERS - STATE BOARDS OF PHARMACY
FROM: Eleni Anagnostiadis, Patient Safety Senior Manager
DATE: October 8, 2004
RE: NABP Comments on the Medicare Modernization Act Proposed Regulations

On October 4, 2004, NABP submitted comments to the Centers for Medicare and Medicaid Services (CMS) on the proposed regulations of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003. Of notable interest to the state boards of pharmacy is the section of the MMA that specifically addresses the provision of pharmacists' services within the Medication Therapy Management Programs (MTMP) of the Medicare Act.

In the letter, NABP highlighted the following areas in an effort to elucidate CMS to the practice of pharmacy and the role that the state boards play in ensuring the protection of the public health.

- Definition of Scope of Pharmacy Practice
- Standards and Competencies Associated with Licensure
- Legal Authority of the State Boards of Pharmacy
- Collaborative Practice Agreements
- Evaluation of Non-Resident Pharmacy License for Remote Caregivers
- Provision of MTMPs by Non-Pharmacist Practitioners

NABP believes that the aforementioned principles highlighted provide an example of key areas of interest to the state boards of pharmacy that should be considered as CMS develops their final regulations. NABP will continue to work with CMS to help ensure that the MTMP services included in the final regulations fall within the scope of practice of pharmacy.

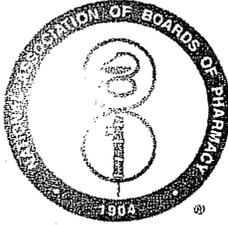
Feel free to contact me at eanagnostiadis@nabp.net with any questions regarding the Medication Therapy Management Program provision of the MMA or NABP's comments to CMS.

Attachments: NABP Letter to CMS

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

National Association of Boards of Pharmacy

700 Busse Highway • Park Ridge, IL 60068 • Tel: 847/698-6227 • Fax: 847/698-0124
Web Site: www.nabp.net



NABP 100 YEARS

1904 BUILDING A REGULATORY 2004
FOUNDATION FOR PATIENT SAFETY

October 4, 2004

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
PO Box 8014
Baltimore, MD 21244-8014

File Code: CMS-4068-P

Dear Dr McClellan:

Thank you for the opportunity to submit the following information in response to the Centers for Medicare and Medicaid Services (CMS) request for comments on the proposed regulations implementing Title I of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA). Our response is relevant to pharmacists' provision of services within Medication Therapy Management Programs (MTMPs) and its impact on the public safety and state regulation of the practice of pharmacy.

The National Association of Boards of Pharmacy (NABP) was founded in 1904. Our members are the pharmacy regulatory and licensing jurisdictions in the United States, District of Columbia, Guam, Puerto Rico, and the Virgin Islands, eight provinces of Canada, two Australian States, New Zealand, and South Africa. The purpose of NABP is to serve as the independent, international, and impartial Association that assists states and provinces in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health. I am submitting these comments as executive director of NABP.

Although the concept of MTMP services is presently an area of considerable attention due to the enactment of the MMA of 2003, the state boards of pharmacy and NABP have been involved in defining the scope of pharmacy practice and the standards and competencies associated with licensure of pharmacists for more than 100 years. The state boards of pharmacy were the first entities to legally define the practice of pharmacy and establish regulations to regulate pharmacy practice and pharmacists. It is through the state boards of pharmacy that pharmacists are assessed as competent to practice and the scope of the practice of pharmacy amended as standards and practice therapies change.

National Association of Boards of Pharmacy

700 Busse Highway · Park Ridge, IL 60068 · Tel: 847/698-6227 · Fax: 847/698-0124
Web Site: www.nabp.net

NABP serves its member boards of pharmacy by developing and administering competency assessment examinations required by the states for licensure (NAPLEX and MPJE¹), maintaining disciplinary and licensure transfer clearinghouses for the states to allow for the interstate transfer of licensure of pharmacists' licenses, and working with the states to produce model laws and regulations to address issues and concerns which the state boards of pharmacy are charged to regulate. Model regulations developed by NABP and subsequent state laws and regulations adopted by the states outline the parameters of the scope of practice of pharmacy. The state boards of pharmacy and NABP recognize the importance of pharmacists providing MTMP services within a regulatory framework that focuses on patient safety and complies with existing states' definitions of the practice of pharmacy and scope of authority of the pharmacist.

Legal Authority of the State Boards of Pharmacy

The "Board of Pharmacy" or "Board" in each state is the legally constituted governmental regulatory body charged to regulate the practice of pharmacy and licensure of pharmacists and pharmacies. As defined in the various practice acts of the state boards of pharmacy, the purpose of the State Practice Act and regulations is clear:

"It is the purpose of this Act to promote, preserve, and protect the public health, safety, and welfare by and through the effective control and regulation of the Practice of Pharmacy; the licensure of Pharmacists; the registration of Pharmacy Technicians; the licensure, control, and regulation of all sites or Persons, in or out of this State, that Distribute, Manufacture, or sell Drugs (or Devices used in the Dispensing and Administration of Drugs), within this State, and the regulation and control of such other materials as may be used in the diagnosis, treatment, and prevention of injury, illness, and disease of a patient or other individual."

When implemented, MTMP services will fall under the consideration of the state boards of pharmacy and how the states have defined the practice of pharmacy and scope of services which pharmacists are legally able to provide to patients. NABP requests that CMS work with the states and NABP to ensure that the definition of the practice of pharmacy and allowable activities of the pharmacist do not conflict with the proposed implementation of the MTMP services.

NABP Addresses Practice of Pharmacy in the *Model Act*

Many elements of the MTMP outlined in the MMA fall under the scope of pharmacy practice. *The Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* defines the scope of pharmacy practice as:

¹NAPLEX is the computer-adaptive North American Pharmacist Licensure Examination, which is a requirement of all states for licensure. NABP has developed and administered the North American Pharmacist Licensure Examination (NAPLEX) since the mid 70s. Every pharmacist who wishes to practice pharmacy in the United States of America is required to pass the NAPLEX. The NAPLEX Blueprint (Appendix A) outlines the competency statements that reflect the knowledge, judgment, and skills expected of entry-level pharmacists. Upon review of those competencies, it is evident that pharmacists are equipped with the knowledge and skills to successfully implement MTMS.

MPJE is the computerized Multistate Pharmacy Jurisprudence Examination required by 47 states.

The “Practice of Pharmacy” means 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 definition of the “Practice of Pharmacy” in the states is the critical factor of the state practice acts and regulations. Boards of pharmacy must have full knowledge of the whereabouts of Drugs and provision of services by pharmacists in the legitimate stream of intrastate and interstate commerce in order to protect patients from incompetent or dangerous practitioners, prevent diversion, effectuate recalls, ensure the quality of Drugs Dispensed or Administered to patients, and effectively protect the public. Again, NABP is requesting that CMS work with the states and NABP to determine how the definition of MTMP services impact or are impacted by state practice acts and regulations and to work closely with state boards of pharmacy to provide for effective supervision and regulation of MTMPs.

Collaborative Pharmacy Practice and MTMPs

In recent years, the concept of collaborative practice has evolved and codifies the relationship between pharmacists and other health care practitioners utilizing a multidisciplinary health care team approach. The *NABP Model Act*, and more than 40 state practice acts, similarly define collaborative pharmacy practice as the “Practice of Pharmacy whereby one or more Pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or more Practitioners under protocol whereby the Pharmacist may perform certain patient care functions authorized by the Practitioner or Practitioners under certain specified conditions and/or limitations.”

The purpose of entering into a collaborative pharmacy practice agreement is for pharmacists to work in collaboration with other practitioners to provide drug therapy management to patients. The ultimate goal is to provide the best possible services to the patients to ensure they are receiving the best possible therapy for their condition. Patient safety should be the pillar of any program or service developed by CMS or any other entity providing healthcare services to the public.

The *NABP Model Rules* contain a comprehensive list of elements that should be included in a Collaborative Pharmacy Practice Agreement (Appendix B). For clarification purposes, collaborative practice is separate and independent of prescriptive authority. This is a significant clarification. In some reviews of the MTMP services, there is the mistaken belief that state practice acts and regulations must grant pharmacists prescriptive authority in order to participate in the provision of MTMP services. This is simply not true.

The more relevant areas for consider when reviewing whether MTMP services will be allowed in a state is the definition of the "Practice of Pharmacy" and "Collaborative Practice" regulations. The ultimate determining factor will be the definition of the "Practice of Pharmacy." Again, there is a misconception that in order for MTMS to be allowed in a state, the state must have "Collaborative Practice" regulations in place. This is not true if the definition of the "Practice of Pharmacy" is modeled after the *NABP Model Act* definition or broad enough to allow for the inclusion of MTMP services. The impact of "Collaborative Practice" regulations is to further define the scope of services allowed under the "Practice of Pharmacy." In regard to MTMP services, "Collaborative Practice" regulations could serve to enhance and assist pharmacists in implementing MTMP services.

Although not specifically listed, NABP is currently researching the practice acts and regulations of these states to determine if the act and regulations are broad enough to allow for MTMP services and do not restrict the provision of these services. It is NABP's opinion that a broad definition of the "Practice of Pharmacy" and no specific prohibition for providing MTMP services or MTMP-like services should allow for the implementation of this pharmacist activity.

Evaluation of Non-Resident Pharmacy License for Remote Caregivers

Although those defining and implementing MTMPs may envision that the provision of these services will follow traditional therapy patterns, consideration must be given to the extent and impact of interstate activities. The immediate questions that should be addressed are whether states will allow for the practices of telemedicine and telepharmacy and what requirements and restrictions are in place for these variations from traditional, face-to-face care. For pharmacy practice and regulators non-resident pharmacies and related services are a primary focus.

A "Non-Resident Pharmacy," as defined in the *NABP Model Act* and state practice acts, means a Pharmacy located outside of the State. Nearly every state requires non-resident pharmacies to be licensed or registered in the state where they are shipping medications. An example of a non-resident pharmacy is a mail order facility that is located in one state but ships medications to patients in another state.

Regulatory activity regarding non-resident pharmacies has significantly increased in the past year, closely associated with importation issues, counterfeit drugs, and patients purchasing medications from the internet. In order to determine the non-resident requirements and the similarity/variation among the states, NABP recently conducted a survey of the state boards of pharmacy to determine which states have specific requirements for nonresident versus resident pharmacies, how the states assure quality and compliance, whether or not the state requires an inspection, and the number of complaints and how they are investigated.

NABP's survey found that nearly every state requires non-resident pharmacies to be licensed in their state; most do not require the individual pharmacists to be licensed in their state. The nonresident pharmacies comparison chart (Appendix C) included with this statement highlights examples of similarities and variances that exist in the nonresident pharmacies between the states.

Mark B. McClellan, MD, PhD

October 4, 2004

Page 5

Pharmacists must be licensed in the state in which they are physically located. Only a handful of states require non-resident pharmacists to be licensed in their particular state. NABP is not sure at this time how states will view the provision of MTMPs across state lines. It would appear that if non-resident pharmacists begin performing specific MTMP services, the state boards may, upon evaluation of their regulations and the pharmacist scope of practice, require non-resident pharmacists to become licensed in the state where the patient resides.

Provision of MTMPs by Non-Pharmacist Practitioners

A standard, which will essentially be the standard of practice defined and regulated by the boards of pharmacy for pharmacists, must be required for non-pharmacist practitioners providing MTMP services. Basic MTMP services could be performed by *all* pharmacists licensed in good standing with their state board of pharmacy without additional education or certification. The monitoring of these services from the health and safety of the patient would fall within the realm of current state regulation and provide a valid safeguard for patients. The same cannot be said if non-pharmacist practitioners engage in the provision of MTMP services.

In closing, NABP cannot underscore the importance of patient safety as it pertains to MTMP services and the need to work closely with the states to define the scope and implementation of MTMPs. CMS must develop regulations to ensure that the MTMP services provided to the Medicare beneficiaries are executed by pharmacists or other qualified non-pharmacist, healthcare professionals. While many arguments can be made to support the rapid adoption of MTMP services, careful consideration should be given to the details of the structure of MTMPs to ensure the focus is on patient safety, public protection, and the provision of quality health care. Both NABP and the state boards of pharmacy are willing to assist CMS in any capacity to help ensure that the services provided are within the scope of practice of pharmacy and that every patient benefit from the services provided to them.

Thank you, once again, for the opportunity to address this important issue.

Sincerely,

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

CAC/eza

Enclosures: Appendix A – NAPLEX Blueprint
Appendix B – Collaborative Pharmacy Practice Excerpt
Appendix C – Nonresident Pharmacies Comparison Chart

National Association of Boards of Pharmacy
 Non-Resident Pharmacies Survey



34 Boards Responded

<i>State</i>	<i>Do you have specific requirements for non-resident vs. resident, if so, please list-</i>	<i>How do you assure quality and compliance?</i>	<i>Do you require an inspection component such as copy of last inspection, etc.?</i>	<i>How many complaints do you receive each year against nonresident pharmacies?</i>	<i>Describe how are they investigated-</i>	<i>Do you rely on VIPPS or another national accreditation program?</i>
<i>AZ</i>	No, requirements are the same except pharmacists are not required to be licensed in Arizona. (See regulation R4-23-607. Nonresident Permits.)	Arizona State Board of Pharmacy assures quality and compliance by verifying out of state license/permits.	No	Less than 2 (two)	Arizona forwards complaints to the agency in the jurisdiction.	No
<i>AR</i>	All requirements are the same except counseling and exemption. (See out-of-state regulations at www.arkansas.gov/asbp)	Arkansas assures quality and compliance by requiring a licensed pharmacist on staff (physically) at each location.	Yes			
<i>CA</i>	In addition to the ownership information required for all applicants, non-resident pharmacies are also required to provide: a copy of their last inspection report; a statement indicating that they maintain records of controlled substances or dangerous devices dispensed to California patients, so that those records are readily retrievable from other drugs dispensed; two prescription labels that include a toll free number; a list of pharmacists and their license numbers for those who fill prescriptions for California residents; an original letter from your state board verifying your state license is current and in good standing with the state seal embossed on the letter.	California requires a letter from your state board verifying your state license is current and in good standing or with any disciplinary action. California may also visit the home state's website.	Yes	24	California conducts an investigation via letter. If the information received is substantiated, the board may cite and fine the pharmacy. Once resolved, the board will notify the licensing agency in the state the pharmacy is located in.	VIPPS is sometimes used.

National Association of Boards of Pharmacy
Non-Resident Pharmacies Survey



34 Boards Responded

<i>State</i>	<i>Do you have specific requirements for non-resident vs. resident, if so, please list-</i>	<i>How do you assure quality and compliance?</i>	<i>Do you require an inspection component such as copy of last inspection, etc.?</i>	<i>How many complaints do you receive each year against nonresident pharmacies?</i>	<i>Describe how are they investigated-</i>	<i>Do you rely on VIPPS or another national accreditation program?</i>
<i>CO</i>	Prerequisite for registration of out of state pharmacies is that non-resident pharmacies must submit a copy of the most recent board inspection.	Colorado relies on the state where the pharmacy is located.	Yes	Less than 5 (five)	Colorado refers to the state board where located.	No
<i>CT</i>	See Connecticut regulations: Section 20-627. Nonresident pharmacy. Definitions. Certificate of registration. Requirements; Section 20-628. Shipping, mailing or delivering legend devices or drugs; Section 20-629. Suspension or revocation of certificate; Section 20-650. Advertising.	Connecticut assures quality and compliance by current licensure.	Connecticut requires a copy of the most recent inspection report.	Not documented	Complaints are investigated by referring to the state of licensure.	No
<i>DE</i>	Yes, resident and non-resident requirements are listed in statute and regulation. (See Web site at www.professionallicensing.state.de.us)	Delaware assures quality and compliance through licensure, license procedure and complaints addressed.	Yes	1 (one)-5 (five) a year - Non-resident complaints have routinely centered around quantity dispensed issues.	Complaints are investigated by contact made and complaint discussed with licensee.	Yes
<i>DC</i>	No					
<i>FL</i>	See Statute 465.0156 Registration of nonresident pharmacies	Florida relies on the state where pharmacy is located to assure quality and compliance.	No	12-15 per year	Most complaints are referred to the state of residence.	No

National Association of Boards of Pharmacy
Non-Resident Pharmacies Survey



34 Boards Responded

<i>State</i>	<i>Do you have specific requirements for non-resident vs. resident, if so, please list-</i>	<i>How do you assure quality and compliance?</i>	<i>Do you require an inspection component such as copy of last inspection, etc.?</i>	<i>How many complaints do you receive each year against nonresident pharmacies?</i>	<i>Describe how are they investigated-</i>	<i>Do you rely on VIPPS or another national accreditation program?</i>
<i>HI</i>	Out-of-state pharmacies who fill prescriptions for individuals residing in Hawaii must be permitted under our miscellaneous permit. Hawaii requires that the out-of-state pharmacy be already licensed/permitted in another state. Hawaii does not license individual pharmacists for out-of-state pharmacies. (See Web site at www.state.hi.us/dcca/pvl - Requirements and instructions for filing – Miscellaneous Permit)	Verification from the state of domicile that the pharmacy and pharmacists are in good standing, unencumbered, etc.	No	This information is not readily available. Complaints and investigations are handled by the Regulated Industries Complaints Office.	See answer to question #4.	No
<i>ID</i>	See statute 54-1740 through 54-1750 – “Out-of-State Mail Service Pharmacy Licensing Act”			We receive very few formal complaints (which are what we act on). We have had 2 (two) \$1000 fines for violation of our product selection rules.	Complaints are investigated by our compliance section - we have not really had to rely on another state.	No
<i>IN</i>	See Indiana law IC 25-26-17 Chapter 17. Nonresident Pharmacies	Indiana assures quality and compliance based on “home” state licensure and inspection. Law requires that the “home” state’s requirements are equivalent to Indiana’s in-state requirements.	Yes, we require a copy of last inspection.	Average of 6 (six) over the past 4 (four) years	Complaints are investigated by the Indiana Office of the Attorney General, usually in cooperation with the “home” state’s Attorney General.	We recognize VIPPS, but it is not a requirement.

National Association of Boards of Pharmacy
Non-Resident Pharmacies Survey



34 Boards Responded

<i>State</i>	<i>Do you have specific requirements for non-resident vs. resident, if so, please list-</i>	<i>How do you assure quality and compliance?</i>	<i>Do you require an inspection component such as copy of last inspection, etc.?</i>	<i>How many complaints do you receive each year against nonresident pharmacies?</i>	<i>Describe how are they investigated-</i>	<i>Do you rely on VIPPS or another national accreditation program?</i>
<i>KS</i>	Pharmacy has to be licensed in good standing in the state it is located. Each pharmacist dispensing drugs in Kansas has to be licensed in state where he is practicing. Pharmacy has to provide the name of responsible pharmacist who shall receive communication from board, pay a registration fee, and keep records of drugs dispensed in Kansas available on request. They must have an incoming toll free phone number, be open normal business hours with a minimum of 40 hours – 6 days a week, and must have resident agent. We also review all complaint and conviction data of owners.	Facilities and records of pharmacy are subject to inspection. Satisfactory inspection reports by the licensing entity using similar standards as Kansas may be accepted in lieu of inspection by the board.	No	Approximately 2 (two) - 5 (five)	Contact resident state board of pharmacy for assistance. We also make direct contact with responsible pharmacist in charge, and ask for written response to complaint. Phone contact with responsible pharmacist.	We rely on VIPPS for all internet mail order accreditation.
<i>LA</i>	No, we expect them to comply with all of our laws and rules to the extent that does not place them in violation of their resident state's rules.	Louisiana relies on resident state board of pharmacy.	Yes	Louisiana has about 340 such permits. In fiscal year ending, June 30, 2004, the board logged approximately 20 complaints; about 1/3 were internet operations, another 1/3 were late renewals, and another 1/3 were failure to pay Medicaid fees.	Louisiana in-house counsel works via telephone and mail, calling on other boards as needed.	No
<i>MD</i>	(See Pharmacy Act Ho, § 12-403. Required standards.)	Maryland relies on Board in state of original license.	Yes, a copy of last inspection.	Few, actually rare.	Information given to home state.	No

National Association of Boards of Pharmacy
Non-Resident Pharmacies Survey



34 Boards Responded

<i>State</i>	<i>Do you have specific requirements for non-resident vs. resident, if so, please list-</i>	<i>How do you assure quality and compliance?</i>	<i>Do you require an inspection component such as copy of last inspection, etc.?</i>	<i>How many complaints do you receive each year against nonresident pharmacies?</i>	<i>Describe how are they investigated-</i>	<i>Do you rely on VIPPS or another national accreditation program?</i>
<i>MS</i>	Mississippi has no specific requirements for resident vs. nonresident pharmacies.	Mississippi assures quality and compliance by verifying that a pharmacy license is in good standing with the state in which it is located before issuing a nonresident permit.	Mississippi does not require a copy of the last inspection.	Not sure how many nonresident complaints the board gets, but probably less than 10. Most pertained to a mail order pharmacy and cost or product selection. (Most seem to be insurance problems, not pharmacy problems.)	Agents in this office phone the facility about the complaint. If a phone call is not sufficient, we call the Board of Pharmacy in that state.	Mississippi does not rely on VIPPS.
<i>MO</i>	(See Rule 4 CSR 220-2.020 Pharmacy Permits, and 4 CSR 220-2.025 Nonresident Pharmacies.)	Random check of host state inspection reports.	No, not on the application, but we are planning to.			
<i>NE</i>	Yes, Nebraska licenses nonresident pharmacies as Mail Service Pharmacies. They are required to employ a Nebraska licensed pharmacist to assure compliance with the Mail Service Pharmacy Act.	Nebraska licensed pharmacist requirement to assure compliance with the Mail Service Pharmacy Act.	Yes, requirement of last 2 (two) inspections unless they are new (opened recently) in their state, so they have only had one inspection.	No, but we do ask whether their pharmacist in charge or the pharmacy has been disciplined since their last renewal. The board can discipline their license for past discipline.	Either Nebraska pharmacy inspectors or Nebraska Investigation Division.	Only that we check VIPPS, but not very many are found to have VIPPS.
<i>NV</i>	No specific differences, except resident pharmacies must report controlled substance dispensing to prescription monitoring program.	Nevada relies on the state of situs that licensure and standards are met. We request confirmation.	No	Very minimal, 1 (one) or possibly 3 (three) per year.	Nonresident pharmacies are investigated by forwarding the complaint to the regulatory agency appropriate for that pharmacy.	Yes, Nevada's regulations require either the VIPPS certification or attestation. The pharmacy has adopted the same standards.

National Association of Boards of Pharmacy
Non-Resident Pharmacies Survey



34 Boards Responded

<i>State</i>	<i>Do you have specific requirements for non-resident vs. resident, if so, please list-</i>	<i>How do you assure quality and compliance?</i>	<i>Do you require an inspection component such as copy of last inspection, etc.?</i>	<i>How many complaints do you receive each year against nonresident pharmacies?</i>	<i>Describe how are they investigated-</i>	<i>Do you rely on VIPPS or another national accreditation program?</i>
<i>NH</i>	Yes, as specified in RSA 318:37, II and Chapter Ph 900 of the board's administrative rules. (See New Hampshire rules)	Rely on VIPPS certification and the cooperation of boards of pharmacy where the non-resident mail order pharmacy is domiciled.	Yes, New Hampshire requires a copy of the most recent inspection, conducted by the domiciled board of pharmacy, to be submitted with the annual renewal application.	Not more than 12-15 per 12 month period.	Vast majority of concerns/complaints are resolved by speaking with the patient. If necessary, a call to the mail order pharmacy provides an explanation and/or resolution.	Yes
<i>NY</i>	Yes, see regulation S 63.8 Registration of nonresident establishments; S 6808-b. Registration of nonresident establishments.	From the state board from their home state.	No	Very few	No	No
<i>NC</i>	Yes, see regulation §90-85.21A. Applicability to out-of-state operations; 21 NCAC 46.1607 Out-of-State Pharmacies.	Investigate complaints; communicate with board in state where located; legislation in process to require permit holder to employ a North Carolina licensed pharmacist.	No	Approximately 10	North Carolina asks the host state to investigate.	Yes
<i>ND</i>	Yes, see Law – Article 61-08 Out-of-State Pharmacies.	North Dakota relies on the resident board's inspection, and requires a copy of the last inspection, and also a copy of the pharmacy's license.	Yes	One a year	North Dakota writes to the pharmacy for an explanation of the incident; a copy of the explanation goes to the resident board. The board cooperates with the resident board in acquiring evidence and prosecuting the complaint.	North Dakota uses VIPPS as one of the components in their licensing review.

National Association of Boards of Pharmacy
 Non-Resident Pharmacies Survey



34 Boards Responded

<i>State</i>	<i>Do you have specific requirements for non-resident vs. resident, if so, please list-</i>	<i>How do you assure quality and compliance?</i>	<i>Do you require an inspection component such as copy of last inspection, etc.?</i>	<i>How many complaints do you receive each year against nonresident pharmacies?</i>	<i>Describe how are they investigated-</i>	<i>Do you rely on VIPPS or another national accreditation program?</i>
<i>OK</i>	Yes, see Rule 535:15-3-9. Non-resident pharmacies.	Oklahoma relies on the state board where the pharmacy is located.	Oklahoma reserves that right, but again relies on the state of origin.	Less than 12 a year.	Oklahoma turns information over to the state board of the state they are located in.	No
<i>OR</i>	Yes, Oregon requires the nonresident pharmacies to send verification from their licensing state, current status with the state, and any actions taken against the pharmacy.	Oregon leaves the quality and assurance to each state and uses certification by the resident state.	No	4 (four) to 5 (five)	Complaints are investigated as a normal case with correspondence.	No
<i>PA</i>	Pennsylvania State Board of Pharmacy has no authority to license/regulate nonresident pharmacies.					
<i>SC</i>	South Carolina has the same requirements for nonresident pharmacies vs. resident pharmacies.	South Carolina assures quality and compliance through the state board in which the facilities are located.	Yes	Last year South Carolina received 8 (eight) complaints on nonresident pharmacies, and that is about average.	All cases are investigated by a pharmacist investigator. Necessary files and records are obtained for review from the facility in question as well as other regulatory entities that may be involved. Cases are reviewed by an investigative review committee that approves any recommendation for disciplinary action. Any actions (formal or non-disciplinary) are reviewed and approved by the full board.	South Carolina utilizes VIPPS.

National Association of Boards of Pharmacy
Non-Resident Pharmacies Survey



34 Boards Responded

<i>State</i>	<i>Do you have specific requirements for non-resident vs. resident, if so, please list-</i>	<i>How do you assure quality and compliance?</i>	<i>Do you require an inspection component such as copy of last inspection, etc.?</i>	<i>How many complaints do you receive each year against nonresident pharmacies?</i>	<i>Describe how are they investigated-</i>	<i>Do you rely on VIPPS or another national accreditation program?</i>
<i>SD</i>	Go to www.state.sd.us/doh/pharmacy , see Law SDCL-36-11-19.2 to 19.8	South Dakota requires a copy of state license, pharmacy address, contact person, pharmacist-in-charge phone number, report any license restrictions, and list of owner phone number for public access 800 number.	South Dakota requires a copy of the latest inspection, and sometimes makes contact with the state to verify information (spot check).	Most complaints are against mail-order located in this state.	If South Dakota has a complaint outside this state, the state where the licensed non-resident pharmacy is located is contacted.	South Dakota asks the question if VIPPS certified. Some are, most are not.
<i>TN</i>	Must have a pharmacist-in-charge who is licensed in Tennessee. Must submit a copy of most recent inspection and subsequent inspections. (See Rule 1140-1-.08)	See question #1.	See question #1.	Less than 1% of overall complaints,	Complaints that require a response are handled directly. Complaints requiring investigation are deferred to the board of jurisdiction. Boards are copied on all correspondence.	No
<i>TX</i>	See Board Rules 291.101-291.105	The board relies on the state board of pharmacy where the pharmacy is located to assure compliance.	At the time of initial application, the pharmacy must provide a copy of its most recent inspection as well as a statement from the resident board of pharmacy which verifies the license of the pharmacy and the license of the pharmacist-in-charge.	In FY2003 (September 1, 2002 – August 31, 2003) the Texas State Board of Pharmacy closed 56 complaints on non-resident pharmacies.	Usually complaints involving non-resident pharmacies are referred to the state board of pharmacy where the pharmacy is located for action. See the Texas Pharmacy Act, Section 565.053.	No

National Association of Boards of Pharmacy
Non-Resident Pharmacies Survey



34 Boards Responded

<i>State</i>	<i>Do you have specific requirements for non-resident vs. resident, if so, please list-</i>	<i>How do you assure quality and compliance?</i>	<i>Do you require an inspection component such as copy of last inspection, etc.?</i>	<i>How many complaints do you receive each year against nonresident pharmacies?</i>	<i>Describe how are they investigated-</i>	<i>Do you rely on VIPPS or another national accreditation program?</i>
<i>VA</i>	See Law §54.1-3434.1. Nonresident pharmacies to register with Board. Virginia is planning to propose changes next legislative session.	Rely currently on resident state board.	Yes, this is a problem with states that do not inspect prior to opening new pharmacies.	Approximately 20-30	Referred to resident state currently.	No, require resident state licensure.
<i>WA</i>	Yes, Washington has specific laws, which address the application and licensing requirements for nonresident pharmacies – RCW 18.64.350 through 450.	The board assures quality and compliance through: Verification of license status; providing applicable rules and regulations to licensed pharmacies – education; and customer service – a uniform process for receiving, investigating and determining appropriate actions.	Yes, the original application packet submitted to the board for consideration for licensure requires a copy of the most recent inspection conducted by the state's licensing/regulatory agency.	The Washington Board receives approximately 6 (six) -10 complaints per year for nonresident pharmacies.	The nature of the complaint would determine what actions/investigation is pursued. A violation of pharmacy law would be referred to the state board/regulatory agency in which the pharmacy is located. Actions limiting the resident license would directly impact the license issued by Washington State. If the complaint is not a violation of pharmacy law, the board sends a letter informing the licensee of the complaint and the case is closed.	No, to date Washington has not relied on any national accreditation programs; however, if necessary we have contacted individual boards via telephone or Internet for license verification.
<i>WV</i>	West Virginia's requirement is a toll free phone number.	Generally rely on home state to ensure legitimate practice.	Yes	Generally 4 (four)-5 (five), usually about delayed delivery or switching of products.	Contact mail order PIC, if needed work with home state board of pharmacy.	No, have sought legislation to require it. No success yet.
<i>WI</i>	Wisconsin does not license non-resident pharmacies.					

National Association of Boards of Pharmacy
 Non-Resident Pharmacies Survey



34 Boards Responded

<i>State</i>	<i>Do you have specific requirements for non-resident vs. resident, if so, please list-</i>	<i>How do you assure quality and compliance?</i>	<i>Do you require an inspection component such as copy of last inspection, etc.?</i>	<i>How many complaints do you receive each year against nonresident pharmacies?</i>	<i>Describe how are they investigated-</i>	<i>Do you rely on VIPPS or another national accreditation program?</i>
WY	Yes, a copy of state license, a copy of most recent board inspection, a copy of DEA registration and an application which is a little different from resident.		Yes	Very few complaints.	Contact pharmacy, communicate back and forth.	No



NAPLEX Blueprint
(Revised 7/03)

The NAPLEX Competency Statements

The NAPLEX Competency Statements provide a blueprint of the topics covered on the examination. They offer important information about the knowledge, judgment, and skills you are expected to demonstrate as an entry-level pharmacist. A strong understanding of the Competency Statements will aid in your preparation to take the examination.

**Area 1 Assure Safe and Effective Pharmacotherapy and Optimize Therapeutic Outcomes
(Approximately 54% of Test)**

- 1.1.0 *Obtain, interpret and evaluate patient information to determine the presence of a disease or medical condition, assess the need for treatment and/or referral, and identify patient-specific factors that affect health, pharmacotherapy, and/or disease management.*
 - 1.1.1 Identify and assess patient information including medication, laboratory and disease state histories.
 - 1.1.2 Identify and/or use instruments and techniques related to patient assessment and diagnosis.
 - 1.1.3 Identify and define the terminology, signs, and symptoms associated with diseases and medical conditions.
 - 1.1.4 Identify and evaluate patient factors, genetic factors, biosocial factors, and concurrent drug therapy that are relevant to the maintenance of wellness and the prevention or treatment of a disease or medical condition.

- 1.2.0 *Identify, evaluate, and communicate to the patient or health-care provider, the appropriateness of the patient's specific pharmacotherapeutic agents, dosing regimens, dosage forms, routes of administration, and delivery systems.*
 - 1.2.1 Identify specific uses and indications for drug products.
 - 1.2.2 Identify the known or postulated sites and mechanisms of action of pharmacotherapeutic agents.
 - 1.2.3 Evaluate drug therapy for the presence of pharmacotherapeutic duplications and interactions with other drugs, food, diagnostic tests, and monitoring procedures.
 - 1.2.4 Identify contraindications, warnings and precautions associated with a drug product's active and inactive ingredients.
 - 1.2.5 Identify physicochemical properties of drug substances that affect their solubility, pharmacodynamic and pharmacokinetic properties, pharmacologic actions, and stability.
 - 1.2.6 Interpret and apply pharmacodynamic and pharmacokinetic principles to calculate and determine appropriate drug dosing regimens.
 - 1.2.7 Interpret and apply biopharmaceutic principles and the pharmaceutical characteristics of drug dosage forms and delivery systems, to assure bioavailability and enhance patient compliance.

- 1.3.0 *Manage the drug regimen by monitoring and assessing the patient and/or patient information, collaborating with other health care professionals, and providing patient education.*
 - 1.3.1 Identify pharmacotherapeutic outcomes and endpoints.
 - 1.3.2 Evaluate patient signs and symptoms, and the results of monitoring tests and procedures to determine the safety and effectiveness of pharmacotherapy.
 - 1.3.3 Identify, describe the mechanism of, and remedy adverse reactions, allergies, side effects and iatrogenic or drug-induced illness.
 - 1.3.4 Prevent, recognize, and remedy medication non-adherence, misuse or abuse.
 - 1.3.5 Recommend pharmacotherapeutic alternatives.

Appendix A



Area 2 Assure Safe and Accurate Preparation and Dispensing of Medications (Approximately 35% of Test)

- 2.1.0 *Perform calculations required to compound, dispense, and administer medication.*
 - 2.1.1 Calculate the quantity of medication to be compounded or dispensed; reduce and enlarge formulation quantities and calculate the quantity of ingredients needed to compound the proper amount of the preparation.
 - 2.1.2 Calculate nutritional needs and the caloric content of nutrient sources.
 - 2.1.3 Calculate the rate of drug administration.
 - 2.1.4 Calculate or convert drug concentrations, ratio strengths, and/or extent of ionization.

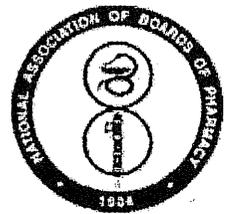
- 2.2.0 *Select and dispense medications in a manner that promotes safe and effective use.*
 - 2.2.1 Identify drug products by their generic, brand, and/or common names.
 - 2.2.2 Determine whether a particular drug dosage strength or dosage form is commercially available, and whether it is available on a nonprescription basis.
 - 2.2.3 Identify commercially available drug products by their characteristic physical attributes.
 - 2.2.4 Interpret and apply pharmacokinetic parameters and quality assurance data to determine equivalence among manufactured drug products, and identify products for which documented evidence of inequivalence exists.
 - 2.2.5 Identify and communicate appropriate information regarding packaging, storage, handling, administration, and disposal of medications.
 - 2.2.6 Identify and describe the use of equipment and apparatus required to administer medications.

- 2.3.0 *Prepare and compound extemporaneous preparations and sterile products.*
 - 2.3.1 Identify and describe techniques and procedures related to drug preparation, compounding, and quality assurance.
 - 2.3.2 Identify and use equipment necessary to prepare and extemporaneously compound medications.
 - 2.3.3 Identify the important physicochemical properties of a preparation's active and inactive ingredients; describe the mechanism of, and the characteristic evidence of incompatibility or degradation; and identify methods for achieving stabilization of the preparation.

Area 3 Provide Health Care Information and Promote Public Health (Approximately 11% of Test)

- 3.1.0 *Access, evaluate, and apply information to promote optimal health care.*
 - 3.1.1 Identify the typical content and organization of specific sources of drug and health information for both health-care providers and consumers.
 - 3.1.2 Evaluate the suitability, accuracy, and reliability of information from reference sources by explaining and evaluating the adequacy of experimental design and by applying and evaluating statistical tests and parameters.

- 3.2.0 *Educate the public and health-care professionals regarding medical conditions, wellness, dietary supplements, and medical devices.*
 - 3.2.1 Provide health care information regarding the prevention and treatment of diseases and medical conditions, including emergency patient care.
 - 3.2.2 Provide health care information regarding nutrition, lifestyle, and other non-drug measures that are effective in promoting health or preventing or minimizing the progression of a disease or medical condition.
 - 3.2.3 Provide information regarding the documented uses, adverse effects and toxicities of dietary supplements.
 - 3.2.4 Provide information regarding the selection, use and care of medical/surgical appliances and devices, self-care products, and durable medical equipment, as well as products and techniques for self-monitoring of health status and medical conditions.



*Model State Pharmacy Act
and Model Rules of the
National Association of Boards of Pharmacy*

June 2003

Collaborative Pharmacy Practice Excerpt
(Pages 91-93)

Model Rules for Pharmaceutical Care

Section 3. Pharmacy Practice.

J. Collaborative Pharmacy Practice

(1) Collaborative Pharmacy Practice Agreement.

A Pharmacist planning to engage in Collaborative Pharmacy Practice shall have on file at his or her place of practice the written Collaborative Pharmacy Practice Agreement. The initial existence and subsequent termination of any such agreement and any additional information the Board may require concerning the Collaborative Pharmacy Practice Agreement, including the agreement itself, shall be made available to the Board for review upon request. The Agreement may allow the Pharmacist, within the Pharmacist's Scope of Practice Pursuant to the Collaborative Pharmacy Practice Agreement, to conduct Drug Therapy Management activities approved by the Practitioner. The collaboration that the Practitioner agrees to conduct with the Pharmacist must be within the scope of the Practitioner's current practice. Patients or caregivers shall be advised of such agreement.

(2) Contents.

The Collaborative Pharmacy Practice Agreement shall include:

- (a) Identification of the Practitioner(s) and Pharmacist(s) who are parties to the Agreement;
- (b) The types of Drug Therapy Management decisions that the Pharmacist is allowed to make, which may include:
 - (i) A detailed description of the types of diseases, Drugs, or Drug categories involved, and the type of Drug Therapy Management allowed in each case;
 - (ii) A detailed description of the methods, procedures, decision Criteria, and plan the Pharmacist is to follow when conducting Drug Therapy Management; and

Appendix B

- (iii) A detailed description of the activities the Pharmacist is to follow in the course of conducting Drug Therapy Management, including documentation of decisions made and a plan or appropriate mechanism for communication, feedback, and reporting to the Practitioner concerning specific decisions made. In addition to the Agreement, documentation shall occur on the prescription record, patient profile, a separate log book, or in some other appropriate system;
- (c) A method for the Practitioner to monitor compliance with the Agreement and clinical outcomes where Drug Therapy Management by the Pharmacist has occurred and to intercede where necessary;
- (d) A description of the Continuous Quality Improvement Program used to evaluate effectiveness of patient care and ensure positive patient outcomes.
- (e) A provision that allows the Practitioner to override a Collaborative Practice decision made by the Pharmacist whenever he or she deems it necessary or appropriate;
- (f) A provision that allows either party to cancel the Agreement by written notification;
- (g) An effective date; and
- (h) Signatures of all collaborating Pharmacists and Practitioners who are party to the agreement, as well as dates of signing.

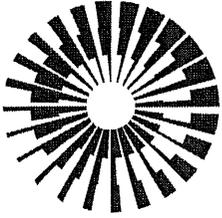
Amendments to a Collaborative Pharmacy Practice Agreement must be documented, signed, and dated.

- (3) **Initiation of the Collaborative Pharmacy Practice Agreement**

The Collaborative Pharmacy Practice Agreement must be coupled with a medical order from the Practitioner to initiate Drug Therapy Management for any particular patient.
- (4) **Documentation of Drug Therapy Management.**

Documentation of Drug Therapy Management must be kept as part of the patient's permanent record and be readily available to other health care professionals providing care to that patient and who are authorized to receive it. Documentation of Drug Therapy Management shall be considered Protected Health Information.
- (5) **Review.**

At a minimum, the written agreement shall be reviewed and renewed and, if necessary, revised every year.



EVERGREEN PHARMACEUTICAL OF
CALIFORNIA, an Omnicare Company

14735 Califa St
Van Nuys, California 91411
888-452-4808
fax 888-452-4809

Rosie Silverstein, Pharm D, CGP
Consultant Coordinator
Omnicare, Southern California.

Stan Goldenberg,, President, State Board of Pharmacy,

Dear Stan,

Thank you so much for taking the time to help me understand this issue.

Omnicare has a progressive program for offering therapeutic interchange for the residents we serve who reside in long term care facilities. We have identified medications that are equally effective, but less expensive, within several drug classes. We fax the attending physician a letter asking him to authorize the change for a specific resident. Once we receive the signed letter from the MD, we forward a copy of the signed letter to the nursing home and fill the new order.

Our question is: Can our call center located in Texas review our records for opportunities. A Texas pharmacist would review the letters before faxing. The Texas call center would fax out the letters. The signed letters would then be forwarded to California and a California pharmacist would fill the order.

Alternatively, can the call center in Texas review our records for opportunities. A California pharmacist would review the letters before faxing. Then the Texas call center would fax out the letters and forward any signed letters to California for filling.

I look forward to hearing from you soon so that we can proceed with this cost savings program.

Rosie Silverstein, Pharm D
323-336-3510

Regional Call Center for Therapeutic Interchange

Therapeutic Interchange is a national Omnicare initiative. The goal is to switch equally effective medications within a class to alternatives that are less costly.

The Regional Call Center Database is located and managed in San Antonio at a licensed pharmacy and supervised by a licensed pharmacist. The database identifies non-preferred drugs and evaluates for consideration for Therapeutic Interchange conversion to an Omnicare preferred drug.

The procedure is as follows:

1. Files are automatically transferred every night of that day's prescription activity for all California pharmacies. These files are sent from the Rescot servers to a computer located in the Regional Call Center in San Antonio. This is an automatic process that does not require human intervention.
2. These files are screened through the database for Therapeutic Interchange candidates.
3. Convert the Therapeutic Interchange candidates to proposed preferred prescription recommendations.
4. The California pharmacy data is run through the database. All candidate prescriptions are prepared for on-screen review and approval by a licensed registered pharmacist in California.
5. All approved prescriptions are faxed to the California physician for approval or rejection.
6. California physician faxes back approved and denied patient specific Therapeutic Interchange's to the San Antonio Regional Call Center.
7. Database updates the status of the patient specific Therapeutic Interchange request.
8. California pharmacies receive copies of the approved and denied patient specific Therapeutic Interchanges and takes appropriate action.

Since the above procedure includes the direct involvement of a California licensed pharmacist practicing in one of our California licensed pharmacies and since all the call center is doing is just putting the information together for the pharmacist to review at this stage we don't feel that there has been any compromising of any California pharmacy regulation.

What we would like for the Board to consider is if our Regional Call Center would have a California out-of-state pharmacy license and employ a California licensed pharmacist could we do Step #4 at the Regional Call Center.

JOHN P. BRODY
ROBERT G. COHEN
KENNETH R. COOKSON
LAWRENCE F. FEHELEY
DONALD W. GREGORY
ALLEN L. HANDLAN
PAUL R. HESS
THOMAS W. HILL
DANIEL G. HILSON
CHARLES J. KEGLER
TODD M. KEGLER
R. KEVIN KERNS
HELEN MAC MURRAY
DAVID M. McCARTY

LARRY J. McCLATCHEY
PAUL D. RITTER, JR.
RICHARD W. SCHUERMANN, JR.
ROBERT G. SCHULER
S. MARTIJN STEGER
GEOFFREY STERN
ROGER P. SUGARMAN
KEVIN L. SYKES
JOHN R. THOMAS
TIMOTHY T. TULLIS
CHRISTOPHER J. WEBER
MELVIN D. WEINSTEIN
MICHAEL E. ZATEZALO

KEGLER BROWN & RITTER

A LEGAL PROFESSIONAL ASSOCIATION

2004 OCT 25 AM 10:30

STEPHEN C. BARSOTTI
MARY F. BRENNING
E. ROD DAVISSON
LISA M. DIEM
EVE M. ELLINGER
STEPHEN D. ESTELLE
LORIANN E. FUHRER
DAVID T. GRAHAM
ADAM J. HALL
STUART W. HARRIS
MELISSA R. HOEFFEL
RASHEDA Z. KHAN
JOHN LOWE IV
JENNIFER L. MACKANOS
TRACI A. McGUIRE
JAYME P. MOORE
ANGELA G. PARSONS
JEFFREY D. PORTER
ANNE D. POUGET
REBECCA R. PRICE

MARK R. REITZ
JEAN M. SUH
MALINDA L. SUSALLA
STEPHANIE P. UNION
NICHOLAS E. WILKES
MICHELE S. WOROBIEC*

OF COUNSEL

JOHN C. DEAL
CHARLES R. DYAS, JR.
THOMAS D. KITCH
ROBERT D. MAROTTA
TED M. McKINNISS*
RANDALL W. MIKES
S. MICHAEL MILLER
MICHELE A. SHUSTER
PATSY A. THOMAS

*Resident in Marion Office

October 20, 2004

Patricia F. Harris
Executive Officer
California State Board of Pharmacy
400 R St, Suite 4070
Sacramento CA 95814

Dear Ms. Harris:

Our firm represents a client that is in the process of developing a centralized data processing system for its pharmacy operations that will allow it to streamline workflow and information across the full resources of its operations. Centralized processing will allow our client to manage and distribute its workflow through a centralized location and data processing system, thereby allowing it to maintain and enhance the critical pharmacist-patient relationship while taking advantage of the accuracy and efficiency of automated solutions.

Our client envisions conducting data processing and drug utilization review at a centralized location for multi-state dispensing facilities. The system includes an enhanced electronic audit trail that will provide a greater number of checks implemented throughout the dispensing system, with individual pharmacist responsibility for each step in the process.

While there are many regulatory and business issues that remain to be addressed before our client is able to move forward with implementation of centralized processing, there are several questions we have that will determine the optimal business process. We have conducted extensive legal research on each one of these issues and while several states have addressed the questions statutorily, it appears to be an issue of first of impression in California. The questions that we have are based on the following scenario:

Scenario

A prescription originates in California. It is sent electronically or via facsimile to an out-of-state centralized processing facility. The out-of-state centralized processing facility inputs the prescription label information and performs the drug utilization review. The prescription is filled and dispensed at the California pharmacy.

Based on this scenario, what would the Board's position be on the following questions?

Patricia F. Harris
October 20, 2004
Page 2

Questions

1. Will the California Board of Pharmacy allow an out-of-state centralized processing facility to input the prescription label information and conduct the drug utilization review for fulfillment in a California Pharmacy?
2. If the out-of-state centralized processing facility is not permitted to perform the drug utilization review, can the out-of-state centralized processing facility input the prescription label information and the California pharmacy perform the drug utilization review and dispense the prescription?
3. Will the California Board of Pharmacy require the out-of-state centralized processing facility to be licensed in California?
4. Will the California Board of Pharmacy require the out-of-state pharmacist, located at the centralized processing facility, to be licensed in California?
5. As part of its approval process, does the California Board of Pharmacy inspect the out-of-state centralized processing center?
6. If an error occurs with the data processing of the prescription label information or during the drug utilization review at the out-of-state centralized processing facility, that was in no way associated with the work performed by the California dispensing pharmacy, would the California Board of Pharmacy hold the out-of-state dispensing pharmacy liable for that error?

Additionally, my client would like enhance the dispensing process by verifying the unit amount of a prescription to be dispensed using bar code scanners technology. The verification would be performed by a pharmacy technician, under the supervision of a pharmacist. Bar code scanning technology lends itself well to our client's existing and proposed central processing model. Our client uses single unit packaging for dispensing to long-term care facilities and each package is bar coded. Research shows that the use of bar coding reduces the instances of dispensing errors and as a result bar coding systems are becoming more widely utilized in institutional settings such as long term care facilities and hospitals. Recently, the United States Food and Drug Administration (FDA) promulgated a rule requiring bar coding on certain human and biological drug products. When releasing this new rule the FDA cited the significant reduction in medication errors that has resulted from the use of bar code scanner technology.

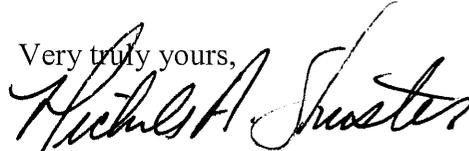
KEGLER BROWN
HILL & RITTER
A LEGAL PROFESSIONAL ASSOCIATION

Patricia F. Harris
October 20, 2004
Page 3

If the scenario or questions require any clarification or if you would like to meet to discuss the issues presented, I would be happy to arrange a meeting with you and our client.

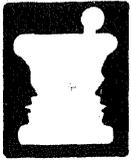
Thank you in advance for your time and attention to these issues.

Very truly yours,



Michele A. Shuster

MAS/lkz



California State Board of Pharmacy

400 R Street, Suite 4070, Sacramento, CA 95814
Phone (916) 445-5014
Fax (916) 327-6308
www.pharmacy.ca.gov

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

August 24, 2004

Dan Luce, Manager Pharmacy Affairs
Walgreens
200 Wilmont Road
Deerfield, CA 60015

Dear Mr. Luce:

This is to acknowledge receipt of your letter dated July 30, 2004, requesting the Board of Pharmacy's review of the new Walgreens business model, termed "VISION."

The Board of Pharmacy is charged with enforcing the authorizations and proscriptions in its statutes and regulations, and does not grant permission to individual licensees or groups thereof to engage in particular conduct. To do so might constitute underground regulation by the Board of Pharmacy. Based on the information provided in your letter, it appears that the appropriately licensed entities and personnel are performing the functions as required and authorized by California pharmacy law. I remind you that it is part of the corresponding responsibility of every pharmacist and /or pharmacy filling a prescription to ensure legitimacy, propriety, and accurate dispensing (e.g. Health and Safety Code sec. 11153, Cal. Code Regs., title 16, secs. 1716, 1761).

I trust the above has responded to your inquiry.

Sincerely,

A handwritten signature in cursive script that reads "P. F. Harris".

Patricia F. Harris
Executive Officer



RECEIVED BY CALIF.
BOARD OF PHARMACY

July 30, 2004

2004 AUG -9 PM 3: 03

Patricia Harris, Executive Director
California State Board of Pharmacy
400 R St, Suite 4070
Sacramento, CA 95814

Dear Ms. Harris:

I recently spoke with California Board of Pharmacy member Ruth Conroy. She relayed the information from your discussion on the best way to approach the Board regarding a request for a review of the Walgreens new business model, termed "VISION".

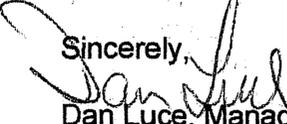
Please consider this letter a request for you to review the program. If the Board determines that a waiver of any rule is required, we would request such a waiver at that time. We are prepared to appear before the appropriate committee and/or full board if needed.

Succinctly stated, VISION is a pharmacy business model that essentially splits the activities required for prescription dispensing between multiple pharmacy locations. In this proposed model, the original ("intake") pharmacy would receive the prescription from the patient or prescriber and a digital image of the prescription order would be generated. The image would then be made available in an on-line electronic holding queue, accessible by other licensed Walgreens pharmacies. Once accessed, staff at the second ("processing") pharmacy would enter the order into the shared real time, on-line prescription file for the pharmacist to review and analyze the prescription, perform drug utilization review ("DUR") and all other cognitive activities required in order to confirm that the prescription is appropriate and can be dispensed to the patient. Once these cognitive functions are completed, a prescription label would be generated at the intake pharmacy for filling, final product verification and subsequent dispensing to the patient. This type of bifurcation of the prescription filling process has been referred to by some as "central processing", since a central pharmacy location is used to process prescriptions for dispensing at other pharmacy locations. Although at this point, VISION does not plan to utilize a central location to perform the order entry, review and DUR activities, the same principles applicable to central processing apply.

To maintain patient safety and prevent prescription errors, Walgreens will ensure that each prescription is appropriately identified throughout the process. Specifically, each prescription will be assigned a unique prescription number at the point of entry into the shared real time, on-line prescription file and that number will remain linked to the prescription throughout the dispensing process. To ensure accountability, Walgreens will maintain a readily retrievable, non-alterable record of all pharmacy personnel who participated in any and all aspects of the order entry, review, DUR and product verification processes.

Thank you for considering this request. Please contact me at your earliest convenience if you have any questions.

Sincerely,


Dan Luce, Manager Pharmacy Affairs
(847) 914-2354



"Cacciatore, Gary"
<Gary.Cacciatore@cardinal.com>

07/30/2004 11:52 AM

To: "Patricia F. Harris (E-mail)"
<patricia_harris@dca.ca.gov>
cc:
Subject: Off-Site Services

Patty,

I hope all is well with you. As you know, Cardinal Health is providing off-site review and order entry services to California hospitals from our Pharmacy Service Center located in Irvine. We are currently servicing approximately 12 hospitals and have several more hospitals that will be signing up for this service. You will recall that we had several discussions with you and the Board and it was determined that this service could be provided pursuant to California Business and Professions Code 4071.1. With your assistance, we obtained permission to include controlled substance orders pursuant to Section 1164.5 of the Health and Safety Code.

This service improves patient care by allowing orders to be reviewed and approved by a pharmacist from a remote location on a prospective basis rather than a retrospective basis. Despite this patient safety benefit, some of the hospitals utilizing the service have been having problems with inspectors from the California Department of Health Services who have stated that they don't approve of this type of service. Do you or Bob have a relationship with someone at DHS that I could contact about this? Would it be possible for one of you to inform them that we followed all required statutory requirements for getting this service approved?

One other question, we have found a number of hospitals are using an after-hours service whereby the nurses are faxing orders to an off-site facility which simply reviews them and faxes back the orders as "okay" indicating a nurse can then provide a first dose of the medication. Since this type of service is not entering orders into the hospital's computer system, it does not fall under 4071.1. Is a hospital allowed to utilize such a service?

(Sorry, I didn't have Bob's email address to copy him on this.)

Thanks,

Gary

Gary Cacciatore
Regulatory Counsel and Director of Regulatory Affairs
Cardinal Health, Inc.
1330 Enclave Parkway
Houston, Texas 77077
281-749-4126
FAX: 281-749-2083
gary.cacciatore@cardinal.com <mailto:gary.cacciatore@cardinal.com>

Click to add my contact info to your organizer:
<http://my.infotriever.com/ip9bm5yd>

§ 4998.5

HEALING ARTS Div. 2

conduct under any statute, rule, or regulation now or hereafter in effect. In the conduct of its practice, it shall observe and be bound by those statutes, rules, and regulations to the same extent as a person holding a license as a licensed clinical social worker.

(Formerly § 4998.6, added by Stats.1985, c. 820, § 1. Renumbered § 4998.5 and amended by Stats.1999, c. 657 (A.B.1677), § 23. Amended by Stats.2000, c. 135 (A.B.2539), § 7.)

Historical and Statutory Notes

Subordination of legislation by Stats.2000, c. 135 (A.B.2539), to other 2000 legislation, see Historical and Statutory Notes under Business and Professions Code § 651.

Former § 4998.5, added by Stats.1985, c. 820, § 1, derived from former § 9074, added by Stats.1972, c. 1286, p. 2567, § 5, relating to

income attributable to shareholder who is a disqualified person, was renumbered Business and Professions Code § 4998.4 and amended by Stats.1999, c. 657 (A.B.1677), § 22.

Derivation: Former § 9076, added by Stats. 1972, c. 1286, p. 2567, § 5.

Code of Regulations References

Disciplinary guidelines, see 16 Cal. Code of Regs. § 1888.

Library References

Licenses ☞ 18, 25.
Westlaw Topic No. 238.
C.J.S. Agriculture § 4.5.
C.J.S. Licenses §§ 34, 41, 45 to 46.

Legal Jurisprudences

Cal Jur 3d Heal Art § 11.

§ 4998.6. Rules and regulations

The board may formulate and enforce rules and regulations to carry out the purposes and objectives of this article, including rules and regulations requiring (a) that the articles of incorporation or bylaws of a licensed clinical social worker corporation shall include a provision whereby the capital stock of that corporation owned by a disqualified person, as defined in the Moscone-Knox Professional Corporation Act, or a deceased person shall be sold to the corporation or to the remaining shareholders of that corporation within the time that the rules and regulations may provide, and (b) that a licensed clinical social worker corporation shall provide adequate security by insurance or otherwise for claims against it by its patients arising out of the rendering of professional services.

(Formerly § 4998.7. Renumbered § 4998.6 and amended by Stats.1999, c. 657 (A.B. 1677), § 24. Amended by Stats.2000, c. 135 (A.B.2539), § 8.)

Historical and Statutory Notes

Subordination of legislation by Stats.2000, c. 135 (A.B.2539), to other 2000 legislation, see Historical and Statutory Notes under Business and Professions Code § 651.

Former § 4998.6, added by Stats.1985, c. 820, § 1, derived from former § 9075, added by Stats.1972, c. 1296, p. 2567, § 5.

Stats.1972, c. 1286, p. 2567, § 5, relating to unprofessional conduct, was renumbered Business and Professions Code § 4998.5 and amended by Stats.1999, c. 657 (A.B.1677), § 23.

Derivation: Former § 9077, added by Stats. 1972, c. 1296, p. 2567, § 5.

Cross References

"Board" defined for purposes of this Code, see Business and Professions Code § 22.

130

TELEPHONE ADVICE SERVICES Ch. 15

§ 4999

Library References

Corporations ☞ 54.
Licenses ☞ 18.
Westlaw Topic Nos. 101, 238.

C.J.S. Corporations §§ 111, 114, 116, 120.
C.J.S. Licenses § 34.

§ 4998.7. Renumbered Business and Professions Code § 4998.6 and amended by Stats.1999, c. 657 (A.B.1677), § 24

Historical and Statutory Notes

The renumbered section, added by Stats.1985, c. 820, § 1, derived from former § 9077, added by Stats.1972, c. 1286, p. 2567, § 5, related to rules and regulations.

Library References

Corporations ☞ 54.
Licenses ☞ 18.
Westlaw Topic Nos. 101, 238.

C.J.S. Corporations §§ 111, 114, 116, 120.
C.J.S. Licenses § 34.

Chapter 15

TELEPHONE MEDICAL ADVICE SERVICES

Section

4999. Registration requirement; proof of accreditation; exemptions; protection of the public.
- 4999.1. Application for registration; contents.
- 4999.2. Requirements for registration.
- 4999.3. Suspension or revocation of registration; grounds; procedure.
- 4999.4. Duration of registration; renewal.
- 4999.5. Fees for registration.
- 4999.6. Rules and regulations.
- 4999.7. Persons licensed under other provisions.
- 4999.8. Study; report.
- 4999.9. Emergency regulations.

Chapter 15 was added by Stats.1999, c. 535 (A.B.285), § 1.

Cross References

Disability insurers, telephone medical advice services, registration pursuant to this chapter, see Insurance Code § 10279.

Health care service plans, telephone medical advice services, registration pursuant to this chapter, see Health and Safety Code § 1348.8.

§ 4999. Registration requirement; proof of accreditation; exemptions; protection of the public

(a) On and after January 1, 2000, no business entity that employs, or contracts or subcontracts, directly or indirectly, with, the full-time equivalent of five or more persons functioning as health care professionals, whose primary function is to provide telephone medical advice, shall engage in the business of providing telephone medical advice services to a patient at a California address unless the business is registered with the Telephone Medical Advice Services Bureau. The department may adopt emergency regulations further defining

131

§ 4999

HEALING ARTS Div. 2

when a health care professional's primary function is providing telephone medical advice.

(b) Any business entity required to be registered under subdivision (a) that submits proof of accreditation by the American Accreditation Healthcare Commission, URAC, the National Committee for Quality Assurance, the National Quality Health Council, or the Joint Commission on Accreditation of Healthcare Organizations shall be deemed provisionally registered by the bureau until the earlier of the following:

(1) December 31, 2000.

(2) The granting or denial of an application for registration pursuant to subdivision (a).

(c) A medical group that operates in multiple locations in California shall not be required to register pursuant to this section if no more than five full-time equivalent persons at any one location perform telephone medical advice services and those persons limit the telephone medical advice services to patients being treated at that location.

(d) Protection of the public shall be the highest priority for the bureau in exercising its registration, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

(Added by Stats.1999, c. 535 (A.B.285), § 1. Amended by Stats.2000, c. 857 (A.B.2903), § 2.1; Stats.2002, c. 107 (A.B.269), § 22.)

Historical and Statutory Notes

Subordination of legislation by Stats.2000, c. 857 (A.B.2903), to other 2000 legislation, see Historical and Statutory Notes under Business and Professions Code § 1618.5.

Changes in statutory references from the Department of Managed Care to the Department of Managed Health Care, from the Advisory Com-

mittee on Managed Care to the Advisory Committee on Managed Health Care, and from the Managed Care Fund to the Managed Health Care Fund by Stats.2000, c. 857 (A.B.2903), see Historical and Statutory Notes under Business and Professions Code § 1618.5.

Cross References

"Department" defined for purposes of this Code, see Business and Professions Code § 23.

Code of Regulations References

Telephone medical advice,

Definitions, see 16 Cal. Code of Regs. § 4001.

Good professional practice, see 16 Cal. Code of Regs. § 4021.

Library References

Health ☞ 114.

Westlaw Topic No. 198H.

§ 4999.1. Application for registration; contents

Application for registration as an in-state or out-of-state telephone medical advice service shall be made on a form prescribed by the department, accompanied by the fee prescribed pursuant to Section 4999.5. The department shall

132

TELEPHONE ADVICE SERVICES Ch. 15

§ 4999.2

make application forms available no later than July 1, 2000. Applications shall contain all of the following:

(a) The signature of the individual owner of the in-state or out-of-state telephone medical advice service, or of all of the partners if the service is a partnership, or of the president or secretary if the service is a corporation. The signature shall be accompanied by a resolution or other written communication identifying the individual whose signature is on the form as owner, partner, president, or secretary.

(b) The name under which the person applying for the in-state or out-of-state telephone medical advice service proposes to do business.

(c) The physical address, mailing address, and telephone number of the business entity.

(d) The designation of an agent for service of process in California.

(e) A list of all in-state or out-of-state staff providing telephone medical advice services that are required to be licensed, registered, or certified pursuant to this chapter. This list shall be submitted to the department on a quarterly basis on a form to be prescribed by the department and shall include, but not be limited to, the name, address, state of licensure, category of license, and license number.

(f) The department shall be notified within 30 days of any change of name, location of business, corporate officer, or agent of service.

(Added by Stats.1999, c. 535 (A.B.285), § 1.)

Cross References

"Department" defined for purposes of this Code, see Business and Professions Code § 23.

Code of Regulations References

Telephone medical advice, quarterly reports, see 16 Cal. Code of Regs. § 4023.

Library References

Health ☞ 155.

Westlaw Topic No. 198H.

§ 4999.2. Requirements for registration

(a) In order to obtain and maintain a registration, in-state or out-of-state telephone medical advice services shall comply with the requirements established by the department. Those requirements shall include, but shall not be limited to, all of the following:

(1)(A) Ensuring that all staff who provide medical advice services are appropriately licensed, certified, or registered as a physician and surgeon pursuant to Chapter 5 (commencing with Section 2000) or the Osteopathic Initiative Act, as a dentist pursuant to Chapter 4 (commencing with Section 1600), as a dental hygienist pursuant to Section 1758 et seq., as a psychologist pursuant to Chapter 6.6 (commencing with Section 2900), as a marriage and family therapist pursuant to Chapter 13 (commencing with Section 4980), as an optometrist pursuant to Chapter 7 (commencing with Section 3000), as a

133

§ 4999.2

HEALING ARTS Div. 2

chiropractor pursuant to the Chiropractic Initiative Act, and operating consistent with the laws governing their respective scopes of practice in the state within which they provide telephone medical advice services, except as provided in paragraph (2).

(B) Ensuring that all staff who provide telephone medical advice services from an out-of-state location are health care professionals as identified in subparagraph (A) that are licensed, registered, or certified in the state within which they are providing the telephone medical advice services and operating consistent with the laws governing their respective scopes of practice.

(2) Ensuring that all registered nurses providing telephone medical advice services to both in-state and out-of-state business entities registered pursuant to this chapter shall be licensed pursuant to Chapter 6 (commencing with Section 2700).

(3) Ensuring that the telephone medical advice provided is consistent with good professional practice.

(4) Maintaining records of telephone medical advice services, including records of complaints, provided to patients in California for a period of at least five years.

(5) Complying with all directions and requests for information made by the department.

(b) To the extent permitted by Article VII of the California Constitution, the department may contract with a private nonprofit accrediting agency to evaluate the qualifications of applicants for registration pursuant to this chapter, and to make recommendations to the department.

(Added by Stats.1999, c. 535 (A.B.285), § 1. Amended by Stats.2001, c. 728 (S.B.724), § 49; Stats.2002, c. 1013 (S.B.2026), § 51.)

Cross References

"Department" defined for purposes of this Code, see Business and Professions Code § 23.

Code of Regulations References

Telephone medical advice,
Citations for unlicensed businesses, see 16 Cal. Code of Regs. § 4032.
Inspection of records, see 16 Cal. Code of Regs. § 4025.
Recordkeeping, see 16 Cal. Code of Regs. § 4024.
Violations and fines, see 16 Cal. Code of Regs. § 4031.
Telephone medical advice, disciplinary proceedings,
Compliance with citation/order of abatement, see 16 Cal. Code of Regs. § 4033.
Contest of citations, see 16 Cal. Code of Regs. § 4034.

Library References

Health ☞136.
Westlaw Topic No. 198H.

§ 4999.3. Suspension or revocation of registration; grounds; procedure

(a) The department may suspend, revoke, or otherwise discipline a registrant or deny an application for registration as an in-state or out-of-state telephone medical advice service based on any of the following:

TELEPHONE ADVICE SERVICES Ch. 15

§ 4999.4

(1) Incompetence, gross negligence, or repeated similar negligent acts performed by the registrant or any employee of the registrant.

(2) An act of dishonesty or fraud by the registrant or any employee of the registrant.

(3) The commission of any act, or being convicted of a crime, that constitutes grounds for denial or revocation of licensure pursuant to any provision of this division.

(b) The proceedings shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, and the department shall have all powers granted therein.

(c) Copies of any complaint against an in-state or out-of-state telephone medical advice service shall be forwarded to the Department of Managed Care.

(d) The department shall forward a copy of any complaint submitted to the department pursuant to this chapter to the entity that issued the license to the licensee involved in the advice provided to the patient.

(Added by Stats.1999, c. 535 (A.B.285), § 1.)

West's California Code Forms

See West's Cal. Code Forms, Bus. & Prof. § 4999.3—FORM 1.

Cross References

"Department" defined for purposes of this Code, see Business and Professions Code § 23.

Code of Regulations References

Telephone medical advice,
Consumer complaints, disclosure, see 16 Cal. Code of Regs. § 4022.
Substantial relationship criteria, see 16 Cal. Code of Regs. § 4012.

Library References

Health ☞204, 207.
Westlaw Topic No. 198H.

§ 4999.4. Duration of registration; renewal

(a) Every registration issued a telephone medical advice service shall expire 24 months after the initial date of issuance.

(b) To renew an unexpired registration, the registrant shall, before the time at which the license registration would otherwise expire, apply for renewal on a form prescribed by the bureau, and pay the renewal fee authorized by Section 4999.5.

(c) A registration that is not renewed within three years following its expiration shall not be renewed, restored, or reinstated thereafter, and the delinquent registration shall be canceled immediately upon expiration of the three-year period. An expired registration may be renewed at any time within three years after its expiration upon filing of an application for renewal on a form prescribed by the bureau and the payment of all fees authorized by Section 4999.5.

(Added by Stats.1999, c. 535 (A.B.285), § 1. Amended by Stats.2000, c. 857 (A.B.2903), § 2.2.)

§ 4999.4

HEALING ARTS Div. 2

Historical and Statutory Notes

Subordination of legislation by Stats.2000, c. 857 (A.B.2903), to other 2000 legislation, see Historical and Statutory Notes under Business and Professions Code § 1618.5.

Changes in statutory references from the Department of Managed Care to the Department of Managed Health Care, from the Advisory Com-

mittee on Managed Care to the Advisory Committee on Managed Health Care, and from the Managed Care Fund to the Managed Health Care Fund by Stats.2000, c. 857 (A.B.2903), see Historical and Statutory Notes under Business and Professions Code § 1618.5.

Library References

Health ☞ 160, 161.
Westlaw Topic No. 198H.

§ 4999.5. Fees for registration

The department may set fees for registration, as an in-state or out-of-state telephone medical advice service sufficient to pay the costs of administration of this chapter.

(Added by Stats.1999, c. 535 (A.B.285), § 1.)

Cross References

"Department" defined for purposes of this Code, see Business and Professions Code § 23.

Library References

Health ☞ 199.
Westlaw Topic No. 198H.

§ 4999.6. Rules and regulations

The department may adopt, amend, or repeal any rules and regulations that are reasonably necessary to carry out this chapter. A telephone medical advice services provider who provides telephone medical advice to a significant total number of charity or medically indigent patients may, at the discretion of the director, be exempt from the fee requirements imposed by this chapter. However, those providers shall comply with all other provisions of this chapter.

(Added by Stats.1999, c. 535 (A.B.285), § 1. Amended by Stats.2000, c. 857 (A.B.2903), § 2.3.)

Historical and Statutory Notes

Subordination of legislation by Stats.2000, c. 857 (A.B.2903), to other 2000 legislation, see Historical and Statutory Notes under Business and Professions Code § 1618.5.

Changes in statutory references from the Department of Managed Care to the Department of Managed Health Care, from the Advisory Com-

mittee on Managed Care to the Advisory Committee on Managed Health Care, and from the Managed Care Fund to the Managed Health Care Fund by Stats.2000, c. 857 (A.B.2903), see Historical and Statutory Notes under Business and Professions Code § 1618.5.

Cross References

"Department" defined for purposes of this Code, see Business and Professions Code § 23.

"Director" defined for purposes of this Code, see Business and Professions Code § 23.5.

Director review of proposed rule or regulation changes, time to review, see Business and Professions Code § 313.1.

TELEPHONE ADVICE SERVICES Ch. 15

§ 4999.8

Library References

Health ☞ 194, 199.
Westlaw Topic No. 198H.

§ 4999.7. Persons licensed under other provisions

(a) Nothing in this section shall limit, preclude, or otherwise interfere with the practices of other persons licensed or otherwise authorized to practice, under any other provision of this division, telephone medical advice services consistent with the laws governing their respective scopes of practice, or licensed under the Osteopathic Initiative Act or the Chiropractic Initiative Act and operating consistent with the laws governing their respective scopes of practice.

(b) For the purposes of this chapter, "telephone medical advice" means a telephonic communication between a patient and a health care professional, wherein the health care professional's primary function is to provide to the patient a telephonic response to the patient's questions regarding his or her or a family member's medical care or treatment.

(c) For the purposes of this chapter, "health care professional" is a staff person described in Section 4999.2 who provides medical advice services and is appropriately licensed, certified, or registered as a registered nurse pursuant to Chapter 6 (commencing with Section 2700), a physician and surgeon pursuant to Chapter 5 (commencing with Section 2000) or the Osteopathic Initiative Act, a dentist pursuant to Chapter 4 (commencing with Section 1600), a dental hygienist pursuant to Section 1758 et seq., a psychologist pursuant to Chapter 6.6 (commencing with Section 2900), a marriage and family therapist pursuant to Chapter 13 (commencing with Section 4980), an optometrist pursuant to Chapter 7 (commencing with Section 3000), a chiropractor pursuant to the Chiropractic Initiative Act, and who is operating consistent with the laws governing his or her respective scopes of practice in the state in which he or she provides telephone medical advice services.

(Added by Stats.1999, c. 535 (A.B.285), § 1. Amended by Stats.2000, c. 857 (A.B.2903), § 2.4; Stats.2001, c. 728 (S.B.724), § 50.)

Historical and Statutory Notes

Subordination of legislation by Stats.2000, c. 857 (A.B.2903), to other 2000 legislation, see Historical and Statutory Notes under Business and Professions Code § 1618.5.

Changes in statutory references from the Department of Managed Care to the Department of Managed Health Care, from the Advisory Com-

mittee on Managed Care to the Advisory Committee on Managed Health Care, and from the Managed Care Fund to the Managed Health Care Fund by Stats.2000, c. 857 (A.B.2903), see Historical and Statutory Notes under Business and Professions Code § 1618.5.

Library References

Health ☞ 111.
Westlaw Topic No. 198H.

§ 4999.8. Study; report

(a) The department shall conduct a study of issues pertaining to the provision of telephone medical advice services provided by registered and provisionally

§ 4999.8

HEALING ARTS Div. 2

registered telephone medical advice services providers to patients in California by health care professionals licensed, certified, or registered in other states. All data required for the study shall be submitted to the department within 30 days of the end of each calendar quarter. The study shall be based upon information of telephone medical advice service activities occurring between January 1, 2000, and December 31, 2000. The study shall include, and not be limited to, all of the following:

- (1) The number of complaints that were filed with the telephone medical advice service.
- (2) The number of complaints that involved health care professionals licensed in other states.
- (3) The number of complaints referred to licensing entities in California and other states.
- (4) The disposition of complaints filed with the department pursuant to this chapter.
- (5) Complaint information submitted by the Director of the Department of Managed Care pursuant to subdivision (b) of Section 1348.8.

(6) Any other information the department determines to be necessary to evaluate the impact of out-of-state licensees providing telephone medical advice services on the quality of care provided to patients in California.

(b) On or before March 1, 2001, the department shall deliver a report summarizing the findings of the study to both the Assembly Committee on Rules and the Senate Committee on Rules, which shall refer the report to appropriate policy committees. The report shall be prepared utilizing existing agency resources.

(c) The department shall conduct a study of issues pertaining to the provision of medical advice services provided by registered telephone medical advice services to patients in California by health care professionals licensed, certified, or registered in other states. All data required for the study shall be submitted to the department within 30 days of the end of each calendar quarter. The study shall be based upon information of telephone medical advice service activities occurring between January 1, 2001, and December 31, 2001, and shall include, but not limited to, the following:

- (1) The number of complaints that were filed with the telephone medical advice service.
- (2) The number of complaints that were filed with the department pursuant to this chapter.
- (3) The number of complaints that involved health care professionals licensed in other states.
- (4) The number of complaints referred to licensing entities in California and other states.
- (5) The disposition of complaints filed with the department pursuant to this chapter.

TELEPHONE ADVICE SERVICES Ch. 15

§ 4999.9

(6) Complaint information submitted by the Director of the Department of Managed Care pursuant to subdivision (b) of Section 1348.8.

(7) Any other information the department determines to be necessary to evaluate the impact of out-of-state licensees providing telephone medical advice services on the quality of care provided to patients in California.

(d) On or before March 1, 2002, the department shall deliver a report summarizing the findings of the study to both the Assembly Committee on Rules and the Senate Committee on Rules, which shall refer the report to appropriate policy committees. The report shall be prepared from then existing agency resources.

(Added by Stats.1999, c. 535 (A.B.285), § 1.)

Cross References

"Department" defined for purposes of this Code, see Business and Professions Code § 23.
"Director" defined for purposes of this Code, see Business and Professions Code § 23.5.

Library References

Health ☞194.
Westlaw Topic No. 198H.

§ 4999.9. Emergency regulations

The director shall, on or before June 30, 2000, adopt emergency regulations to implement this chapter in accordance with the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code).

The adoption of emergency regulations described in this section shall be deemed to be an emergency and necessary for the immediate preservation of the public peace, health and safety, or general welfare. Emergency regulations adopted pursuant to this section shall be exempt from review by the Office of Administrative Law. The emergency regulations authorized by this section shall be submitted to the Office of Administrative Law for filing with the Secretary of State and publication in the California Code of Regulations and shall remain in effect for no more than 180 days.

(Added by Stats.1999, c. 535 (A.B.285), § 1.)

Cross References

"Director" defined for purposes of this Code, see Business and Professions Code § 23.5.

Library References

Health ☞194.
Westlaw Topic No. 198H.

AGENDA ITEM D

The presentation by the Long Term Care Management Council on its proposed certification program has been cancelled and will be rescheduled for another Licensing Committee meeting in the future.

AGENDA ITEM E

Memorandum

To: Licensing Committee

Date: November 23, 2004

From: Debbie Anderson
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 November 19, 2004, are as follows:

2,574 applications have been received to take the California license exams
202 of these are retake applications

1,196 individuals have become licensed as pharmacists since mid-June

2,010 individuals have been made eligible to take the licensure examinations
179 individuals have also been requalified to take the exams (These applicants have failed one of the exams, and had to requalify.)

1,562 individuals have been verified to the NABP as qualified to take the NAPLEX for California including score transfers

1,696 CPJE examinations have been administered

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

The CPJE's pass rate will be reported at the committee meeting.

AGENDA ITEM F

Memorandum

To: Licensing Committee

Date: November 23, 2004

From: Anne Sodergren
Board of Pharmacy

Subject: Implementation of AB 2682 – Wholesaler and Out-of-State Distributor
Licensing Requirements

Assembly Bill 2682, signed by the Governor on September 29, 2004, makes changes to several Business and Professions Code sections specific to the licensing requirements for wholesalers located outside of California who ship, mail or delivers dangerous drugs or devices into California. Because of the significant changes, the requirements will be phased in over the next two years. Below is brief description of these changes.

- B & P 4043 – Changes that the name of a wholesaler shipping drugs into California from an out-of-state distributor to a nonresident wholesaler. This change is effective January 1, 2006.
- B & P 4161 – Requires any out-of-state distributor who ships, mails, or delivers dangerous drugs or devices into California to be licensed with the board. Previously any business that that shipped into California to another California licensed wholesaler was exempt from obtaining a California license. This changed is effective January 1, 2005.

Effective January 1, 2006, B & P 4161 is again amended to change the name from out-of-state distributor to nonresident wholesaler and to change the title of “exemptee-in-charge” to “designated representative-in-charge.”

- B & P 4162.5 – Requires an applicant for licensure or renewal to submit a surety bond of \$100,000 for each nonresident wholesaler site licensed or to be licensed. The board may accept a surety of bond of \$25,000 if the annual gross receipts of the previous tax year as a nonresident wholesale is \$10,000,000 or less. This section takes effect January 1, 2006.

To facilitate the implementation of these changes, board staff, along with DAG Joshua Room, has reviewed and revised the application forms, requirements and processes for both the wholesaler and nonresident wholesalers. We hope the new forms will be available on the board’s website by December 1, 2004.

In addition, the board will send a notice to all California licensed wholesalers and nonresident wholesalers notifying them of the changes in California Law.