



California State Board of Pharmacy

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

Contact Person: Patricia Harris
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LICENSING COMMITTEE MEETING

December 14, 2005

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

9:30 a.m. – 12:30 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.

Agenda

A. Call to Order 9:30 a.m.

B. Competency Committee Report – CPJE Examination Statistics

C. Development of Proposal to Update the Definition of a Pharmacy, a Nonresident Pharmacy, Pharmacist Practice and Licensure of Out-of-State Pharmacists

D. Proposed Meeting Dates for 2006

Adjournment 12:30 p.m.

Meeting materials will be on the board's Web site by December 7, 2005

AGENDA ITEM B

**California State Board of Pharmacy
CPJE Statistics March 2004 – March 31, 2005**

The charts below display data for all candidates who took the CPJE examination between 3/1/04 through 3/31/05, inclusive.

The board also displays NAPLEX scores associated with any candidate who took the CPJE during this 12-month period and was reported to the board, regardless of when the NAPLEX may have been taken (it could have occurred outside the 12-month reporting period noted above).

Note: a candidate who took the CPJE twice during this period because he or she failed the examination would be counted twice. (California regulations and NABP requirements allow candidates who fail the examination to retake the failed examination after 90 days). However, if more than one NAPLEX was attempted only the last NAPLEX score is reported .

Overall Pass Rates

CPJE

			Percent
			18.6
			81.4
			100.0

NAPLEX

			Percent
			1.6
			98.4
			100.0

Data continues on next pages

Location of School

CPJE

		CPJE			NAPLEX		NAPLEX Total
Count				760			731
	Percent						
Count				976			844
	Percent						
Count				345			288
	Percent						
Count				1			1
	Percent						
Count				2082			1864
	Percent						

Gender

		CPJE		CPJE Total	NAPLEX		NAPLEX Total
Count				1393			1257
	Percent						
Count				689			607
	Percent						
Count				2082			1864
	Percent			100.0%			100.0%

Degree

		CPJE		CPJE	NAPLEX		NAPLEX Total
Count				471			397
	Percent						
Count				1610			1466
	Percent						
Count				1			1
	Percent						
Count				2082			1864
	Percent			100.0%			100.0%

California Schools

		CPJE		CPJE Total	NAPLEX		NAPLEX Total
Count				138			133
Percent							
Count				269			258
Percent							
Count				218			210
Percent							
Count				135			130
Percent							
Count				760			731
Percent				100.0%			100.0%

US Schools of Pharmacy

CPJE Only

	CPJE		Total
			2
			8
			9
			3
			138
			269
			218
			24
			9
			10
			6
			6
			10
			22
			7
			7
			2
			16
			17
			10
			4
			3
			10

16
15
181
12
9
13
7
12
1
13
2
2
49
16
1
32
135
40
9
3
11
6
1
8
14
1
6
1
1
29
4
27
51
4
1
6
1
1
5
4
8
9
2
6
16
13
1
4
2
2

			4
			6
			3
			8
			30
			41
			22
			1
			345
			2082

Graduating school location by country

	CPJE		Total
			3
			1
			1
			1
			13
			1
			1
			1
			1
			34
			1
			1
			4
			1
			2
			2
			51
			2
			3
			1
			6
			1
			29
			6
			2
			7
			3
			63
			3
			2
			5
			3
			1
			4
			2
			1754
			2
			64
			2082

**California State Board of Pharmacy
CPJE Statistics 4/1/05 – 9/30/05**

The charts below display data for all candidates who took the CPJE examination between 4/1/05 through 9/30/05, inclusive.

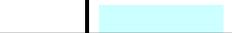
The board also displays NAPLEX scores associated with any candidate who took the CPJE during this six-month period and was reported to the board, regardless of when the NAPLEX may have been taken (it could have occurred outside the six-month reporting period noted above).

The board reports CPJE performance data at six month intervals. The next report will cover performance data for 10/1/05-3/31/06.

Note: a candidate who took the CPJE twice during this period because he or she failed the examination would be counted twice. (California regulations and NABP requirements allow candidates who fail the examination to retake the failed examination after 90 days.)

Overall Pass Rates

CPJE

		Percent
		22.5
		77.5
		100.0

NAPLEX

		Percent
		4.1
		95.9
		100.0

Data continues on next pages

Location of School

CPJE

		CPJE		CPJE Total	NAPLEX		NAPLEX Total
Count				529			519
Percent							
Count				427			404
Percent							
Count				154			137
Percent							
Count				1			1
Percent							
Count				1111			1061
Percent				100.0%			100.0%

Gender

		CPJE		CPJE Total	NAPLEX		NAPLEX Total
Count				765			731
Percent							
Count				346			330
Percent							
Count				1111			1061

Degree

		CPJE		CPJE Total	NAPLEX		NAPLEX Total
Count				194			171
Percent							
Count				917			890
Percent							
Count				1111			1061

California Schools

		CPJE		CPJE Total	NAPLEX		NAPLEX Total
Count				113			108
Percent							
Count				165			165
Percent							
Count				167			164
Percent							
Count				84			82
Percent							
Count				529			519
Percent				100.0%			100.0%

US Schools of Pharmacy

	CPJE	Total
		1
		5
		9
		2
		113
		165
		167
		8
		2
		2
		2
		7
		4
		9
		6
		7
		2
		2
		7
		2
		8
		1
		1
		4
		9
		70
		5

6
5
4
7
3
18
5
27
7
9
84
14
6
1
3
1
3
1
2
1
1
7
3
6
15
3
2
3
1
2
1
1
3
2
2
11
9
5
3
2
3
1
1
4
34
4
1

	Other/FG	68	86	154
Total		250	861	1111

Graduating school location by country

	CPJE		Total
			1
			1
			1
			2
			1
			1
			11
			2
			1
			1
			45
			5
			1
			2
			7
			3
			1
			2
			3
			32
			1
			1
			1
			1
			1
			7
			1
			963
			1
			11
			1111

AGENDA ITEM C

Memorandum

To: Licensing Committee

Date: December 5, 2005

From: Patricia F. Harris 
Executive Officer

**Subject: Development of Proposal to Update
the Definition and Requirements for
Pharmacy, Nonresident Pharmacy,
Pharmacist Practice and Licensure of
Out-of-State Pharmacists**

Since December 2004, the Licensing Committee has been working to respond to inquiries and comments pertaining to the scope of practice of pharmacy, particularly to the practice of pharmacy outside of a traditional pharmacy setting, and to the provision of services to California patients by pharmacies, pharmacists, and ancillary staff outside state lines.

The Committee agreed to address these issues through its quarterly meetings. The board encouraged the Committee to develop a concrete proposal in anticipation of the implementation of provisions of the Medicare Modernization Act (MMA) addressing pharmacists' services within the Medication Therapy Management Programs (MTMP) of the Medicare Act.

Following an initial overview document prepared for the December 2004 meeting, a draft of proposed statutory changes was prepared for the March 2005 meeting. That draft was the basis for discussions and reactions at the March, June and September 2005 meetings.

As the Committee has defined and discussed them, there are three primary areas in which further specification and possible statutory change has been debated:

- (1) Given what has been or may be an increase in the number of entities/premises, both within California and outside of California, that are mostly focusing on "prescription review" and/or "cognitive services" separate from and/or in the absence of traditional "pharmacy" tasks such as the actual filling of prescriptions and dispensing of drugs, what can or should the Board do to license those entities/premises, as "pharmacies" or otherwise;
- (2) When those "review" or "cognitive" services are provided by out-of-state pharmacies or pharmacists to California patients, particularly when out-of-state pharmacists are not located in a licensed premises, should the Board require that: the out-of-state pharmacist have a California license, or an alternative California registration; that the pharmacist at least be affiliated with an entity, i.e., a "pharmacy," that is licensed in California; that

out-of-state “pharmacies,” however defined, have a PIC licensed in California; and/or should the Board depend on discipline by pharmacists’ (and pharmacies’) home states of licensure to ensure compliance;

(3) In order to conform California law to federal expectations, to permit California licensees to practice fully as professional pharmacists, and/or to maximize the opportunities available under Medicare Part D, should the definitions and scope of practice of pharmacy presently stated in Pharmacy Law be expanded and/or further specified by the Board.

The following are action items for Committee consideration at this meeting.

Recommended Action Item 1

Update the definition of pharmacy to include prescription processing and review, patient consultation, drug utilization review, medication therapy management, or other cognitive pharmacy services for patients in this state. A pharmacy would not be required to store and dispense dangerous drugs. Make it an option for pharmacists practicing pharmacy independently to be licensed as a “pharmacy.”

Discussion

One of the primary topics of Committee discussion has been, in light of the apparently increased emphasis on provision of professional “cognitive services” (e.g., DUR, MTM) by pharmacists, which may or may not be provided out of a traditional “pharmacy” premises: (a) whether to license facilities, in California or outside of California, from which such services are provided (which do not otherwise fit the traditional definition of a “pharmacy”) *at all*; and (b) if so, whether to license them as “pharmacies,” some variant thereof, or as something else entirely.

The draft statutory proposal prepared for the March 2005 meeting assumed that facilities in which “pharmacy” was being practiced (whether “pharmacy” as in prescription-filling, or “pharmacy” as in consultation, MTMP, etc.) would need to be licensed as pharmacies. It identified three separate *types* of pharmacies for licensure: (i) “Intake/dispensing” pharmacies - traditional pharmacies; (ii) “Prescription processing” pharmacies - offering prescription review services for another pharmacy or other provider; and (iii) “Advice/clinical center” pharmacies – providing clinical/cognitive services directly to patients or providers. The draft assumed that the three types would not be mutually exclusive, i.e., a given facility could overlap. **(Attachment A)**

There was considerable discussion and opposition to requiring California licensed pharmacists to be licensed as an “Advice/clinical center pharmacy.” It was emphasized that the board needs to recognize the independent practice of pharmacists and the proposal did not. It was argued that the public is adequately protected by licensure of the pharmacist and additional licensure as a pharmacy was not necessary. The recommendation provides pharmacists with an option to be licensed as an “advice/clinical care pharmacy.”

It was also questioned why the board requires an entity that processes prescriptions to be licensed as a pharmacy. It was explained that the processing of prescriptions under current

pharmacy law constitutes the practice of pharmacy and therefore, must be practiced in a licensed pharmacy. It is the location that would receive telephonic and electronic orders for prescriptions and maintain the prescription and patient information, directing the prescription to a particular pharmacy for filling and dispensing. While the pharmacy law authorizes a pharmacist to electronically enter a prescription or order into a pharmacy's or hospital's computer, the law does not allow other pharmacy personnel to process prescriptions under the supervision of a pharmacist. To allow such a practice outside a pharmacy would require explicit language. An option may be to allow the practice pursuant to a contract with a pharmacy as long as the original prescriptions records and record of the pharmacist's review be maintained by the filling pharmacy.

Another option provided was to license the facilities but not call them "pharmacies." Other options included (i) licensing such entities as "pharmacies" under the current definition(s), without revision, (ii) not licensing these entities at all, (iii) deferring the licensure of these entities to some other agency (e.g., Department of Health Services), or (iv) awaiting some consensus at the national level about interstate cooperation thereon. None of these alternatives would require statutory revisions.

Recommended Action Item 2

Update the definition of a nonresident pharmacy to include prescription review and processing, patient consultation, drug utilization review, medication therapy management, or other cognitive pharmacy services for patients in this state. At this time, the proposal would not include a requirement that the pharmacist-in-charge or pharmacist also be licensed in California. It is also recommended to amend B&P 4303 to strengthen the board's authority to discipline a nonresident pharmacy and not rely on the state where the pharmacy is located to take action first.

Action Item 2B

A pharmacist performing these same pharmacy services but not under the umbrella of California nonresident pharmacy would be required to have a California pharmacist license.

OR

Not require an out-of-state pharmacist performing these same pharmacy services to be licensed as a California pharmacist (if not affiliated with a California nonresident pharmacy) but rely on the Board of Pharmacy in the state where the pharmacist is licensed to take appropriate action should a California patient be harmed (consistent with NABP model rule for "telepharmacy" practice.) Currently California has such authority to pursuant to B& P 4301(j) and (o) but would need to clarify the law to include violation of other state laws and regulations.

Discussion

The committee discussed whether and/or how to regulate those out-of-state pharmacists who provide cognitive services and/or prescription processing services to and/or for California patients and providers, particularly where those pharmacists are doing so not through affiliation with or employment by a licensed entity (e.g., nonresident pharmacy, advice center, or prescription processing center), but on a consulting or other non-site-specific basis. During all of the Committee's discussions of this issue, there has been acknowledgment of a need to balance the Board's primary duty to protect the public with its desire not to impede either patient access to services (particularly for California patients) or to squeeze pharmacists out of the marketplace.

This issue has not arisen directly in the past, with regard to out-of-state pharmacists filling and/or dispensing prescription drugs, because until now those out-of-state pharmacists have worked in (or at least this has been the assumption) nonresident pharmacies that were themselves required to maintain licensure. So there has not previously been a perceived need to consider licensing out-of-state pharmacists separately (in California) from the entities in which they practice. However, the definition of a nonresident pharmacy needs to be updated to include all pharmacy services not just the distribution prescription drugs. The definition would be updated consistent with the definition for California pharmacies. **(Attachment B)**

It appears that there has been or may be an industry growth in the number of pharmacists in other states providing services to California patients or providers who are not permanently or indivisibly affiliated with any particular (licensed) premises. This seems particularly likely with regard to cognitive/prescription processing services, which due to imaging/file-sharing advances, are not nearly as tied to a particular "place" as are (or were) dispensing functions.

Secondary and tertiary considerations arose from this discussion as well, including: whether to limit the requirement of California licensure to out-of-state pharmacists providing cognitive or prescription processing services, or to extend it to those dispensing medications as well; whether to require this licensure of all pharmacists providing such services to California patients and/or providers, or only those not affiliated with a licensed entity of some kind; whether to put primary responsibility for record-keeping pertaining to provision of services to California patients on the shoulders of a licensed entity, or on the shoulders of the pharmacist (whether or not licensed in California); and/or if out-of-state pharmacists are not required to be licensed in California, how best to enforce violations of (particularly, California) law committed by those pharmacists.

The wide-ranging discussion at the committee meetings has seemed to acknowledge a possibility of choosing between (this list is not exhaustive or exclusive, only reflective of those options primarily discussed) (a) licensing all out-of-state pharmacists, (b) requiring out-of-state pharmacists to maintain some form of registration short of licensure, (c) licensing only entities under the auspices of which out-of-state pharmacists would (be required to) practice, and/or (d) requiring that the pharmacists-in-charge of these licensed entities also be licensed in California.

The draft statutory proposal provided a combination of (a), (c), and (d), requiring licensure for all out-of-state pharmacists providing cognitive services or prescription processing services to California, and *also* requiring licensure of the pharmacist-in-charge of a nonresident pharmacy.

Concern was expressed that this requirement would be burdensome to nonresident pharmacies and out-of-state pharmacists. Various other options were discussed at the meetings such as a “registration program” for the nonresident pharmacist, some type of national license certification by the National Association of Boards of Pharmacy (NABP), reciprocity, and/or no additional licensure but a requirement that the out-of-state pharmacist meet California practice standards. Another possibility would be striking the requirement that the individual practitioner be licensed in California, instead requiring that the out-of-state pharmacist providing services (or drugs) to California patients practice under the auspices of an entity licensed as a nonresident pharmacy (or other form of site license), with a possible further requirement that the pharmacist-in-charge be a California licensee.

The NABP model rules require that a pharmacist providing telepharmacy services across state lines identify himself or herself to any patient as a “licensed pharmacist,” notify patients of the jurisdiction in which he/she is currently licensed to practice pharmacy, and register (with relevant state boards) to practice telepharmacy across state lines and provide patients with the jurisdiction’s Board address and phone number. Telepharmacy is defined as the provision of pharmaceutical care through the use of telecommunications and information technologies to patients at a distance.

Among the above-listed alternatives to requiring licensure of all out-of-state pharmacists (or at least out-of-state PICs) that have been discussed, two were presented as possible statutory form: (1) the possibility of a non-licensure “certification” of some sort (perhaps supported by NABP), which would require conformance to California standards; and (2) the possibility that licensure would not be required of out-of-state pharmacists so long as services delivered to any California patient were delivered under the auspices of a California-licensed pharmacy/entity.

The California Pharmacists Association (CPhA) provided a similar proposal that would require an out-of-state pharmacist providing cognitive pharmacy services to register as a nonresident provider of pharmacy services. **(Attachment C)**

Action Item 3

Update the definition of the practice of pharmacy by a pharmacist

Discussion

At the last Licensing Committee meeting, there appeared to be consensus to update the definition and scope of practice for pharmacists. **(Attachment D)**

The purpose of the amendments is to update the statutory definition(s) of practice as a pharmacist to (i) better conform to existing practice, (ii) emphasize the professional development of pharmacy, and/or (iii) maximize the potential for California pharmacist practice reimbursement under Medicare Part D.

In brief, the idea behind many of these suggested amendments/revisions is to recognize in statute that the practice of pharmacy means far more than simply counting and dispensing medications,

that it is a professional practice, and that it can be practiced both within and without the four walls of a traditional pharmacy, by licensed professional pharmacists.

In addition, the proposal includes revisions to B&P 4052, which essentially just reduce the size of section 4052 and relocate subparts to sections 4052.1-4052.3) seem non-controversial.

ATTACHMENT A

§ 4037. Pharmacy

(a) "Pharmacy" means an area, place, or premises licensed by the board in which the profession of pharmacy is practiced ~~and where prescriptions are compounded.~~ Only a "dispensing pharmacy," as defined in subdivision (b), may possess, prepare, manufacture, derive, compound, repackage, furnish, sell or dispense controlled substances, dangerous drugs, or dangerous devices. In all other respects, whenever the term "pharmacy" is used in this chapter, it shall be deemed to refer to every one of the types in subdivision (b).

(b) "Pharmacy" includes, but is not limited to:

(1) a "dispensing pharmacy," which is 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;

(2) a "prescription processing pharmacy", which is any area, place, or premises described in a license issued by the board wherein personnel licensed by the board engage in and/or supervise drug order/prescription review by performing functions including, but not limited to, data entry, drug utilization review, patient and/or prescriber contact, claims submission and processing, patient profile review, and allergy and drug-interaction review;

(3) an "advice/clinical center pharmacy," which is any area, place, or premises described in a license issued by the board wherein personnel licensed by the board provide cognitive pharmacy services including, but not limited to, clinical advice or information, telephonic or in-person patient consultation, drug utilization review, and medication therapy management.

(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.

(d) "Pharmacy" shall not include a clinic licensed under Section 4180 or Section 4190.

ATTACHMENT B

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

(a) Any pharmacy located outside this state that ships, mails, or delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state, and/or that performs prescription review, patient consultation, drug utilization review, medication therapy management, or other cognitive pharmacy services for patients in this state, shall be considered a nonresident pharmacy.

(b) All nonresident pharmacies shall register with the board. The board may register a nonresident pharmacy that is organized as a limited liability company in the state in which it is licensed.

ATTACHMENT C



September 21, 2005

Licensing Committee
California State Board of Pharmacy
400 R Street, Ste 4070
Sacramento, CA 95814

Re: Development of Proposal for Pharmacy Performing Drug Utilization Review, Medication Therapy Management, Pharmacist Call Centers and Central Processing of Prescription Drugs for CA Patients

Dear Licensing Committee:

The California Pharmacists Association (CPhA) is providing comments regarding the above referenced subject which was set forth in a memorandum from the Licensing Committee dated June 3, 2005. While we understand that no formal action on this subject has been approved by the Board, we feel it is appropriate to submit comments to the memorandum so that the Licensing Committee and the Board as a whole can consider them in connection with further action on the subject.

From our review of the memorandum and its attachments, we understand that the Licensing Committee is attempting to develop a statutory scheme for regulating the practice of pharmacy beyond traditional dispensing activities. The proposed language appears to suggest that the avenue to achieve this is to expand the definition of a "pharmacy" to include any physical location at which a pharmacist conducts activities requiring licensure.

CPhA recognizes the Board's desire to address the appropriate regulation of the practice of pharmacy as it expands into areas distinct from handling and dispensing of drugs. However, CPhA does not believe that changing the definition of pharmacy is an appropriate and effective means of regulating those activities.

As the Board is aware, traditionally, pharmacies are facilities where dangerous drugs are stored, compounded and dispensed. Record keeping, supervision and other requirements related to the normal activities carried out at pharmacies are based on the storage and dispensing of drugs at that physical location. If the definition were expanded as set forth in the proposed language, then the regulatory scheme for a pharmacist would have to be applied to locations where a pharmacist would be acting within his/her scope of practice, unrelated to dispensing, storage, etc. However, the regulatory scheme for a pharmacy would make no sense when applied to locations where storage and dispensing does not occur. Indeed, this would cause substantial confusion for the profession, and might actually deter licensees from engaging in more comprehensive cognitive services because of the uncertainty of how they are

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regulated. Indeed, this could have the affect of deterring pharmacists from providing these services, leaving other health care professionals to fill the vacuum.

CPhA believes there is a more appropriate and effective approach to regulating non dispensing activities of pharmacists. Although we do not agree that the need for such language has been shown, we also believe there is a way to regulate non resident pharmacists providing services to California residents in a manner that is more effective and legally sustainable than the approach contained in the Board's proposal.

Based on the foregoing, CPhA recommends abandoning consideration of the statutory changes attached to the June 3rd memorandum. Instead, CPhA requests that the Board consider the alternative approach that is attached to this letter. We believe the attachment appropriately addresses the need to regulate non dispensing activities of pharmacists, including regulating the activities of pharmacists licensed outside California when those pharmacists are providing services to California residents.

Sincerely,

A handwritten signature in black ink, appearing to be 'John A. Cronin', written over the word 'Sincerely'.

John A. Cronin, Pharm.D., J.D.
Senior Vice President and General Counsel

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Article 2.5 is added to the Business and Professions Code to read:

Article 2.5. Requirements for Pharmacists Providing Cognitive Pharmacy Services.

Section 4044. Except as otherwise provided in this chapter, it is unlawful for any person to perform any cognitive pharmacy services for, or pertaining to, or at the request of patients, prescribers, or other care providers in this state unless he or she is licensed or registered under this chapter. A pharmacist providing cognitive therapy services, as set forth in section 4045, shall comply with all of the requirements of this Article.

Section 4045. (a) The following definitions govern the provisions of this Article.

(1) "Pharmacist" means either a person issued a license by the board under section 4200, or a person registered under section 4047.

(2) "Cognitive pharmacy services" include clinical advice or information, telephonic or in-patient consultation, drug utilization review and medication therapy management, whether or not provided in a licensed pharmacy.

Section 4046. A pharmacist providing cognitive pharmacy services shall do all of the following:

(a) Comply with the provisions of section 4051.

(b) Document reports by patients and health care providers of adverse outcomes or consequences associated with the delivery of cognitive pharmacy services.

(c) Document medication errors occurring in connection with or discovered as a result of the delivery of cognitive pharmacy services.

(d) Maintain for a period of three years patient records related to the delivery of cognitive pharmacy services and other patient specific information in a readily retrievable form.

Section 4047. (a) It shall be unlawful for any individual residing outside the state to provide cognitive pharmacy service to an individual residing in the state unless the person registers as set forth in this section.

(b) Before an individual residing outside the state may provide cognitive pharmacy services to residents of the state the person shall register with the board as a non resident provider of cognitive pharmacy services. The board shall promulgate regulations governing the forms and procedures for registration.

(c) In order to qualify to register as a non resident provider of cognitive pharmacy services, a person must provide proof of licensure as a pharmacist in good standing in the state form which the services will be provided to California residents, and the entity on whose behalf the services will be provided. In addition, the person must execute a declaration provided by the board acknowledging that all services provided to California residents are subject to the provisions of this chapter and the regulations of the board, and that any material violation of the provisions of this chapter, the regulations of the board or conduct deemed by the board to be unprofessional is grounds for revocation of registration and the right to provide services to California residents.

ATTACHMENT D

§ 4036. Pharmacist

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

§ 4050. Professional status

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

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

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

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

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

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

(c) Except as otherwise provided in this chapter, it is unlawful for any person to perform any prescription review, consultation, drug utilization review, medication therapy management, or

other cognitive services for, pertaining to, or at the request of, patients, prescribers, or other care providers in this state, unless he or she is a pharmacist licensed under this chapter.

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

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

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

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

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

§ 4052. Power to perform procedures and functions; training

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

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

(2) Transmit a valid prescription to another pharmacist.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

~~(C) A pharmacist, pharmacist's employer, or pharmacist's agent may not directly charge a patient separate consultation fee for emergency contraception drug therapy services initiated pursuant to this paragraph, but may charge an administrative fee not to exceed ten dollars (\$10) above the retail cost of the drug. Upon an oral, telephonic, electronic, or written request from a patient or customer, a pharmacist or pharmacist's employee shall disclose the total retail price that a~~

~~consumer would pay for emergency contraception drug therapy. As used in this subparagraph, total retail price includes providing the consumer with specific information regarding the price of the emergency contraception drugs and the price of the administrative fee charged. This limitation is not intended to interfere with other contractually agreed upon terms between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health care service plan or insurer. Patients who are insured or covered and receive a pharmacy benefit that covers the cost of emergency contraception shall not be required to pay an administrative fee. These patients shall be required to pay copayments pursuant to the terms and conditions of their coverage. The provisions of this subparagraph shall cease to be operative for dedicated emergency contraception drugs when these drugs are reclassified as over the counter products by the federal Food and Drug Administration.~~

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

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

~~(2) Prior to performing any procedure authorized by paragraph (5) of subdivision (a), a pharmacist shall have either (A) successfully completed clinical residency training or (B) demonstrated clinical experience in direct patient care delivery.~~

~~(3) For each emergency contraception drug therapy initiated pursuant to paragraph (8) of subdivision (a), the pharmacist shall provide the recipient of the emergency contraception drugs with a standardized factsheet that includes, but is not limited to, the indications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Health Services, the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. The provisions of this section do not preclude the use of existing publications developed by nationally recognized medical organizations.~~

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

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

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

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

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

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

(2) Ordering drug therapy-related laboratory tests.

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

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

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

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

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

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

(2) Ordering drug therapy-related laboratory tests.

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

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

electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this clause within 24 hours.

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

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

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

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

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

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

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

§ 4052.3. Furnishing emergency contraception drug therapy; requirements

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

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

(2) Standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American College of Obstetricians and Gynecologists, the California Pharmacist Association, and other appropriate entities. Both the board and the Medical Board of California shall have authority to ensure compliance with this clause, and both boards are specifically charged with the enforcement of this provision with

respect to their respective licensees. Nothing in this clause shall be construed to expand the authority of a pharmacist to prescribe any prescription medication.

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

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

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

(e) For each emergency contraception drug therapy initiated pursuant to this section, the pharmacist shall provide the recipient of the emergency contraception drugs with a standardized factsheet that includes, but is not limited to, the indications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Health Services, the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. The provisions of this section do not preclude the use of existing publications developed by nationally recognized medical organizations.

§ 4052.41. Skin puncture

Notwithstanding Section 2038 or any other provision of law, a pharmacist may perform skin puncture in the course of performing routine patient assessment procedures or in the course of performing any procedure authorized under Section 1206.5. For purposes of this section, "routine patient assessment procedures" means: (a) procedures that a patient could, with or without a prescription, perform for himself or herself, or (b) clinical laboratory tests that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Health Care Financing

Administration, as authorized by paragraph (11) of subdivision (a) of Section 1206.5. A pharmacist performing these functions shall report the results obtained from a test to the patient and any physician designated by the patient. Any pharmacist who performs the service authorized by this section shall not be in violation of Section 2052.

§ 4306.5. Acts or omissions constituting unprofessional conduct

(a) Unprofessional conduct for a pharmacist may include:

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

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

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

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