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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
PUBLIC BOARD MEETING
MINUTES

DATE: July 26 and 27, 2011

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

BOARD MEMBERS PRESENT:
Stanley C. Weisser, President
Randy Kajioka, PharmD, Vice President
Greg Lippe, Public Member, Treasurer
Neil Badlani, RPh
Ryan Brooks, Public Member
Ramón Castellblanch, Public Member (7/27 only)
Deborah Veale, RPh
Shirley Wheat, Public Member
Tappan Zee, Public Member

BOARD MEMBERS NOT PRESENT: Rosalyn Hackworth, Public Member

STAFF PRESENT:
Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Joshua Room, Deputy Attorney General
Kristy Shellans, DCA Staff Counsel
Carolyn Klein, Legislation and Regulation Manager
Tessa Miller, Staff Analyst

Call to Order

President Stan Weisser called the meeting to order at 9:23 a.m.

President Weisser conducted a roll call. Board Members Zee, Kajioka, Brooks, Wheat, Veale, Badlani, Lippe, and Weisser were present.

I. General Announcements

President Weisser recognized former National Association of Boards of Pharmacy (NABP) Presidents Dennis McAllister and Jerry Moore as well as Fred Weisman from the University of Southern California, School of Pharmacy who were in attendance in the audience.

II. Approval of the Full Board Meeting Minutes of May 3 & 4, 2011

MOTION: Approve the minutes of the May 3 and 4, 2011 Board Meeting.

M/S: Veale/Wheat

Support: 8 Oppose: 0 Abstain: 0

III. ENFORCEMENT COMMITTEE REPORT

a. Presentation by the National Association of Boards of Pharmacy (NABP)

Presentation
Scotti Russell and Josh Bolin provided a presentation on NABP activities and programs. A copy of this presentation is attached, following this meeting summary.

Ms. Russell provided an overview on the Pharmacist Assessment for Remediation and Evaluation (PARE). She reviewed that the PARE provides a multidimensional assessment that the boards of pharmacy may use as a contributory factor when making decisions regarding pharmacist practice deficiencies that result from disregarding pharmacy practice standards, non-compliance with laws and regulations, and/or threats to patient safety. Ms. Russell discussed that the PARE can be used as a tool to evaluate pharmacist's competence when reactivating or reinstating a license. She advised that the exam is internet based and should be administered in a monitored or proctored setting.

Ms. Russell provided that PARE will be available for use in 2012 and will cost $250. She indicated that NABP is seeking volunteer board members to participate in the beta testing of the exam. Ms. Russell also indicated that the PARE will be psychometrically validated and will be updated regularly to address current drug therapies.

Ms. Russell provided an update on the NABP Annual Meeting and Executive Committee. She reviewed five resolutions established by the committee as well as the 2010-2011 Report of the Task Force to Review and Recommend Revisions to the Controlled Substances Act. (These items are available on the NABP Web site.)
Mr. Bolin provided an overview on NABP Government Affairs which provides boards customized support and services to meet the unique needs of their states in areas

including outreach and education, assessment services, compliance-related services, and legislative and regulatory support.

Mr. Bolin reviewed upcoming interactive forums and indicated that NABP will cover the travel costs for one participant from each board to attend.

Mr. Bolin provided an overview on the Prescription Monitoring Interconnect Program for Controlled Substances. He discussed that the program facilitates the transfer of prescription monitoring program (PMP) data across state lines to authorized users to aid in the prevention of substance abuse and diversion of controlled substances.

Board Member Tappan Zee left the meeting room at 9:52 a.m.

Mr. Bolin provided that development of the program is complete and 15 states will be sharing data by the end of 2011, and an anticipated 30 states will be participating by the end of 2012. He stated that NABP will use its existing resources to fund five years of annual participation fees for all participating states so there is no costs to the states.

Mr. Bolin provided that NABP has met with representatives from the California Department of Justice, Bureau of Narcotic Enforcement CURES program to discuss California's participation in the Interconnect Program.

Discussion
The board discussed the CURES program and current challenges to the program in light of current budget restraints, including a reduction in the Bureau of Narcotic Enforcement's budget.

Executive Officer Virginia Herold advised that budgetary impacts on the CURES program and possible participation in the NABP Interconnect Program may need to be addressed by the board in the future.

Board Member Neil Badlani asked whether NABP has a method for monitoring continuing education (CE) credit.

Mr. Zee returned to the meeting room at 10:03 a.m.

Ms. Russell provided that NABP collaborated with the Accreditation Council for Pharmacy Education (ACPE) to establish the CPE Monitor program which tracks ACPE-accredited CE credits. She indicated that a second phase of the program will allow for the tracking of CE from providers not accredited by ACPE by 2012.

Deputy Attorney General Joshua Room asked if there is any other source that lists available CE providers.

Ms. Russell indicated that she is not aware of any other source.

Board Member Ryan Brooks asked whether NABP has produced a manual on best practices to assist the boards with pharmacy related issues such as CE or prescription labeling.

Ms. Russell provided that it is a goal of NABP to produce a best practices manual. She provided an overview on an executive officer forum established to exchange information and communication between boards to address pharmacy issues. Ms. Russell indicated that NABP can also assist boards by issuing a survey on a particular issue on behalf of the board.

Ms. Russell provided that NABP also sends out an E-Newsletter every week to executive officers to provide updates.

Mr. Brooks suggested that the E-Newsletter include a section to document the top five main topics impacting the boards. He discussed that training for public members of the board would be beneficial and also suggested that a section in the E-Newsletter be geared towards information for public board members.

No public comment was provided.

Report of the Enforcement Committee Meeting Held July 25, 2011

b. Discussion and Possible Action Regarding a Request for Exemption from 16 California Code of Regulations Section 1707.5 Label Requirements for Prescription Drug Containers as Authorized by Section 4076.5 of the California Business and Professions Code From the California Pharmacists Association for Skilled Nursing Facilities

Report
Board Member Randy Kajioka provided that the Enforcement Committee discussed a request from the California Pharmacists Association (CPhA) for an exemption from the requirements for patient-centered labels for unit-dose medications dispensed to patients in skilled nursing facilities.

Dr. Kajioka provided that the committee clarified that pursuant to the exemption provisions in Business and Professions Code section 4076.5 (d), an exemption is not required as the unit-dose medications are administered to the patient by a health care professional within the skilled nursing facility. He stated that it was further clarified that the bingo cards dispensed in the facility are labeled in a 10-point font as required.

No public comment was provided.

c. Discussion and Possible Action to Consider Recommendations by the Committee to Amend the Board's *Disciplinary Guidelines* at 16 California Code of Regulations Section 1760, Including to Incorporate Recommendations of the Substance Abuse Coordination Committee (Pursuant to SB 1441, Ridley-Thomas, Chapter 548, Statutes of 2008)

Background

The board has initiated a restructuring and updating of its *Disciplinary Guidelines*. To incorporate changes to the *Disciplinary Guidelines*, the board needs to initiate a rulemaking.

As part of this effort, the board has also determined to incorporate the recommendations of the DCA's Substance Abuse Coordination Committee into the *Disciplinary Guidelines*.

Senate Bill 1441 created the Substance Abuse Coordination Committee (SACC) and required that this committee, by January 1, 2010, formulate uniform and specific standards in specified areas that each healing arts board must use in dealing with substance-abusing licensees, whether or not a board chooses to have a formal diversion program. To facilitate implementation of these standards, the DCA created a workgroup in 2009 consisting of staff from each of the healing arts boards to draft recommended standards for SACC consideration during public meetings. There are 16 standards that were developed.

The most recent version of the SACC standards was approved in April 2011.

In March 2011, a board subcommittee of Stan Weisser and Tappan Zee met in a first step toward incorporating these standards into the *Disciplinary Guidelines*.

At the May 2011 Board Meeting, the board directed staff to develop regulatory language to modify the *Disciplinary Guidelines* to incorporate the SB 1441 standards.

To ensure the relevance, integrity and value of the *Disciplinary Guidelines*, Deputy Attorney General Joshua Room has developed the draft of the *Disciplinary Guidelines*, incorporating three levels of changes for reorganization, incorporation of the Uniform Standards, and suggested modifications from the Board Subcommittee.

Report

Dr. Kajioka provided that the Enforcement Committee discussed the modification of the *Disciplinary Guidelines* to incorporate the SB 1441 standards at its last meeting and made the following recommendation to the board:

> Committee Recommendation: Recommend that the board initiate the rulemaking process to notice the version of the language as presented in the document as authored by Joshua Room reflecting the changes incorporating the SB 1441 Uniform Standards (shown in blue) and

reorganization (shown in red). The changes in green should be maintained in a manner to document the subcommittee's work for historical record.

Discussion

Assistant Executive Officer Anne Sodergren provided an overview of SB 1441. She indicated that board staff has developed proposed changes to incorporate the standards for consideration by the board.

Ms. Sodergren discussed that board staff has also identified additional changes independent of SB 1441 to strengthen the board's monitoring of licensees on probation as well as other restructuring changes in order to consolidate the guidelines. She requested that staff be granted additional time in order to incorporate these changes.

Ms. Sodergren provided that the committee has discussed holding a one-day board meeting in order to review these additional changes in order to notice the language prior to the October 2011 Board Meeting.

DCA Staff Counsel Kristy Shellans discussed that this is an urgent issue as the board is approaching Sunset Review. She stated that the board's implementation of the standards will be evaluated during the Sunset Review process. Ms. Shellans indicated that other healing arts boards have been heavily scrutinized by the Senate Business and Professions Committee with respect to the implementation and noticing of the rulemakings that incorporate the standards into the *Disciplinary Guidelines*. She advised that the board will also be subject to such elevated scrutiny.

Dr. Kajioka recommended that the board hold a meeting on September 7, 2011 to review the proposed language.

No public comment was provided.

MOTION: To table the recommendation made by the Enforcement Committee and direct board staff to continue working on the language and incorporation of the SB 1441 Uniform Standards as well as changes that have been recommended by staff into the *Disciplinary Guidelines* to be reviewed at the September 7, 2011 Board Meeting.

M/S: Kajioka/Badlani

Support: 8 Oppose: 0 Abstain: 0

Other Enforcement Committee Items

d. Selection of Enforcement Committee Meeting Dates for 2011

Ms. Herold provided that the Enforcement Committee Meeting scheduled for September 7, 2011 in Sacramento will now be a meeting of the full board. She indicated that in addition to several enforcement issues, the board will also discuss e-pedigree at this meeting.

The Enforcement Committee will also hold a meeting December 6, 2011 (location TBD).

Confirmed dates and meeting locations will be posted on the board's Web site.

No public comment was provided.

e. Meeting Planned of the Compounding Subcommittee

Ms. Herold provided that the Compounding Subcommittee Meeting scheduled for August 23, 2011 will be rescheduled.

President Weisser indicated that Board Members Kajioka and Badlani are members of this subcommittee.

No public comment was provided.

f. Review of Enforcement Statistics and Performance Standards of the Board

Report
Ms. Herold provided an overview of the statistics as well as the department's performance standards report for the board provided in the meeting materials.

Discussion
Mr. Brooks asked how many pharmacists are licensed in California and how many are investigated annually.

Mr. Herold provided that there are about 40,000 pharmacists and 7,000 pharmacies licensed in California. She stated that the board opens 2,200 investigations each year and formally disciplines about 200 licensees per year.

Mr. Brooks requested a matrix to document this enforcement information.

Ms. Herold provided that the board's Sunset Report will provide this information. She stated that this information will also be presented during the October 2011 Board Meeting.

Mr. Brooks asked to work with board staff on the compilation of this information.

No public comment was provided.

g. Fourth Quarterly Update of the Committee's Strategic Performance Goals for 2010/11

Ms. Herold referenced the fourth quarter's update report on the Enforcement Committee's strategic plan provided in the meeting materials.

No public comment was provided.

President Weisser introduced new Supervising Inspector William Young.

Dr. Young introduced himself to the board and provided background on his career as a pharmacist.

IV. LICENSING COMMITTEE REPORT

There was no meeting of the Licensing Committee this quarter due to travel restrictions on state agencies.

a. Update on the Board's Efforts to Implement 16 California Code of Regulations Section 1702, Mandatory Submission of Fingerprints for Pharmacists

Report

Board Member Greg Lippe provided that California Code of Regulations 1702 establishes new renewal requirements for pharmacists.

Mr. Lippe provided that the regulation specifies that as a condition of renewal, a pharmacist must disclose on the renewal form any arrest or conviction, as specified, since the licensee's last renewal; that a pharmacist applicant must pay the actual cost of compliance with the submission of fingerprints; a requirement that the licensee retain proof of compliance, as specified; and that failure to comply with the fingerprint requirement will result in an application for renewal being considered incomplete. He stated that this regulation was approved by the Office of Administrative Law and took effect December 7, 2010.

Mr. Lippe provided that during previous board and committee discussion, members have been advised about implementation challenges due to staff reductions and programming issues.

Mr. Lippe added however that implementation of the arrest and conviction disclosure requirements was not delayed.

Mr. Lippe provided that after receiving approval from the department's legal office, board staff is mailing correspondence to all affected licensees advising them on the requirement as well as the steps necessary to comply. He stated that licensees outside of California will also be provided with fingerprint cards. Mr. Lippe indicated that these letters should be mailed by the end of July 2011.

Ms. Wheat left the meeting room at 10:39 a.m. and returned to the meeting room at 10:42 a.m.

Public Comment
Fred Weissman asked whether arrest or criminal disclosure will also be included on the intern application.

Ms. Sodergren provided that the intern application already requires this disclosure. She advised that there is currently no reporting requirement for interns post licensure; however, the board does receive subsequent arrest notification from the Department of Justice.

b. Competency Committee Report

California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE)

Mr. Lippe provided that the board instituted a quality assurance review of the CPJE effective April 1, 2011. He explained that this process is done periodically to ensure the reliability of the examination. Mr. Lippe indicated that the quality assurance review was removed in July and results have been released and continue to be released twice a month.

Examination Development

Mr. Lippe provided that both Competency Committee workgroups will meet August 2011 at the annual meeting to discuss examination development. He indicated that each Competency Committee workgroup will also meet once in the fall of 2011 for examination development.

No public comment was provided.

c. Selection of Licensing Committee Meeting Dates for 2011

Members of the Licensing Committee discussed their availability for the following dates:

- September 29, 2011 -- Sacramento

- December 14, 2011 – location to be arranged

Due to a scheduling conflict, the meeting scheduled for September 29, 2011 will be rescheduled. Confirmed dates will be posted on the board's Web site.

d. Licensing Statistics for 2010/11

Mr. Lippe referenced the licensing statistics for 2010/11 as well as the three year comparison statistics provided in the meeting materials.

No public comment was provided.

e. Fourth Quarterly Update of Strategic Plan for the Licensing Committee

Mr. Lippe referenced the fourth quarterly report on the Licensing Committee's goals provided in the meeting materials.

No public comment was provided.

The board recessed for a break at 10:48 a.m.

The board reconvened at 11:06 a.m. Mr. Brooks was not present.

The board took agenda item VI out of order to accommodate the scheduled recognition of pharmacists licensed for 50 years.

VI. LEGISLATION AND REGULATION COMMITTEE

There was no meeting of the Legislation and Regulation Committee this quarter due to travel restrictions on state agencies.

PART I – REGULATIONS

a. Public Notice Period Completed: for Board Discussion and Action to Adopt

Report

Board Member Shirley Wheat reported that the 45-day public comment period for the following sections concluded on June 20, 2011. She indicated that the board did not receive any comments directed at the proposed rulemaking.

1. Add Title 16 Section 1727.2 – Requirements for Pharmacist Interns – To Require Applicants to Submit a Self-Query from the National Practitioner Data Bank –

Healthcare Integrity & Protection Data Bank (NPDB-HIPDB) [45-day comment period: May 6-June 30, 2011]

2. Amend Title 16 Section 1728 – Requirements for Pharmacist Examination – Amend to Require Applicants to Submit a Self-Query from the National Practitioner Data Bank – Healthcare Integrity & Protection Data Bank (NPDB-HIPDB) [45-day comment period: May 6-June 20, 2011]

Ms. Wheat offered a proposal to adopt the proposed regulations.

No public comment was provided.

MOTION: Adopt the proposed regulations to add Title 16 CCR § 1727.2 and to amend Title 16 CCR § 1728; and direct staff to take all steps necessary to complete the rulemaking process, including filing of the final rulemaking package with the Office of Administrative Law; delegate to the executive officer the authority to make any non-substantive changes to the proposed regulations and adopt the proposed regulations at Sections 1727.2 and 1728 as described in the notice.

M/S: Wheat/Veale

Support: 7 Oppose: 0 Abstain: 0

b. Board-Approved – Undergoing Review by the Department of Consumer Affairs (Update Only)

1. Amend Title 16 Sections 1715, 1784, 1735.2, and 1751– Update of Self-Assessment Forms for Pharmacies, Sterile Injectable Compounding Pharmacies, Hospitals and Wholesalers [45-day comment period: March 11 – April 25, 2011]

Report
Ms. Wheat provided that the final rulemaking file is currently being reviewed by the department. She discussed that following department and agency approval, the file will then be submitted to the Office of Administrative Law (OAL) pursuant to the Administrative Procedure Act.

Ms. Wheat provided that pharmacy law requires pharmacies and wholesalers to conduct self-assessments on or before July 1 of each odd-numbered year to promote compliance with various federal and state laws and regulations through self-examination and education. She stated that self-assessment forms also serve as an easy reference guide for a pharmacist-in-charge (PIC) or a designated representative-in-charge (DRIC). Ms. Wheat indicated that a self-assessment is required any time there is a change in the PIC or DRIC, when a new permit/license is issued; or (for a wholesaler) when there is a change of address.

Ms. Wheat provided that until the rulemaking currently under review is approved by OAL, the board has placed the draft, updated self-assessment on its Web page (labeled as “Draft for 2011”) for use by pharmacies, wholesalers and hospitals – should those licensees choose to use the updated self-assessment forms.

There was no board discussion or public comment on this item.

Ms. Wheat provided a brief update on the following rulemakings undergoing review. There was no board discussion or public comment on these items.

2. Amend Title 16 CCR Section 1732.2 – Board Accredited Continuing Education [45-day comment period: October 8-November 22, 2010; February 4-21, 2011]

3. Amend Title 16 Section 1793.5 – Pharmacy Technician Application; Requirement for Applicants to Submit a Self-Query from the National Practitioner Data Bank – Healthcare Integrity & Protection Data Bank (NPDB-HIPDB) [45-day comment period: April 8 – May 23, 2011]

c. Board Approved – Hearing Scheduled July 27, 2011 (Update Only) Add Title 16 Section 1707.6 and to Amend Section 1707.2 Regarding Consumer Notices and Duty to Consult – Consumer Notice for Language Assistance Interpretive Services Provided in Pharmacies and the Ability to Request 12-Point Font on Prescription Drug Container Labels [45-day comment period: May 27- July 11, 2011]

Ms. Wheat provided that on Wednesday, July 27, 2011, the board will conduct a Regulation Hearing regarding its proposal to amend 16 CCR § 1707.2 and to add 16 CCR § 1707.6 regarding Consumer Notices and Duty to Consult.

There was no board discussion or public comment on this item.

d. Board Approved – Under Development (Update Only)

Ms. Wheat referenced the following proposals currently under development.

There was no board discussion or public comment on these items.

1. Proposed Amendments to § 1746 – Emergency Contraception Protocol

Background

The Board of Pharmacy has begun work to update the emergency contraception protocol authorized by California Business and Professions Code section 4052.3 and 16 CCR 1746. These sections authorize a pharmacist to initiate emergency contraception pursuant to a state protocol developed by the Medical Board of California (MBC) and the Board of Pharmacy, and with the assistance of the American College of Obstetricians and Gynecologists, the California Pharmacists Association (CPhA) and other entities.

The current state protocol was developed by the Medical Board in 2004; the board adopted the protocol as a regulation later that year, and 16 CCR 1746 became operative on December 2, 2004. Since that time, there have been changes in the availability of emergency contraception medicine, the manufacturers who produce the medication, and there is a typographical error in the board's regulation that requires correction (mcg instead of mg).

Since the May 2011 Board Meeting, the Executive Officer has finalized a revised draft, working with CPhA's representative (a women's health specialist pharmacist), and two representatives of the American College of Obstetricians and Gynecologists. An updated manuscript has been prepared and will be shared with the MBC at its July 2011 meeting. The Medical Board must approve the modified protocol before the Board of Pharmacy can proceed with a rulemaking to update its regulation at 16 CCR 1746.

As part of this update and review, this board also will need to update the patient information fact sheet – which is required to be provided to patients by the pharmacists using the protocol to dispense emergency contraception. The fact sheet will be vetted by the board's Communication and Public Education Committee.

2. Proposed Amendments to § 1751.9 – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

Background

Business and Professions Code section 4127.1 requires a separate license to compound sterile injectable drug products. Section 4127.1(d) provides exemptions to the licensing requirement for pharmacies that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board. The proposed regulation would specify the criteria the board will utilize to consider approval of accreditation agency requests. Staff is continuing to work with counsel to develop language for consideration at a future meeting.

3. Proposed Amendments to § 1780 – Update the USP Standards Reference Manual (Minimum Standards for Drug Wholesalers) [referred to subcommittee]

Background

Section 1780 of the California Code of Regulations sets minimum standards for drug wholesalers. This regulation currently references the 1990 edition of the United States Pharmacopeia Standards (USP Standards) for temperature and humidity. USP Standards are updated and published annually. Section 1780(b) requires amendment to reflect the 2005 version of the USP Standards and to hold wholesalers accountable to the latest standards, if determined appropriate.

Because of stated concerns about whether referencing the 2005 USP Standards would be an unreasonable burden on wholesalers, at the October 2008 Board Meeting, the board voted to address the issue of updating the USP Standards reference materials within this section.

The board established a subcommittee for this purpose but, as a result of board vacancies, the subcommittee has not held any meetings and no action has been taken with respect to this regulation change.

4. Proposed Amendments to § 1785 – Self-Assessment of a Veterinary Food-Animal Drug Retailer [referred to Licensing Committee]

Background

The requirements of § 1785 establish a self-assessment form for veterinary food-animal drug retailers and requires a designated representative-in-charge to complete this form to ensure compliance with pharmacy law. Self-assessment forms also aid licensees in complying with legal requirements of their operations and, therefore, increase public safety as a result of this compliance.

In 2007 the Enforcement Committee and the Board approved draft amendments to the regulation and related self-assessment form; subsequently, the licensing committee was advised of potential problems with the licensing requirements for designated representatives working at these facilities.

The Licensing Committee has not yet initiated a program review of the Veterinary Food-Animal Drug Retailer program. Staff does not anticipate proceeding with this regulation until such time that the Licensing Committee completes its review.

PART II – LEGISLATION

a. Board-Sponsored Legislation

SB 431 (Emmerson) Pharmacies: Regulation

Ms. Wheat provided that in January 2010, the board voted to pursue legislation to improve the board's enforcement tools as well as to better define the return of medicine via reverse distributors. She stated that these provisions are incorporated in SB 431.

Ms. Wheat referenced the following specific code sections:

a. §4104 – Licensed Employee, Theft or Impairment, Pharmacy Procedure
   Amend to clarify that a pharmacy shall provide the board, within 14 days, evidence of a licensee's theft or impairment. Require a pharmacy to conduct an audit to determine the scope of a drug loss and to provide the board with a certified copy of the audit results.
b. §4105 – Retaining Records of Dangerous Drugs and Devices on Licensed Premises; Temporary Removal; Waivers; Access to Electronically Maintained Records
   Amend to specify the time period for which records shall be provided to the board when requested by an inspector or authorized representative of the board.
c. §4112 – Nonresident Pharmacy; Registration; Provision of Information to Board; Maintaining Records; Patient Consultation
   Require that a nonresident pharmacy cannot allow a pharmacist, whose license has been revoked in California, to provide pharmacist related services to Californians.
d. §4040.5 – Reverse Distributor
   Specifies that a reverse distributor may not accept previously dispensed medicine and that previously dispensed medicine returned to a pharmacy can only be handled by a licensed integrated waste hauler. Defines "dispensed" for purposes of this section only. This provision was approved in concept only by the board in January 2009.
e. §4081 – Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory
   Specifies that records documenting the return of drugs to a wholesaler or reverse distributor must include the quantity or weight of the drug being returned, the date returned and the name(s) to which the drugs were provided. Specifies that records documenting the return of drugs to a licensed integrated waste hauler shall include a list of the volume in weight and measurement, and the date and name of the hauler. Defines "licensed integrated waste hauler" for purposes of this section only. This provision was approved in concept only by the board in January 2009.
f. §4126.5 – Furnishing Dangerous Drugs by a Pharmacy
   Authorizes a pharmacy to furnish drugs to a licensed integrated waste hauler. Needs to authorize a pharmacy to accept returned product from a consumer in the event of a product recall.

Ms. Wheat provided that this bill passed out of Assembly Health Committee on July 6, 2011 and is scheduled to be heard in the Assembly Appropriations Committee August 17, 2011.

Discussion
Ms. Herold provided that the author's office has indicated that there is some interest in an amendment to permit reverse distributor's to take back drugs from patients who no longer want them. This is currently against California's Health and Safety Code which requires licensed waste haulers to pick up such waste.

Ms. Wheat provided that this bill has been amended twice to address concerns. She stated that board staff continues to advocate this legislation and is working with the author's office to address concerns raised.

Public Comment
Mark Harvey, representing EXP Pharmaceutical Services, provided that his organization has worked with the author's office to remove the prohibition on reverse distribution being involved in drug take back. He encouraged the board to consider this amendment.

SB 943 (Senate Committee on Business, Professions & Economic Development) Omnibus
Ms. Wheat provided that at the October 2010 Board Meeting, the board voted to pursue an omnibus provision to eliminate a reference to the previous pharmacists examination in Business and Professions Code section 4200. She stated that this provision is contained in Senate Bill 943.

Ms. Wheat provided that this measure passed out of the Assembly Business, Professions and Consumer Protection Committee on July 6 and is scheduled to be heard in the Assembly Appropriations Committee on August 17, 2011.

No public comment was provided.

Mr. Brooks returned to the meeting room at 11:17 a.m.

b. Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction

1. Board of Pharmacy/Licensing

AB 377 (Solorio) Pharmacy: Centralized Hospital Packaging
Version: As amended, April 14, 2011

Summary: This bill provides for centralized pharmacy packaging in a hospital, allowing the pharmacy to be located outside of a hospital on either the same premises or separate premises that is regulated under a hospital's license. The bill exempts from the definition of manufacturing, repackaging a drug for parenteral therapy, or oral therapy in a hospital for delivery to another pharmacy or hospital, as specified.

Board Position: Support If Amended

Recent Action: This bill is scheduled to be heard in the Senate Appropriations Committee on August 15, 2011.

Ms. Wheat provided that board staff was just advised by CSHP that this will be a 2-year bill. She indicated that there was a recent technical amendment to the bill that did not change the intent of the bill.

No public comment was provided.

2-Year Bills
Ms. Wheat briefly reviewed the following 2-year bills and indicated that these bills have seen no movement.

No public comment was provided on these items.

AB 847 (Lowenthal, Bonne) Pharmacy: Clinics
Version: As Introduced March 10, 2011

Summary: Would expand these provisions to additionally authorize an outpatient setting or an ambulatory surgical center, as specified, to purchase drugs at wholesale for administration or dispensing, subject to the requirements applicable to surgical clinics. The bill would delete the requirement that a clinic operating under these provisions be licensed by the California State Board of Pharmacy and would make that licensure optional.

Board Position: None

SB 632 (Emmerson) Pharmacy
Version: As Amended March 24, 2011

Summary: Would prohibit a pharmacist from interchanging or substituting an opioid analgesic drug, as defined, for an opioid analgesic drug incorporating a tamper resistant technology, as defined, unless the opioid analgesic drug to be interchanged or substituted is described on a list to be prepared by the board. In those situations where the drug is not on the board's list, the bill would require the pharmacist to obtain consent from the prescriber prior to an interchange or substitution.

Board Position: None

2. Controlled Substances

AB 507 (Hayashi) Pain Management
Version: As amended, July 1, 2011

Summary: In its current form, this measure would conform findings and declarations and other references to severe chronic intractable pain and to the California Intractable Pain Treatment Act.

History: As originally introduced, this measure repealed provisions in existing law which permit the Department of Justice (DOJ) to employ a physician to interview and examine any patient in connection with the prescription possession or use of a controlled substance, require the patient to submit to the interview and examination, and permit the physician to testify in prescribed administrative proceedings. Prior to the May 2011 Board Meeting, this measure has been amended twice since the committee reviewed it. The first amendments occurred on April 13, 2011 and removed the proposed changes to the board's unprofessional conduct statute, B&PC 4301. The bill was again amended on April 27, 2011 and again proposed a change to B&PC 4301(d).

Board Position: Oppose (April 27, 2011 version)

Recent Update: This measure has been amended again on June 20, 2011 and July 1, 2011 and proposed changes to the board's unprofessional conduct statute were removed.

Current Status: Hearing scheduled on August 15, 2011 in the Senate Appropriations Committee.

Discussion
Ms. Herold discussed that the bill would have removed "clearly excessive" provisions from existing law that would have compromised the board's consumer protection mandate and would have impaired the board's ability to discipline a pharmacist when he or she fails to exercise professional judgment regarding dispensing. She indicated that board staff met with the bill's author, and as a result, these provisions were removed from the bill.

Ms. Wheat offered a proposal to formally remove the board's position of Oppose and to establish a new position of Watch.

No public comment was provided.

MOTION: Remove position of Oppose and establish a position of Watch on AB 507.

M/S: Wheat/Lippe

Support: 8 Oppose: 0 Abstain: 0

3. Reporting Requirements/Records

AB 1280 (Hill) Ephedrine: Retail Sale
Version: As amended, May 26, 2011

Summary: The bill contains provisions requiring the secure storage and monitoring of products containing any amount of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, as specified. This bill proposes a real-time tracking system beginning on or after July 1, 2012 through December 2018.

Board Position: Watch

Current Status: Hearing scheduled for August 15, 2011 in Senate Appropriations Committee.

Ms. Wheat provided that this measure was amended twice since the May 2011 Board Meeting.

No public comment was provided.

SB 315 (Wright) Ephedrine and Pseudoephedrine
Version: As Introduced February 14, 2011

Summary: This bill would classify pseudoephedrine as a prescription drug.

Board Position: Support

Discussion
Ms. Sodergren provided that these two bills take two different approaches towards controlling pseudoephedrine sales. She discussed that AB 1280 would implement a tracking system for pseudoephedrine sales; whereas, SB 315, currently a 2-year bill, would make pseudoephedrine a prescription only product.

Ms. Sodergren provided that there are some concerns regarding the privacy and housing of the data with respect to the tracking system provided for in AB 1280. She stated that there is also concern that this approach may not actually combat the intent of restricting sales and "smurfing" of pseudoephedrine.

No public comment was provided.

SB 360 (DeSaulnier) Controlled Substance Utilization Review and Evaluation System
Version: As amended, July 7, 2011

Summary: This bill would revise Schedule I and Schedule II to add additional opiates, revise Schedule III to add additional depressants, anabolic steroid products, and materials, compounds, mixtures, or preparations containing chorionic gonadotropin (a hormone), and Schedule IV to add additional depressants and stimulants.

Board Position: Watch

Recent Action: Hearing scheduled for August 17, 2011 in Senate Appropriations Committee.

Recent Update: This measure has been amended twice since the May 2011 Board Meeting. Most notably, this measure would specify reporting to the CURES system would be linked to the federal schedule of controlled drugs, not the state schedule. Board staff has identified the areas where the state and federal schedules vary. More information is included in the bill analysis for this measure.

Discussion
The board discussed the discrepancies between the state and federal schedules of controlled drugs. Concern was expressed regarding California giving up its ability to schedule drugs.

Public Comment
Steve Gray, representing Kaiser Permanente, provided that if the bill passes, follow up education will be necessary for pharmacists, computer programmers, and database programmers as databases will have to be reprogrammed according to the federal schedule rather than the California schedule. He also suggested that an article be included in *the Script* to address this issue.

SB 850 (Leno) Medical Records: Confidential Information
Version: As Amended, June 22, 2011

Summary: This bill would require an electronic health or medical record system to automatically record and preserve any change or deletion of electronically stored medical information, and would require the record to include, among other things, the identity of the person who accessed and changed the medical information and the change that was made to the medical information.

Board Position: None. The board has not previously discussed this measure.

Ms. Wheat provided that this bill is scheduled for hearing on August 17, 2011 in the Assembly Appropriations Committee.

The board suspended the remainder of the Legislation Report in order to recognize pharmacists celebrating 50 years of service.

V. RECOGNITION AND CELEBRATION OF PHARMACISTS LICENSED FOR 50 YEARS IN CALIFORNIA

President Weisser recognized Wayne Mallouf. Mr. Mallouf was presented with a 50-year pin by his wife, Jaclyn Mallouf.

President Weisser recognized Tom Barnett for his 51 years as a licensed pharmacist. Mr. Barnett was presented with a 50-year pin.

The board resumed the Legislation Report.

4. Healing Arts/DCA

SB 541 (Price) Regulatory Boards: Expert Consultants
Version: As amended, June 21, 2011

Board Position: Support (April 13, 2011 version)

Recent Action: This bill was amended June 21, 2011 to specify that the proposed change shall not be construed to expand the scope of service of an expert.

Current Status: Hearing scheduled for August 17, 2011 in the Assembly Appropriations Committee.

Ms. Wheat provided that this bill would authorize boards to enter into an agreement with an expert consultant, subject to the standards regarding personal service contracts described, to provide enforcement and examination assistance. She stated that the bill would require each board to establish policies and procedures for the selection and use of these consultants.

Ms. Wheat briefly reviewed the following bills. There was no board discussion or public comment.

AB 675 (Hagman) Continuing Education
Version: As Amended April 5, 2011

Summary: This bill would specify that continuing education or competency courses that advance or promote labor organizing on behalf of a union, or that advance or promote statutory or regulatory changes, political candidates, political advocacy, or political strategy shall not be considered content relevant to the practice regulated by the board and shall not be acceptable for meeting requirements for licensure renewal.

Board Position: None

AB 958 (Berryhill) Regulatory boards: Limitation Periods
Version: As introduced February 18, 2011

Summary: This bill would require the board to file an accusation within one year after the board discovers the violation.

Board Position: None

SB 544 (Price) Healing Arts
Version: As amended, April 14, 2011

Summary: The bill would require cooperation between state agencies and all boards within the department when investigating a licensee, and would require a state agency to provide to the board all licensee records in the custody of the state agency. The bill would require all local and state law enforcement agencies, state and local governments, state agencies, licensed health care facilities, and any employers of any licensee to provide licensee records to any board within the department upon request by that board, and would make an additional requirement specific to the Department of Justice.

Board Position: None

SB 667 (Wyland) Naturopathic Doctors
Version: As amended, March 31, 2011

Summary: This bill would provide that a naturopathic doctor is not prohibited from ordering, prescribing, or administering a nonprescription substance that becomes a substance requiring a prescription based solely on its route of administration.

Board Position: None

5. Other

AB 389 (Mitchell) Bleeding Disorders: Blood Clotting Products
Version: As amended, March 30, 2011

Board Position: Watch

Current Status: Hearing scheduled for August 15, 2011 in the Senate Appropriations Committee.

Ms. Wheat provided that this bill would impose specified requirements on providers of blood clotting products for home use for products used for the treatment and prevention of symptoms associated with bleeding disorders, including all forms of hemophilia.

Discussion
Ms. Shellans asked whether staff concerns regarding jurisdiction and challenges in enforcing some of the provisions have been addressed with the author's office.

Ms. Herold provided that she has met with the sponsors of the bill. She discussed that many of the provisions are currently the standard of practice, but are not mandated.

Ms. Herold indicated that the board may need regulations to clarify some of this language in the bill. Ms. Herold discussed that it is unclear if the board would have jurisdiction over the home nursing services and the quality of the care provided.

Dr. Kajioka expressed concern regarding the impact the provisions will have on the board and the scope of pharmacy practice. He offered a proposal to oppose the bill.

Ms. Herold advised that there is currently no opposition to the bill.

The board further discussed the intent of the bill and the impact it would have on the board as the responsible agency for the enforcement of the provisions. Concern was expressed that pharmacies that have previously provided an emergency or one-time supply of this expensive medication would be considered a "provider" and will be required to stock the medication on a regular basis.

Supervising Inspector Robert Ratcliff provided that he believes this bill is a solution for which there is no problem. He discussed that based on his experience in home care pharmacies, patients develop a relationship with a pharmacy that can provide the goods and services that they need. Dr. Ratcliff stated that hemophilia patients cannot expect every pharmacy to have these drugs in stock. He stated that instead, these patients will find a specialty pharmacy or a community pharmacy that will provide the drugs they need.

Public Comment

Dick Story provided comment on the relationship between hemophilia patients and home care pharmacies. He discussed that this relationship allows the patient to obtain the drugs they need.

Steve Gray, representing Kaiser Permanente, provided comment on hemophilia. He indicated that this condition is not diagnosed instantaneously and requires many different drugs to treat it. Dr. Gray indicated that Kaiser has worked with the bill's author and is now comfortable with the provisions as they have been substantially modified to be more reasonable and do not require retail pharmacies to provide these drugs.

Philip Swanger, representing CSHP, provided that CSHP has also worked with the bill's author and has modified its Support if Amended position to a position of Support.

Ms. Herold provided that she will meet with the bill's author to discuss the board's concerns and opposition to the bill.

MOTION: Remove position of Watch and establish a position of Oppose on AB 389.

M/S: Kajioka/Lippe

Support: 5 Oppose: 0 Abstain: 3

AB 604 (Skinner) Needle Exchange Programs
Version: As amended, July 14, 2011

Board Position: Support (April 5, 2011 version)

Ms. Wheat provided that this bill would authorize, until January 1, 2019, the State Department of Public Health to approve certain entities to provide hypodermic needle and syringe exchange services in any location where the department determines that the conditions exist for the rapid spread of HIV, viral hepatitis, or any other potentially deadly or disabling infections that are spread through the sharing of used hypodermic needles and syringes.

Ms. Wheat provided that recent amendments to this measure put a sunset date of January 1, 2019 on the authority of CDPH to NEP programs.

No public comment was provided.

SB 41 (Yee) Hypodermic Needles and Syringes
Version: As amended, June 28, 2011

Board Position: Support If Amended

Current Status: Ordered to third reading in the Assembly.

Ms. Wheat provided that this bill would allow, until January 1, 2015, a physician or pharmacist to furnish 30 or fewer hypodermic needles and syringes solely for personal use to a person 18 years of age or older. She stated that the bill addresses the storage of products to ensure they would be available only to authorized personnel, would require that disposal options are provided to consumers, and would require pharmacies to provide written information or verbal counseling at the time of furnishing on how to access drug treatment.

Ms. Wheat provided that this measure has been amended three times since the May 2011 Board Meeting.

Discussion
Mr. Lippe asked whether the recent amendments to the bill address the board's position of Support if Amended.

Ms. Sodergren discussed that the board established its position with regards to potential unintended consequences if the repeal of the section prohibiting a person from possessing a hypodermic needle or syringe remained in the bill. She indicated that the amended bill does include provisions about the unlawful possession of needles. Ms. Sodergren advised that these provisions are established in the Health and Safety Code, not in the Business and Professions Code.

The board discussed whether the recent amendments to the bill satisfy the board's concerns to warrant a Support position.

Mr. Room discussed that he does not believe the provisions are an adequate substitute for Section 4140 regarding unlawful possession of a hypodermic needle.

It was the consensus of the board to maintain its position of Support if Amended on SB 41.

Ms. Wheat requested that board staff communicate to the bill's author that the recent amendments to the bill do not sufficiently address the board's concerns.

SB 514 (Simitian) Dextromethorphan: Sale to Minors Prohibited
Version: As amended, May 10, 2011

Board Position: Support

Recent Action: This measure was amended on May 10, 2011 to specify that an infraction of this provision may be punishable by a fine not to exceed $250.00.

Current Status: Ordered to third reading in the Assembly.

Ms. Wheat provided that this bill would make it illegal to sell dextromethorphan to a person under the age of 18 without a prescription.

Ms. Wheat provided that this measure was amended on May 10, 2011 to specify that an infraction of this provision may be punishable by a fine not to exceed $250.00.

Discussion
Mr. Lippe expressed concern that the fine may not be aggressive enough to deter this activity as the fee is assessed to the pharmacy.

Board Member Deborah Veale discussed that dextromethorphan is typically abused by teenagers; and, as such, the fine may be appropriate. She offered support to this bill.

Public Comment
Steve Gray, representing Kaiser Permanente, indicated that Kaiser generally supports this bill. He expressed concern that there is no exemption for emancipated minors and indicated that the bill is too specific with regards to the identification that is required. Dr. Gray also expressed concern regarding the use of a cash register that is equipped with an age-verification feature to monitor age restricted items "if feasible."

Ms. Sodergren provided that the author's office has indicated that it does not expect retailers to purchase registers that are equipped with an age-verification feature. Rather, if a retailer does have the available technology, they are expected to use it.

Dr. Kajioka provided comment in opposition to the bill. He discussed that the provisions seem counterproductive and are not stringent enough to encourage due diligence and compliance by the pharmacy.

Mr. Brooks left the meeting room around 12:30 p.m.

Mr. Lippe offered a proposal to oppose this bill.

The board took no action on this bill.

6. Additional Legislation Impacting the Board or Its Regulatory Jurisdiction

AB 1424 (Perea) Franchise Tax Board: Delinquent Tax Debt
Ms. Wheat provided that this bill would require the State Board of Equalization and the Franchise Tax Board to each make available a list of the 500 largest tax delinquencies at least twice each calendar year. She stated that his bill would require the Franchise Tax Board to include additional information on the list with respect to each delinquency, including the type, status, and license number of any occupational or professional license held by the person or persons liable for payment of the tax and the names and titles of the principal officers of the person liable for payment of the tax if that person is a limited liability company or corporation. Ms. Wheat indicated that this bill would specify that a license may be suspended for failure to pay tax delinquencies.

Ms. Wheat provided that a hearing is scheduled for August 15, 2011 in the Senate Appropriations Committee.

Discussion
Ms. Wheat expressed concern regarding the financial burden this bill would impose on the board.

Mr. Lippe offered a proposal to oppose this bill.

Ms. Shellans clarified that the bill would authorize the board to enact regulations to collect an additional fee to assist in the processing costs and other costs related to these provisions.

Ms. Shellans discussed that this bill specifies that the board can “opt out;” but does allow for the Board of Equalization or the Franchise Tax Board to suspend a license if the board had not done so or has chosen to “opt out.”

Mr. Lippe stated that it is not appropriate to suspend a license because the licensee did not pay their tax bill.

Ms. Wheat provided that it is not the board’s job to collect taxes.

Ms. Veale provided that the board's focus is patient safety. She stated that this bill is not in line with this focus.

No public comment was provided.

MOTION: Establish a position of Oppose on AB 1424.

M/S: Lippe/Wheat

Support: 7 Oppose: 0 Abstain: 0

PART III – Legislation and Regulation Committee

President Weisser referenced the Fourth Quarterly Report on the Legislation and Regulation Committee's Goals for 2010/11 provided in the meeting materials.

There was no board discussion or public comment.

Public Comment

Steve Gray, representing Kaiser Permanente, discussed that many pharmacy organizations are experiencing problems when trying to obtain patient medication therapy records from other pharmacy organizations. He recommended that the board address and evaluate the professional standard in this area.

DCA Director Brian Stiger congratulated the board and board staff on its success in obtaining 12 of 13 hiring freeze exemptions requested. He indicated that the board has the best success rate in this area in the department.

Mr. Stiger provided that the governor has appointed Reichel Everhart to DCA as senior advisor to the director. He indicated that with the addition of new executive staff, the executive office hopes to resume providing director's reports at future board meetings.

President Weisser commended board staff for their continued hard work and dedication to the board.

Michael Negrete, representing the Pharmacy Foundation of California, suggested that the board review and discuss the requirements for patient consultation for new prescriptions and the rules concerning patient refusal.

Mr. Brooks returned to the meeting room at 12:53 p.m.

The board recessed for a lunch break at 12:54 p.m.

The board reconvened at 2:34 p.m. Mr. Zee and Ms. Wheat were not present.

VII. COMMUNICATION AND PUBLIC EDUCATION COMMITTEE REPORT AND ACTION

There was no meeting of this Communication and Public Education Committee this quarter

a. Update of the State's Emergency Contraception Protocol Regulation (16 California Code of Regulations Section 1746.) and Consumer Fact Sheet

Report

Mr. Brooks provided that the board has begun work to update the emergency contraception protocol authorized by California Business and Professions Code section 4052.3 and 16 California Code of Regulations section 1746.

Mr. Brooks provided that the current state protocol was developed by the Medical Board in 2004 and then later adopted by the board as a regulation.

Mr. Brooks provided that since the May 2011 Board Meeting, the executive officer has completed edits into a revised protocol from CPhA's representative (a women's health specialist pharmacist), and two representatives of the American College of Obstetricians and Gynecologists. He stated that this revised protocol has been submitted to the Medical Board of California, which must approve the modified protocol. Mr. Brooks indicated that this review will occur at the July 29, 2011 meeting of that board.

Mr. Brooks provided that the board will then need to proceed with a rulemaking to update the requirements as a regulation. He stated that as a final part of the rulemaking, the board will need to update the patient information fact sheet, which is required to be provided to patients by the pharmacists using the protocol to dispense emergency contraception.

Mr. Zee and Mrs. Wheat returned to the meeting room at 2:36 p.m.

Discussion

President Weisser referenced the protocol provided in the meeting materials. He discussed that the language is inconsistent as it refers to both a "patient" and a "man or woman." President Weisser suggested that this language be changed to "individual."

Mr. Brooks sought clarification regarding a pharmacist's right to refuse to dispense emergency contraception. He asked whether the pharmacy is required to maintain a list of pharmacies that will dispense this medication.

Ms. Herold provided that Business and Professions Code section 733 provides that a licensee may decline to dispense this medication only if they have previously notified their employer. She explained that the employer must establish protocols to ensure that patients have timely access to this medication despite the licensee's refusal.

Mr. Room further clarified and read the requirements of Section 733 and explained that the burden is on the pharmacy to ensure that the patient has access to the medication.

Public Comment
A member of the public provided comment on the liability of the referring pharmacy if the second pharmacy is unable to provide the emergency contraception.

b. Update on Public Outreach Activities

Mr. Brooks referenced the following public and licensee outreach activities performed during the fourth quarter of Fiscal Year 10/11 include:

- April 27, 2011 – Executive Officer Herold provides an update on board activities to senior executive members of the Healthcare Distribution Management Association in a Sacramento meeting.
- May 5, 2011 – Supervising Inspector Dang provides a CE presentation on new pharmacy laws to over 70 pharmacists at an association meeting in Los Angeles.
- May 11, 2011 – Executive Officer Herold provides a presentation on California's patient-centered labeling requirements to over 100 individuals at the annual Ralphs manager meeting in Orange County.
- May 21, 2011 – Executive Officer Herold provides a presentation to over 100 attendees on the board's citation and fine and enforcement programs at the CPhA Celebrate Pharmacy Conference in Oakland. Board Inspector Hunt provides a presentation on responsibilities on how to survive a board inspection and the roles of a PIC at the same conference. New Supervising Inspector Young also provides a presentation on addressing prescription drug abuse.
- June 1, 2011 – Executive Officer Herold participates in the mandatory DCA day-long training for new board members in Los Angeles on the roles of the executive officer, roles of a board member, and the components of the state enforcement, legislative and budget programs in operation at the boards.
- June 2, 2011 – Executive Officer Herold provides a Webinar-like presentation at an Axway conference in New Jersey on California's e-pedigree requirements.
- June 28, 2011 – Executive Officer Herold participates in a conference call of western states' pharmacy board directors hosted by the NAPB. This call was initiated at Ms. Herold's request to allow discussion of regulatory issues involving neighboring states.
- June 29, 2011 – Executive Officer Herold tapes a "postcript blog" with Community Catalyst in Washington DC on the security of the pharmaceutical supply chain and the issues identified in California surrounding the 2008 heparin recalls. This is part of the PEW Trust's forthcoming report on the 2008 heparin contamination which affected the supply of heparin in the US.

There was no board discussion or public comment on this item.

c. Fourth Quarterly Report on the Committee's Goals for 2010/11

Mr. Brooks referenced the fourth quarter's strategic plan update for the Communication and Public Education Committee Goals provided in the meeting materials.

There was no board discussion or public comment on this item.

VIII. FUTURE MEETING DATES OF THE BOARD OF PHARMACY FOR 2012

The board discussed their availability for the following proposed dates. The board considered the cost associated with traveling to attend the meetings and the timeline with respect to pending regulations. Finalized dates will be posted on the board's Web site.

2011

- September 7, 2011 (Proposed location – Los Angeles)
- October 18 – 19, 2011 (Proposed location - San Diego)

2012

- January 25 – 26, 2012 or January 31 and February 1, 2012 (Proposed location – San Francisco)
- May 1 – 2, 2012 (Proposed location – Sacramento)
- July 25 – 26, 2012 or July 17 – 18, 2012 (Proposed location – Loma Linda)
- October 24 – 25, 2012 (Proposed location – San Diego)

Mr. Zee left the meeting room at 3:02 p.m. and returned at 3:04 p.m.

IX. PUBLIC COMMENT ON ITEMS NOT ON THE AGENDA/AGENDA ITEMS FOR FUTURE MEETINGS

No public comment was provided.

The board recessed for a break at 3:10 p.m. The board reconvened at 3:30 p.m.

X. PETITION FOR REINSTATEMENT OF LICENSE

- Robert Mix, RPH 27779 – Petition for Reinstatement of Pharmacist License

The board heard a petition from Mr. Mix regarding reinstatement of his pharmacist license.

XI. CLOSED SESSION

The board convened in closed session pursuant to Government Code section to deliberate on the petition for reinstatement and other disciplinary matters.

RECESS FOR DAY

The board meeting was recessed at 5:00 p.m.

Wednesday, July 27, 2011

The board reconvened at 8:00 a.m. on Wednesday, July 27, 2011. Board Member Hackworth was not in attendance.

XII. CLOSED SESSION

The board convened in closed session pursuant to Government Code section 11126(c)(3) to deliberate on disciplinary matters.

OPEN SESSION

The open session was called to order at 10:13 a.m.

XIII. REGULATION HEARING

Regulation Hearing Regarding a Proposal to Add Title 16 Section 1707.6 and to Amend Section 1707.2 Regarding Consumer Notices and Duty to Consult – Consumer Notice for Language Assistance Interpretive Services Provided in Pharmacies and the Ability to Request 12-Point Font on Prescription Drug Container Labels [45-day comment period: May 27- July 11, 2011]

President Weisser called the hearing to order at 10:14 a.m.

The board briefly discussed the rulemaking process. It was clarified that written comments and the comments made during the oral testimony will be discussed by the board during a subsequent agenda item.

Ms. Herold provided that the development and design of the notices will be completed outside of the rulemaking process.

Oral Testimony

Michael Negrete, Pharmacy Foundation of California

I am Dr. Michael Negrete. I am a pharmacist and CEO of the Pharmacy Foundation of California. I did submit written testimony. I emailed it on Sunday night to the board. I do want to summarize and highlight a couple of things. First, is a bit of a concern I have about mandating the use of very specific verbiage and not providing an opportunity for other individuals, maybe with health literacy expertise or research, to use language that may more effectively convey the messages that the notices intend to convey. A member of my Board of Directors, Beccah Rothschild, MPA, is the Director of Health Literacy for Health Research for Action at UC Berkeley. I did run the proposed text by her and she had a bunch of great comments I would be happy to provide you in writing. I just received them recently. I will just read one of them to give you an idea of the kinds of improvements I would like to be able to see the board provide some flexibility to use. Her first comment was that the proposed language is between a 12th and 14th grade reading level based on a validated reading ability test. She says the average adult reads between 7th and 9th grade reading levels. There is obviously a great disconnect between what is the proposed language and what people are able to read and understand. She has other comments too. My worry is that just mandating specific language would basically prohibit people from actually being able to come up with better language with more impact. So, I would like to be able to see some flexibility put in there for individuals to submit a sign and get it approved by the board and use that instead.

Also, I would like to see the notice provide a clear, visible, prominently displayed message about the consultation requirement. Of all the things that could be included in the notice, that actually has evidence. Our research has shown that consumers understand and appreciate the value of the consultation. Putting it in a prominently displayed location on the sign in the pharmacy could help do that. I think a lot of consumers, if they see that speaking with the pharmacist is the law, they will then think there is a good reason for that law and be more inclined to make sure that they get their consultation. Additionally, while the front end staff should be fully aware of the requirement, we found that often times those individuals are the least trained individuals in the pharmacy and have the highest rate of turnover in the pharmacy. Ensuring that the sign is there in a very obvious, prominently displayed place will make sure that they are also aware of the requirement and that they are reminded of the requirement. Also, seeing the requirement there, we believe will also provide a greater level of

accountability to provide the services deserved by an informed consumer. So, I would like to see a statement to that effect there.

Third, I have a little bit of concern about the language that says where the notice is to be placed. I think the language is similar or identical to the current language which says "conspicuous to and readable by a prescription drug consumer." My concern is that I have seen a lot of pharmacies, using the current language, that think its ok to post the sign in a waiting area adjacent to the pharmacy. My problem is that, with electronic prescribing and auto, telephonic, and electronic refills, a lot of people don't even enter the pharmacy until their prescription has already been filled. There is no need for them to wait in the waiting area. If they do have to wait, they usually prefer to shop around the pharmacy rather than sit in the waiting area. Frankly, that's something that pharmacists prefer them to do as well. I would like to see some clarity defined around "the notice must be posted in a place conspicuous and readable to a consumer from any place in the pharmacy where a prescription may be dropped off and or picked up including drive-thrus."

Finally, just for the sake of conciseness and clarity and having an impact, the part of the regulation requiring the right to interpreter services, I would ask the board the board to consider not having that added to the notice as it is already cluttered with a lot of information.

In closing, and this may be beyond the scope of the regulation, I would like the board to consider some kind of requirement for mail order prescriptions. If we think that there is information that is so important for consumers to know and to require that it be posted in thousands of pharmacies across the state, it seems to me that it would make sense that we should also make sure that information is also provided to consumers who receive a prescription via mail. So, that's something I would like the board to consider if not now, at a future meeting.

Mr. Brooks: Do you know how many prescriptions are sent by mail?

Dr. Negrete: As far as the percentage of overall prescriptions, I do not. But, I know it's an increasing percentage. I can do some research.

Thank you for taking the time to let me provide these comments. I look forward to working with the board to provide a notice that will have some public benefit to the consumers of California.

Paige Talley, California Pharmacists Association (CPhA)

I am Paige Talley with the California Pharmacists Association. We have one major concern. You took out the right of conscience and we would like that placed back in. There are certain circumstances under which a pharmacist can decline to fill a prescription. That is in the current poster language; it's not in this one. We think it's important to have that there. We echo a lot of what Michael (Negrete) said.

Ms. Veale: Paige, do you have any proposed language you can provide us?
Ms. Shellans: Is your proposal just to keep the current language in the poster?

Ms. Talley: We don't have a problem with the current language. It was just taken out and we would like to see it back in.

Carrie Sanders, California Pan-Ethnic Health Network (CPEHN)

My name is Carrie Sanders with the California Pan-Ethnic Health Network. First of all, we did send in comments and I really you appreciate you taking them into consideration. I want to start by thanking the board for providing notices and for amending the consumer notices to include the requirement that pharmacies have the translated notice to consumers of the right to oral interpretation. I think is very important, particularly in California where the demographic is 40 percent limited English-proficient patients.

We urge the adoption of a "20,000 threshold." The languages that you have are prevalent languages. Those languages can change depending on population changes, etc. So, having a threshold makes a list not as arbitrary as just a set number of languages. It takes into account the fact that demographics change. Just to note for example, DMHC's notice is in 12 languages. The Department of Insurance, with respect to SB 53, actually has 14 different languages. It seems like those are arbitrary lists without including a threshold to give a definition or reason behind that number.

I would just say one other comment, with respect to concerns about additional requirements. As the board knows, this is not an added responsibility to provide oral interpretation. We agree with the board that this was set forth in prior regulation as well as the original intent of the law. Under Title 6 of the Office of Civil Rights, all Californians have the right to oral interpretation of information, particularly consumer information in order to protect against discrimination and other adverse health consequences.

Mr. Room: The board has been advised by counsel that using a threshold would lack clarity for purposes of our regulatory process. It says in your letter that using your 20,000 threshold, an additional five languages would be added. Which of those are the additional two that takes the Department of Insurance from 12 to 14? I guess the larger question is which languages do you feel would be the minimum to add to the board's

current list of languages? I think counsel has advised the board that it might be better for clarity purposes to list the languages as opposed to setting a threshold because that's difficult for the pharmacists to know what it means. I understand your point that it will be shifting; but, the board has chosen to say that we will amend the list if we need to. So, if you could supply what languages you think are necessary that would be more helpful.

Ms. Sanders: It's sort of a complicated answer. We are talking about languages that are prevalent and people believe that (if) 20,000 people in the state speak that language that they should have a notice in that language. I wouldn't necessarily be able to say this one versus that one.

Mr. Room: So you would say all five that are listed in your comments.
Ms. Sanders: That's what we would argue. Regardless, having that threshold whether you use 20,000 or a different threshold is a way to show the measurement of how you come up with that list and to take the other changes into account.

Mary Staples, National Association of Chain Drug Stores (NACDS)

I am Mary Staples with the National Association of Chain Drug Stores, representing 28 companies that operate 3,400 pharmacies throughout the state of California. I am here today on behalf of my members to urge you to adopt as proposed this rule. I know you have all worked hard on this for quite some time, a couple of years. We have tried to provide constructive input throughout the process. It's been a compromise; but, I think we are in a good place to move forward. We would hate to see this rule delayed any further as it will take the board some time to design and to translate this information into posters and to provide those to pharmacies. What we have hanging up on pharmacy walls right now is inadequate. I think this is a positive step forward and we would like to see it happen sooner rather than further delayed. Thank you very much.

Steve Gray, Kaiser Permanente

Steve Gray, representing Kaiser Permanente. First of all, I note that there is a surprising lack of attendance. I thought there would be more people here given this important subject. So, therefore I feel obligated to take up the rest of the time. We also echo the sentiments in general that were expressed by the representative from NACDS. We complement the board for going forward with this in general and to move forward to get a better notice going and so forth. We do have a couple of suggestions that either need clarification or you need to modify some of the language in the regulation.

The first one we want to complement on is the ability for the alternatives and the flexibility that are represented in 1707.6 where you talk about as an alternative to the printed notice the pharmacy may also display the notice. Above that, you already adopted language that says that the executive officer can be delegated the authority to

approve alternatives to the language and so forth. But, it's not clear. I hope that you would just change perhaps the sequence of the language. I would like for it to say that the executive officer also has the authority to approve alternatives to such things as the size of the screen, the 60 seconds, etc. If you are going to adopt alternative language and graphics and so forth, and then still try to fit it in a 24 inch screen, measured diagonally, and it has to rotate every 60 seconds, this really limits the flexibility. I realize that there needs to be a minimum, and I think that's covered in the language of the posted notice; but, I think the flexibility also needs to be to the technical aspects of the display screens as well as to the wording, or sequence, or formats, etc. It may just be moving the language around a little bit to give the executive officer that. And then going forward, I understand that as the industry develops these alternatives, rather than putting a heavy burden on the board and the executive officer of many different applications, then we can get more specific or allow certain things to be automatically approved and continue the innovation. The goal here is truly communication. It's not just to have a poster up.

One of the things that we have been dealing with, and I think its just because some of the people we deal with are pharmacists who are over precise, there are close door pharmacies and there are hospital pharmacies that are not even labeled on the outside that they are a pharmacy, and yet inspectors come in to those pharmacies and say "where is your poster." This makes no sense to us that a poster or a notice that is intended for public viewing has to be posted inside the four walls of a hospital or a closed door pharmacy which the public never enters. We see these on our inspection reports and so forth. So, that might just be a clarification of board policy. Or, what you might want to do is add some words that say "shall be posted if the pharmacy is in fact open to the public." Something to clarify for the ever-increasing number of inspectors, which is not a bad thing.

The second thing I would like to call your attention to is the language that talks about quote "this pharmacy must provide any medicine or device legally prescribed to you." We also support what CPhA said in terms of getting language back in that is more explicit about the right of conscience. We think that if it's up there in a board approved language, it will avoid a lot of controversy and a lot of very unfortunate and perhaps very confrontational situations if the public can be made aware. We think these are very rare instances; but, they tend to be very emotional when they do occur. So the right of conscience needs to be more explicit.

Ms. Shellans: Do you have any specific recommendations?

Dr. Gray: The current language is better than no language at all. We could always do better. I think what CPhA reported is that it just needs to be something that you can point to and say I as a pharmacist have met the requirements of the right of conscience.

The other thing we are concerned about, and this is fairly unusual. The last part says "if a medicine or device is not immediately available, the pharmacy will work with you to help you get your medicine or device in a timely manner." If you take that with 1702, the

duty to consult, we have a situation which we have adopted in which there are certain medications where we will not accept a refusal to consult. The medication is so dangerous that we will not dispense the medication if the patient or the patient's representative tries to walk away without taking the time to listen to the pharmacist's guidance. We would have the medication in stock and we would say we are not going to fill this prescription if you insist on walking away or you refuse to stay for consult. They will get the medication somewhere else and submit a claim even though its covered under their Kaiser drug benefit.

Mr. Brooks: Can you explain how that procedure works?

Dr. Gray: It's exactly as simple as I said. I would come out to a patient and say that "this medication is (to make) your blood thinner. We want to talk to you about it since this medication is so dangerous. We want to go over it with you. Your responsibility as a patient is to let us know about your diet changes and your exercise changes." If the patient says "I know all that" and tries to walk away we will not dispense that medication. Methotrexate is a drug that is very dangerous. If it is used wrong, it will kill the patient. If it is used at the right schedule it is beneficial for what it was prescribed. There is a growing number of drugs which we say we are not going to dispense if we can't get the cooperation from the patient on the duty to consult. They have the right to get that prescription and to get it covered by the health plan. We will pay for it, even at a much higher cost, if they refuse and go somewhere else. We just want either in the duty or somewhere in the language, or again, by recognition by the board in the policy that there is going to be some times when we are going to have the drug in stock but we are going to refuse to dispense it if the patient does not cooperate with the duty to consult.

Dr. Castellblanch: I have always let the Kaiser pharm tech bully me and tell me "you can't have this until you go talk to that person." And now it has crossed my mind, is that legal? I don't know what counsel has on that. Is that a basis to refuse to dispense?

Mr. Room: Yes, definitely. I think the board is confused as to how this is a problem that relates to the notice language that you identified previously. Are you saying that somehow you might be perceived to be violating the right for that patient to have a drug be immediately available to them and somehow that can cause friction between the patient and the Kaiser pharmacist by virtue of the notice language?

Dr. Gray: The language talks about the pharmacist has a duty to provide consultation. It also talks about the patient has the right to refuse consultation. And further down in 1706, it talks about "the pharmacy must provide any medicine or device legally prescribed to you, unless: it is not covered by your insurance, you are unable to pay the cost of a copayment; or the pharmacist determines doing so would be against the law or potentially harmful to you. If the medication is not immediately available, …" If we can pull back somewhere in that first sentence, where we say "without consultation it might be harmful" or something like that, you may not need to change the language. I wanted to make the board aware that we take this so seriously with some medications that we

will refuse to dispense even though its immediately available if the patient does not cooperate with the consultation.

Lastly, I would just like to comment on the previous testimony. I know that we spent hours talking about this issue of the languages that would be listed as the minimum quantity. I would like to revisit that the conclusion I think the board came to, that the pharmacy needs to know specifically how they can comply. Leaving it to pharmacies to figure out some type of threshold in their community or in the state, when state agencies cannot agree on a threshold or what languages, is unacceptable. There is a 150+ languages spoken in this state that we know of. Obviously, pharmacies always have the ability to add languages to their notice. The board took care of that by saying "in at least the following languages." We support that language for those reasons as it is proposed. Thank you.

Additional Comments

Carolyn Klein, Legislation and Regulation Manager for the Board of Pharmacy, read the following written comment received via email from the California Commission on Aging (CCoA) into the record. The comments were signed by CCoA Chair Harvard L. Staggs.

> Following are comments from the California Commission on Aging (CCoA) regarding the Board of Pharmacy's (CBoP) proposed regulatory change for Title 16 Sec. 1707.6.
>
> Posting requirements
>
> The CCoA has concerns regarding provisions authorizing the posting of consumer notification on video. The 60 second display requirements may be inadequate for an individual with limited reading skills or poor eyesight.
>
> The CCoA would ask the board to require that, even when video notification is available, a printed hard copy must be simultaneously posted in an easily visible and unobstructed location.
>
> Notice to consumers
>
> The CCoA believes the proposed CBoP notification could be confusing to persons not familiar with font sizes. We would recommend that written notification posted at pharmacies actually be printed in the referenced font sizes for greater clarification, as follows:
>
> "You have the right to ask for and receive from any pharmacy prescription drug labels printed in:
>
> 12 point font or 14 point font."

Paige Talley, California Pharmacists Association (CPhA)

Closed door pharmacies should be exempted from this because they don't have outpatient traffic. They should not be cited for not having the poster when the community doesn't come in.

The hearing concluded at 10:47 a.m.

XIV. DISCUSSION AND POSSIBLE ACTION TO MAKE CHANGES IN RESPONSE TO COMMENTS OR TO ADOPT OR AMEND PROPOSED TEXT AT 16 CCR SECTIONS 1707.6 AND 1707.2 REGARDING CONSUMER NOTICES AND DUTY TO CONSULT—CONSUMER NOTICE FOR LANGUAGE ASSISTANCE INTERPRETIVE SERVICES PROVIDED IN PHARMACIES AND THE ABILITY TO REQUEST 12 POINT FONT ON PRESCRIPTION DRUG CONTAINER LABELS

Discussion

Ms. Shellans provided that any change to the proposed language would result in a 15-day comment period. She stated that any substantial change not related to the rulemaking would require a 45-day comment period.

Mr. Room provided that, with exception to the suggested requirements for mail order prescriptions, he does not believe that any of the suggested changes received during the comment period would require a 45-day comment period.

Mr. Lippe asked whether there are any suggestions that would be difficult to implement.

Mr. Room discussed that incorporating a threshold for notice languages may cause problems for adoption of the regulation.

Ms. Shellans clarified that the regulation may be rejected for clarity purposes if a threshold is included. She stated that the board has discussed this issue and voted to list the 12 required languages.

The board discussed topics of concern raised during the written and oral comments that were received during the 45-day comment period and the regulation hearing. Comments were summarized on a proposed text handout provided in the meeting materials.

Topic: Ethical, Moral or Religious Objection
Ms. Veale discussed that the board has received many comments regarding the removal of the language regarding a pharmacist's right to decline to fill a prescription for ethical, moral or religious reasons. She expressed concern regarding the removal of this language.

Mr. Room read the following text as proposed:

> This pharmacy must provide any medicine or device legally prescribed for you, unless: it is not covered by your insurance; you are unable to pay the cost of a copayment; or the pharmacist determines doing so would be against the law or potentially harmful to health. If a medicine or device is not immediately available, the pharmacy will work with you to help you get your medicine or device in a timely manner.

Ms. Wheat discussed that the original language was modified to this proposed text to help eliminate verbiage to increase readability. She stated that the board discussed that as the notice is directed to the consumer, consumers are more concerned with their rights rather than the rights of the pharmacist. Ms. Wheat recommended that the board maintain the proposed language as written.

Board Member Ramón Castellblanch discussed that the small font used on the current posters is difficult to read. He recommended that the posters be redesigned with a larger font and focus on the rights of the consumer.

The board further discussed a pharmacist's right of conscience pursuant to Business and Professions Code section 733 as well as situations where a pharmacy is unable to dispense because the drug or device is not in stock. Discussion focused on whether or not this information should be included in the notice and how including it would increase the length of the notice and possibly impact the overall readability of the notice. It was suggested that pharmacies can post their own notice indicating reasons why service may be refused.

Ms. Herold discussed that informing consumers of why a pharmacy can decline to fill a prescription helps to avoid confrontations that can disrupt the marketplace and patient care.

MOTION: Amend the proposed language for § 1707.6 (b) to read:

> If a medicine or device is not immediately available or if an individual pharmacist objects to providing that drug to you on ethical, moral or religious grounds, the pharmacy will work with you to help you get your medicine or device in a timely manner.

M/S: Veale/Lippe

Support: 3 Oppose: 6 Abstain: 0

Topic: Notice Posted in Closed-Door Pharmacies
Mr. Room discussed that the board received comments regarding the requirement that the notices be posted in pharmacies with limited retail prescription services or "closed-door pharmacies." He stated that every pharmacy is required to post the notices pursuant to Business and Professions Code section 4122.

Mr. Zee left the meeting room at 11:15 a.m.

Ms. Wheat recommended that the proposed language remain as is. She discussed that the board's inspectors can use enforcement discretion for this requirement.

The board took no action on this item.
Topic: Consumer Right to Consultation
Mr. Room provided that Dr. Negrete has suggested that the notice include a statement clearly notifying consumers that pharmacists are required to provide them with a consultation on all new prescriptions.

The board discussed that pharmacies develop their own process for how a consultation is initiated. The board evaluated whether the notice should include info regarding the consultation requirement for every new prescription.

Mr. Lippe shared a personal experience in which a pharmacist checked off the consultation box on his behalf because he indicated that he did not have any questions on his prescription. He stated that consumers will not know that they are entitled to a consultation if this right is not included on the notice.

Mr. Room stated that the average consumer may not know if they have received an adequate consultation.

Dr. Kajioka discussed that the board and pharmacy associations should provide better outreach to consumers regarding the information that they should know about their prescriptions.

Mr. Room discussed that the current notice lists several questions that consumers should have answered regarding their prescriptions. He stated that the board needs to determine whether the notice should also include a statement indicating that consultation is required for every new prescription.

Mr. Lippe offered a proposal to include the following statement in the notice regarding a patient's right to consultation for every new prescription:

> California law requires a pharmacist to speak with you every time you get a new prescription.

Ms. Herold discussed the there will need to be some artistic flexibility to alter the order of the information when designing the notice. She provided comment in support of adding this language.

Mr. Zee returned to the meeting room at 11:26 a.m.

Public Comment
Dr. Negrete provided that including this information in the notice will help to stimulate an interaction with the pharmacist and ensure that consumers know that consultation is a requirement and not just a right.

Ms. Veale suggested that alternate language be proposed to replace "California law requires."

Mr. Lippe maintained his proposal as proposed.

MOTION: Amend the proposed language for § 1707.6(b) to include:

> California law requires a pharmacist to speak with you every time you get a new prescription.

M/S: Lippe/Badlani

Support: 6 Oppose: 3 Abstain: 0

Topic: Evaluation of the Language as Proposed
Mr. Room discussed that Dr. Negrete has suggested that the proposed text be evaluated to explore issues including health literacy and the relative importance of various messages to help determine the order and size of each statement on the notice.

Ms. Herold provided that artistic flexibility will allow the board to modify the presentation of the language. She clarified that the actual verbiage cannot be altered.

Public Comment
Dr. Negrete discussed that concern has been expressed regarding the wordiness of the proposed language regarding the information a consumer should know about their prescription. He suggested that a provision be included to allow for the approval of similar language to be approved by the board. Dr. Negrete stated that such a provision will allow time for the language to be evaluated and for new language to be proposed.

The board took no action on this item.

Topic: § 1707.6 (c) – Interpreter Services

Mr. Room reviewed that the board received a comment from Mike Podgurski suggesting that the words “or similar” be added in subdivision (c) as the brochure that he is currently using regarding the availability of interpreter services does not use the same language as required by the proposed text.

The board took no action on this item.

Topic: § 1707.6 (c) – Languages

Mr. Room provided that the board has received several comments suggesting that the board use a threshold for when a pharmacy must provide notices in additional languages rather than specifying the 12 languages in the proposed text.

Dr. Castellblanch discussed that counsel has advised the board that for clarity purposes, the languages should be specified within the regulation. He stated that languages can be added to this list as needed.

The board took no action on this item.

Topic: § 1707.6 (c) – Drive-thru Pharmacies

Ms. Shellans provided that Dr. Negrete has suggested that § 1707.6 be amended to address the visibility of the notice at drive-thru pharmacies.

Mr. Room provided that Dr. Negrete has suggested that the notice be required to be posted anywhere in the pharmacy a drug may be picked up or dropped off.

Dr. Castellblanch provided comment in support of this suggestion. He discussed that drive-thru pharmacies are very common and warrant the attention of the board.

The board took no action on this item.

Topic: §1707.6 (a) – Notice Alternatives

Ms. Shellans provided that Dr. Gray suggested that flexibility be added to the proposed text to allow for alternatives with respect to the display and other requirements for a video image notice.

Mr. Brooks offered a proposal to delegate authority to the executive officer or a committee of the board to approve alternative formats or display methodology for video image notices.

The board discussed this proposal. It was clarified that the specific requirements regarding the video screen size and the display times as specified in the proposed text are the standard minimum that must be used unless an alternative format is approved.

Dr. Castellblanch discussed that the California Commission on Aging (CCoA) has expressed that a 60 second display requirement may be inadequate for individuals with limited reading skills or poor eyesight. He advised that the board should be cognizant that any changes to this requirement should not be below the 60 second minimum.

Mr. Room clarified that only individual exemptions would be granted on a case by case basis.

MOTION: Amend § 1707.6 (a) to include the following language at the end of the subdivision:

> The pharmacy may seek approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.

M/S: Brooks/Lippe

Support: 6 Oppose: 0 Abstain: 3

Topic: Requirements for Mail Order Pharmacies
Ms. Shellans advised that Dr. Negrete's suggestion to develop requirements for mail order pharmacies is beyond the scope of the regulation and would require an additional 45-day comment period.

The board took no action on this item.

Topic: 60 Second Display for Video Image Notices
Ms. Shellans provided that the CCoA expressed concern regarding the adequacy of the 60 second notice display for video image notices.

Mr. Brooks provided that the board's previous motion to grant flexibility in this area addresses this concern.

The board took no action on this item

Topic: Referenced Font Sizes
Ms. Shellans provided that the CCoA recommended that the notice actually be printed in the referenced font sizes for greater clarification.

Dr. Castellblanch asked how difficult it would be to provide an example of 10-point and 12-point fonts on the notice.

Mr. Room provided that the font size on the notice will most likely be larger than a 10-point or 12-point font. He advised that the board has discussed the option of leaving a blank space on the notice for each pharmacy to post example labels in each font size.

Dr. Castellblanch stated that the phrase "12-point font" is obscure and should be clarified to consumers.

Mr. Room discussed that the board has evaluated other terms and determined that this phrase is the most appropriate for use on the notice.

The board took no action on this item.

Topic: Written and Video Notice Required
Ms. Shellans provided that the CCoA has also suggested that even when video notification is available, a printed hard copy must also be posted.

The board took no action on this item.

Topic: Refusal of Patient Consultation
Ms. Shellans provided that Dr. Gray expressed concern that the notice did not adequately explain a pharmacy's ability to refuse to dispense a prescription if a patient refuses consultation.

Ms. Shellans indicated that Mr. Room has advised that he believes this issue is covered under § 1707.6 (b) where it reads that a pharmacist can decline to dispense a medicine or device if "the pharmacist determines doing so would be against the law or potentially harmful to health."

The board took no action on this item.

Approval of Modified Text
The board discussed the timeline for the rulemaking process for the modified text. It was clarified that the board's committees can move forward with the designing of the notice and the video notice during this time.

A proposal to approve the proposed text as modified was accepted.

No public comment was provided.

MOTION: Direct staff to take all steps necessary to complete the rulemaking process, authorize the executive officer to make any non-substantive changes, and authorize staff to send out a 15-day modified text notice that includes the changes discussed at the July 27, 2011 meeting. If no adverse comments are received, authorize the

executive officer to adopt the regulations in Sections 1707.2 and 1707.6 as noticed in the modified text notice.

M/S: Castellblanch/Wheat

Support: 8 Oppose: 0 Abstain: 1

Modified Text

Title 16. Board of Pharmacy
Proposed Language

To Amend §1707.2 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1707.2. ~~Notice to Consumers and~~ Duty to Consult.

(a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all care settings:

(1) upon request; or

(2) whenever the pharmacist deems it warranted in the exercise of his or her professional judgment.

(b)(1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in which the patient or agent is present:

(A) whenever the prescription drug has not previously been dispensed to a patient; or

(B) whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength or with the same written directions, is dispensed by the pharmacy.

(2) When the patient or agent is not present (including but not limited to a prescription drug that was shipped by mail) a pharmacy shall ensure that the patient receives written notice:

(A) of his or her right to request consultation; and

(B) a telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record.

(3) A pharmacist is not required by this subsection to provide oral consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the patient's discharge. A pharmacist is not obligated to consult about discharge medications if a health facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code Section 1250 has implemented a written policy about discharge medications which meets the requirements of Business and Professions Code Section 4074.

(c) When oral consultation is provided, it shall include at least the following:

(1) directions for use and storage and the importance of compliance with directions; and

(2) precautions and relevant warnings, including common severe side or adverse effects or interactions that may be encountered.

(d) Whenever a pharmacist deems it warranted in the exercise of his or her professional judgment, oral consultation shall also include:

(1) the name and description of the medication;

(2) the route of administration, dosage form, dosage, and duration of drug therapy;

(3) any special directions for use and storage;

(4) precautions for preparation and administration by the patient, including techniques for self-monitoring drug therapy;

(5) prescription refill information;

(6) therapeutic contraindications, avoidance of common severe side or adverse effects or known interactions, including serious potential interactions with known nonprescription medications and therapeutic contraindications and the action required if such side or adverse effects or interactions or therapeutic contraindications are present or occur;

(7) action to be taken in the event of a missed dose.

(e) Notwithstanding the requirements set forth in subsection (a) and (b), a pharmacist is not required to provide oral consultation when a patient or the patient's agent refuses such consultation.

~~(f) In every pharmacy subject to the provisions of Business and Professions Code Section 4122, there shall be prominently posted in a place conspicuous to and readable by prescription drug consumers the following notice:~~

~~"NOTICE TO CONSUMERS"~~

~~At your request, this pharmacy will provide its current retail price of any prescription without obligation. You may request price information in person or by telephone.~~

~~Ask your pharmacist if a lower-cost generic drug is available to fill your prescription.~~

~~Prescription prices for the same drug vary from pharmacy to pharmacy. One reason for differences in price is differences in services provided.~~

~~Before taking any prescription medicine, talk to your pharmacist; be sure you know:~~

~~What is the name of the medicine and what does it do?~~

~~How and when do I take it - and for how long? What if I miss a dose?~~

~~What are the possible side effects and what should I do if they occur?~~

~~Will the new medicine work safely with other medicines and herbal supplements I am taking?~~

~~What foods, drinks or activities should I avoid while taking this medicine?~~

~~Ask your pharmacist if you have additional questions.~~

~~(g) In addition to the "NOTICE TO CONSUMERS" referred to in subdivision (f), every pharmacy subject to the provisions of Business and Professions Code §4122 shall prominently post in a place conspicuous to and readable by prescription drug consumers the following notice:~~

~~Know your rights under California law concerning medicine and devices prescribed to you.~~

~~You have the right to receive medicine and devices legally prescribed to you, unless:~~

~~1. The medicine or device is not in stock in the pharmacy,~~

~~2. The pharmacist, based upon his or her professional judgment determines providing the item:~~

~~• is against the law,~~

~~• could cause harmful drug interaction, or~~

~~• could have a harmful effect on your health~~

~~This pharmacist may decline to fill your prescription for ethical, moral or religious reasons, but the pharmacy is required to help you get the prescription filled at this or another nearby pharmacy timely.~~

~~The pharmacy may decline to provide the medicine or device if it is not covered by your insurance or if you are unable to pay for the item or any copayment you owe.~~

~~If the pharmacy is unable to fill your prescription, you are entitled to have the prescription returned to you or transferred to another nearby pharmacy. Ask about our procedure to help you get an item that we don't have in stock.~~

~~Any questions? Ask the pharmacist!~~

Note: Authority cited: Sections 4005, 4076 and 4122, Business and Professions Code. Reference: Sections ~~733,~~ 4005, 4076 and 4122, Business and Professions Code and Section 1707.5 of Division 17 Title 16 of the California Code of Regulations.

To Add § 1707.6. to Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1707.6. Notice to Consumers.

(a) In every pharmacy there shall be prominently posted, in a place conspicuous to and readable by a prescription drug consumer, a notice containing the text in subdivision (b). Each pharmacy shall use the standardized poster-sized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval. As an alternative to a printed notice, the pharmacy may also or instead display the notice on a video screen located in a place conspicuous to and readable by prescription drug consumers, so long as: (1) The video screen is at least 24 inches, measured diagonally; (2) The pharmacy utilizes the video image notice provided by the board; (3) The text of the notice remains on the screen for a minimum of 60 seconds; and (4) No more than five minutes elapses between displays of any notice on the screen, as measured between the time that a one-screen notice or the final screen of a multi-screen notice ceases to display and the time that the first or

The pharmacy may seek approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.

(b) The notice shall contain the following text:

NOTICE TO CONSUMERS

California law requires a pharmacist to speak with you every time you get a new prescription.

You have the right to ask for and receive from any pharmacy prescription drug labels in 12-point font.

Interpreter services are available to you upon request at no cost.

Before taking your medicine, be sure you know: the name of the medicine and what it does; how and when to take it, for how long, and what to do if you miss a dose; possible side effects and what you should do if they occur; whether the new medicine will work safely with other medicines or supplements; and what foods, drinks, or activities should be avoided while taking the medicine. Ask the pharmacist if you have any questions.

This pharmacy must provide any medicine or device legally prescribed for you, unless: it is not covered by your insurance; you are unable to pay the cost of a copayment; or the pharmacist determines doing so would be against the law or potentially harmful to health. If a medicine or device is not immediately available**,** the pharmacy will work with you to help you get your medicine or device in a timely manner.

You may ask this pharmacy for information on drug pricing and use of generic drugs.

(c) Every pharmacy, in a place conspicuous to and readable by a prescription drug consumer, at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, shall post or provide a notice containing the following text:

Point to your language. Interpreter services will be provided to you upon request at no cost.

This text shall be repeated in at least the following languages: Arabic, Armenian, Cambodian, Cantonese, Farsi, Hmong, Korean, Mandarin, Russian, Spanish, Tagalog, and Vietnamese.

Each pharmacy shall use the standardized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.

The pharmacy may post this notice in paper form or on a video screen if the posted notice or video screen is positioned so that a consumer can easily point to and touch the statement identifying the language in which he or she requests assistance. Otherwise, the notice shall be made available on a flyer or handout clearly visible from and kept within easy reach of each counter in the pharmacy where

or handout shall be at least 8 1/2 inches by 11 inches.

Note: Authority cited: Sections 4005 and 4122, Business and Professions Code. Reference: Sections 733, 4005, 4076.5 and 4122, Business and Professions Code, and Section 1707.5 of Division 17 of Title 16 of the California Code of Regulations.

XV. ORGANIZATIONAL DEVELOPMENT COMMITTEE REPORT

There was no meeting of the Organizational Development Committee this quarter.

a. Budget Update/Report

1. Budget Report for 2010/11

President Weisser referenced the budget reports provided in the meeting materials and highlighted the following figures:

Expenditures (as of June 2011):	$10,622,285
Maximum spending authority for year:	$12,800,000
Revenue Collected (as of June 2011):	$12,328,678

President Weisser noted that the board's travel expenditure accounted for less that one percent of the board's expenditures.

President Weisser provided that the budget has been approved and includes a $14.4M spending authorization for the board. He advised that a more detailed budget will be provided during the next meeting.

Mr. Brooks left the meeting room at 12:04 p.m.

There was no board discussion or public comment.

2. Fund Condition Report

President Weisser reviewed the following fund condition figures prepared by the department:

2009/10	$12,411,000	13.9 months in reserve (actual)
2010/11	$13,791,000	11.6 months in reserve
2011/12	$11,407,000	9.5 months in reserve
2012/13	$9,843,000	8 months in reserve

Mr. Brooks returned to the meeting room at 12:06 p.m.

Discussion
The board discussed its current funds. The board was advised that the fund does not include penalties that will be recovered or collected during the year. It was further clarified that the board can pursue a fee increase in the future if necessary.

No public comment was provided.

3. Update on BreEZe, DCA's Plans for a New Computer System

Report
President Weisser provided that nearly two years ago, DCA's proposed Consumer Protection Enforcement Initiative also sought computer system upgrades with a new proposal for a department-wide computer system called BreEZe. He stated that once in place the new system would allow for online renewal and application processing, and will also replace the board's Consumer Affairs Systems and the Applicant Tracking System. President Weisser explained that BreEZe will piggyback on the efforts of the initial I-Licensing system and will ultimately allow for improved services for applicants and licensees as well as provide for a more robust internal computer system.

President Weisser provided that the board will be in the second phase of programs transitioning to the new system. He advised that as such, the board is about 2 years away from changing to this new system.

Discussion
Ms. Herold discussed that the board has committed a significant amount of resources to this project to ensure the board's operational needs are met. She advised that additional staff will be redirected to this effort to ensure the necessary transition plans and data clean-up are in place to mitigate problems during the transition. Ms. Herold stated that this major commitment of board resources to BreEZe is justified by the board's need for the system.

No public comment was provided.

4. Reimbursement to Board Members

President Weisser referenced the expenses and per diem payments to board members provided in the meeting materials.

There was no board discussion or public comment on this item.

b. Recognition Program of Pharmacists Who Have Been Licensed 50 Years

President Weisser provided that since July 2005, the board has acknowledged 1,091 pharmacists with 50 or more years of licensure as pharmacists in California. He stated that there were 4 pharmacists who reached this milestone between May and July 2011. President Weisser indicated that when a pharmacist reaches this milestone, the board sends a certificate and an invitation to attend a future board meeting for public recognition.

There was no board discussion or public comment on this item.

Mr. Zee left the meeting room at 12:10 p.m.

c. Personnel Update

1. Board Member Vacancies

President Weisser provided that currently, the board has 10 board members, and three board member vacancies. He indicated that the vacant positions are Governor appointments and are for professional members.

2. Staff Changes

Ms. Herold commended Ms. Sodergren for her work to secure 12 freeze exemptions to hire additional investigative staff. She indicated that the board is currently recruiting for four investigator positions. Ms. Herold discussed that adequate staff is needed to provide public protection and to provide the service that the board's licensees deserve with respect to issuance of permits and responding to inquiries.

The board currently has a total of 22 vacant positions. The breakdown is as follows:

13 - Supervising inspector and inspector positions

4 - Associate analysts responsible for the following duties:
- Criminal Conviction Investigations
- Legislation and Probation Monitoring
- Public Outreach and HIPDB reporting
- Enforcement
- Responding to requests for public information and subpoenas

1 - Staff analyst who performs application investigations & fingerprint reviews

3 - Office technicians responsible for the following duties:
- Processing pharmacy technician applications (One of two approved positions will be filled August 1, 2011)

- Processing change of pharmacist-in-charge and designated representative-in-charge applications as well as discontinuance of business notices.

1 - Office assistant providing clerical support

There was no board discussion or public comment on this item.

d. Discussion and Possible Action Regarding the Future Sunset Review of the Board of Pharmacy by the California Legislature

Ms. Herold reviewed the following Sunset Review process and referenced the questionnaire provided in the meeting materials.

- Fall 2011: submission of the sunset report to the Legislature
- Fall to spring: legislative assessment of the board's performance, both in writing and during legislative hearings
- Ideally during the 2012 legislative year, a bill is introduced extending the board's sunset date and recommending specific modifications to the board's legislative provisions

Mr. Zee returned to the meeting room at 12:12 p.m.

Ms. Herold provided that this report is due November 1, 2011. She indicated that the report will be discussed during the October 2011 Board Meeting.

There was no board discussion or public comment on this item.

e. Future Evaluation of the Board's Executive Officer

Ms. Herold provided that the board will review the executive officer's performance in the near future. She stated that President Weisser is currently reviewing survey documents to be used for this review.

There was no board discussion or public comment provided.

f. Sunset Review of the Board of Pharmacy

The board discussed the Sunset Review during a previous agenda item. There was no additional discussion or public comment on this item.

g. Fourth Quarterly Report on the Committee's Goals for 2010/11

President Weisser referenced the fourth quarterly report on the Organizational Development Committee's goals provided in the meeting materials.

Ms. Herold reported that the board has saved $20,000 by eliminating paper board packets and switching to electronic copies.

No public comment was provided.

The board recessed for a break at 12:15 p.m.

The board reconvened at 1:05 p.m.

XVI. STRATEGIC PLAN WORKSHOP FOR THE BOARD OF PHARMACY

Background
The Board of Pharmacy's Strategic Plan is being revised and updated into a plan for the next five years.

This review process began in March 2011, when all board staff participated in an assessment of the board's strengths, weaknesses, opportunities and threats, and a review of the current plan's strategic issues to be addressed.

In June 2011, the Organizational Development Committee, comprised of Board President Weisser and Vice President Kajioka, selected a facilitator to lead the board in the update of the plan. A meeting was held with the selected consultant early in July, and plans finalized for the process and outcomes that will be pursued during the strategic planning session at this July board meeting.

Also in July 2011, the board used its subscriber alert system to solicit comments from stakeholders via a short survey that was available for 10 days. The board received 116 responses, two were from consumers, the others were from individuals who identified themselves as licensees.

Workshop
The board convened a strategic plan workshop, led by consultant Daniel Locafano of MIG. Results of the workshop are attached, following this meeting summary.

XVII. PUBLIC COMMENT FOR ITEMS NOT ON THE AGENDA/AGENDA ITEMS FOR FUTURE MEETINGS

No public comment was provided.

XVIII. CLOSED SESSION

This scheduled closed session was not needed.

The meeting was adjourned at 5:25 p.m.

NABP Update

Josh Bolin, Government Affairs Director
Scotti Russell, Government Affairs Manager

PARE

- “Pharmacist Assessment and Remediation Evaluation”
- The purpose of the PARE is to provide a multidimensional assessment that the boards of pharmacy may use as a contributory factor when making decisions regarding pharmacist practice deficiencies that result from disregarding pharmacy practice standards, non-compliance with laws and regulations, and/or threats to patient safety.

PARE (cont.)

- Designed to assess non-entry level competence
- Some possible uses for PARE
  - Pharmacists who may have been out of active practice for some time, either by choice or as a result of a suspension or revocation
  - Pharmacist whose competence is in question due to practice errors or other reasons
  - Pharmacists transferring a license from another state whose competency is in question for some reason
- This tool will continue to evolve depending on how boards want to use it
- Divided into 3 separate and distinct content areas

PARE (cont.) 3 content domains

1. The Practice of Pharmacy and Medication Safety (50%)
   - Safe and effective preparation and dispensing of medications
   - Prevention of medication errors
   - Continuous quality improvement
2. Pharmacist Care (25%)
   - Patient assessment, clinical pharmacology, therapeutics
   - Drug information
   - Promotion of wellness and public health
3. Professional Ethics/Pharmacist Judgment (25%)
   - Professional ethics
   - Decision/Actions affecting patient care
   - Code of ethics, professional behavior

PARE (cont.)

- Exam to consist of 210 items
- 70 questions for each area
- $250 cost to take the test
- Time allowed to test is still being determined
- Available by 2012
- Volunteer board members needed to participate in the beta testing-beginning soon-we would welcome participation by California board members

Annual Meeting Update

- Executive Committee Elections
  - EC comprised of three officers, eight members, and a chairperson
- This year open officer and member positions: president-elect, treasurer, District 3, District 4, and District 8.
- District 4 and 8 contested
  - District 4: William J. Cover-IN and Sarah St. Angelo-IN (Cover elected)
  - District 8: Jeannine Dickerhofe-CO and Hal Wand-AZ-incumbent (Wand elected)

2011-2012 Executive Committee

William T. Winsley, Chairperson (OH)
Malcolm J. Broussard, President (LA)
Michael A. Burleson, President-Elect (KY)
Karen M. Ryle, Treasurer (MA)

District 1: James Devita (MA)
District 2: Edward McGinley (NJ)
District 3: Mark Conradi (AL)
District 4: William Cover (IN)
District 5: Lloyd Jessen (IA)
District 6: Joe Adams (LA)
District 7: Catherine Lew (OR)
District 8: Hal Wand (AZ)

5 Resolutions (full text on website)

- Full text on website
- New task force on technology, evaluate and recommend changes to the model act to support where appropriate
- New task force to recommend changes to the model act related to pharmacy/pharmacist responsibilities in the prevention, detection, and investigation of drug losses
- Encourage the exploration of new models of care for pharmacists to participate in primary health care
- Support for the development and implementation of the PMP interconnect
- Annual recognition resolution

2010-2011 Report of the Task Force to Review and Recommend Revisions to the Controlled Substances Act

- Charge:
  - Review selected provisions of the CSA and accompanying administrative regulations;
  - Identify those provisions that may require review and revision; and
  - Recommend legislative and regulatory changes to amend the CSA and accompanying administrative regulations.

Some CSA Task Force Recommendations

Full report on web site

- Definition changes to include separate definitions for “administer,” “dispense,” and “prescribe and pharmacists included in “practitioner”
- LTCF changes to include definition changes to “agent” and the inclusion of “medical record orders” in the definition of “prescription” to take care of some of the LTC issues with DEA rules and current practice
- Recommendations for changes to prescription elements and allowable changes that could be made by a pharmacist.
- Uniform time limit for validity of all CS prescriptions
- Changes to labeling requirements to allow for focus on patient centered labels
- Remove requirement for pharmacists to transfer prescriptions from database to database

Background on Government Affairs

- Directive of NABP Executive Committee
- Started activities in early 2010
- Launched officially in September 2010

Outreach and Education

- Gain understanding of board of pharmacy in each state
- Emerging pharmacy practice, legal, and regulatory issues
- Unique approaches to regulation
- Needs and challenges

Customized Level of Assistance

- Examination Programs
- Accreditation Programs
- Licensure
- Assessment
- Member Services

Assessment Services

- Operational Processes
  - Licensing
  - Discipline and Compliance
  - Policy
- NABP Programs and Services
- Training and Education
- Legislative and Regulatory Support
- Staffing Recommendation

Compliance-Related Services

- Compliance Officer Training
  - Classroom
  - Live
- Inspection Services
  - Wholesale Drug Distributors
  - Pharmacies
  - Controlled Substance Registrants

Legislative and Regulatory Support

- NABP Model Act
- Legislative/Regulation Tracking
- Written Comment
- Public Testimony

Goals for Government Affairs

- Programs and Services
- Education
- Relationship Building

Interactive Forums

- Executive Officer – September 21-22
- Compliance Officer – December 1-2
- NABP will cover travel costs for one participant from each Board

NABP Interconnect

- Since the mid 2000s, sponsored by the Bureau of Justice Assistance, PMPs and other interested parties have been working toward a solution
- Last year, some of our membership came to us and asked us to try to take their work to the next level and create a system that would facilitate data sharing from state to state

NABP Interconnect

- Does not house or store any Protected Health Information
- Enforces the unique rules of each state against the request
- Allows the states to maintain control over the systems they worked so hard to get enacted and operational

Sample Response Report

MOU/Contracting Process

- Programs will contract/enter into an agreement directly with NABP to participate in the NABP Interconnect
- Avoids multiple state-to-state contracts/memorandums of understanding (MOU)
- Allows the hub to handle the “rules reconciliation”
- NABP responsibilities vs. state responsibilities
- States agree to conduct investigations for misuse of information through the hub by their users
- Dispute resolution
- 30-day “out clause”

Cost to Participate

- NABP is absorbing **all costs** associated with the development and implementation of NABP Interconnect
- NABP will cover the costs of the annual base fee to participate in the system
- NABP will cover **annual participation fees for utilization of NABP Interconnect for five years**

Timeline for Implementation

- Development is complete
- NABP is now working with PMP software vendors to complete the relevant interface
- PMPs are beginning to configure their PMP on the PMP Interconnect Administrative Console
- PMPs will begin sharing data later this summer
- More PMPs will be brought online in Q3-Q4

MOU Updates

- 9 MOUs Executed: CT, IN, KS, MS, ND, OH, SC, VA, WV
- 4 MOUs in final review stages: AZ, LA, MI, NV
- 15+ other PMPs have expressed an intent to sign on with PMP Interconnect

Questions?