



California State Board of Pharmacy

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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 30-31, 2014

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

BOARD MEMBERS

PRESENT: Stanley C. Weisser, President
Amy Gutierrez, PharmD, Vice President
Deborah Veale, RPh, Treasurer
Greg Lippe, Public Member
Gregory Murphy, Public Member
Victor Law, RPh
Allen Schaad, RPh
Ramón Castellblanch, PhD, Public Member
Albert Wong, PharmD
Lavanza Butler, RPh
Rosalyn Hackworth, Public Member

**BOARD MEMBERS
NOT PRESENT:** Ryan Brooks, Public Member

STAFF

PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Michael Santiago, DCA Staff Counsel
Robert Ratcliff, Supervising Inspector
Carolyn Klein, SSM2
Debbie Damoth, SSM1
Laura Hendricks, Staff Analyst

Note: A webcast of this meeting can be found at:
<http://www.pharmacy.ca.gov/about/meetings.shtml>

Wednesday, July 30, 2014

Call to Order

9:02 a.m.

I. GENERAL ANNOUNCEMENTS AND OVERVIEW OF CURES REGISTRATION PROCEDURES FOR BOARD OF PHARMACY

President Weisser called the meeting to order at 9:02 a.m. He announced that CURES registration would be taking place in the lobby both days of the board meeting from 9-11 a.m.

President Weisser announced that Dr. Gutierrez is a finalist for the Next Generation Pharmacists Award – Civic Leader.

President Weisser reported that Ms. Herold has been appointed as an executive member of the National Association of Boards of Pharmacy (NABP) .pharmacy committee.

President Weisser conducted a roll call. Board members present: Gregory Lippe, Greg Murphy, Victor Law, Allen Schaad, Rosalyn Hackworth, Amy Gutierrez, Stanley Weisser, Lavanza Butler, Deborah Veale and Albert Wong. Board members absent: Ryan Brooks.

Note: Ramon Castellblanch arrived late at 12:40 p.m.

II. APPROVAL OF THE FULL BOARD MEETING MINUTES OF APRIL 23-24, 2014

Mr. Lippe noted that he is no longer the board treasurer and this needed to be corrected in the minutes for April and June.

Motion: Approve the April board meeting minutes with the corrections noted by Mr. Lippe.

M/S: Veale/Law

Support: 10 Oppose: 0 Abstain: 0

III. APPROVAL OF THE FULL BOARD MEETING MINUTES OF JUNE 26, 2014

Motion: Approve the June board meeting minutes with the corrections noted by Mr. Lippe.

M/S: Gutierrez/Lippe

Support: 9 Oppose: 0 Abstain: 1

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

No comments from the board or from the public.

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

President Weisser recognized Peter Ghorso for 50 years of service as a pharmacist.

VI. PRESENTATION BY DEBBIE BARROW, PHARMD, ON STERILE COMPOUNDING IN A SMALL HOSPITAL PHARMACY

Debbie Barrow is the Director of Pharmacy at Mariners Hospital in Tavernier, Florida. Dr. Barrow provided a presentation on how Mariners Hospital came into compliance with USP 797. During the presentation Dr. Barrow emphasized that small hospitals do not need to spend millions of dollars to come into compliance with USP 797, there are practical and relatively simple ways to ensure patients receive quality, sterile compounded medications.

The entire presentation can be viewed following these minutes. Below is a brief overview of the presentation.

USP 797

- What does it mean to me?
 - Clean facility
 - Specific training and testing
 - Knowledge of CSP (sterile compounded product) sterility and stability
 - Air quality evaluation and maintenance
- Why comply?
 - Prevent harm to my patients

How Do I Comply?

- Read the rules and regulations
- Review the CSPs you prepare
- Review where CSPs are prepared
- Determine institution risk level assessment
- Perform GAP analysis
- Action Plan
- Presentation to Administration

Don't Forget The Basics

- Labeling
- High Risk Medications
- Tall man lettering
- LASA
- Storage requirements

USP 797 Compliance Action Plan

- Expense
 - Educate Administration
 - Need for space
 - Cost of risk reduction strategies on volumes (premix, POC, outsourcing, etc)
- Space
 - Clean room vs. Isolator
 - Storage
- Staffing and Personnel Training
 - Written Plan
 - Education
 - Continuous assessment
 - Conscientious well trained staff

Summary – It is not a one-time effort

- Requires study
- Requires a plan
- Requires written SOP and P&P
- Requires written training and competencies
- Requires money
- Requires monitoring and quality assessment
- Requires homework to stay updated

The board found the presentation to be very insightful to the reality of sterile compounding in small hospitals.

Mr. Law asked how many beds there were in the hospital. Dr. Barrow responded that when she started there were 45 beds, now they are a 25-bed critical care hospital.

Mr. Law asked how many pharmacists the hospital employed. Dr. Barrow responded that when she first started they had one pharmacist and one technician, now they have enough pharmacists and technicians to cover the operation of a night pharmacy.

Dr. Schaad asked if their chemo hood is vented to the outside. Dr. Barrow confirmed and recommended finding a vendor who had experience in the area.

Dr. Gutierrez commented that it seemed like the hospital would be ready to meet the new USP 800 standards. Dr. Barrow responded that they are ready, however, for some small hospitals it could be costly to come into compliance with some of the venting requirements.

BJ Bartleson, from the California Hospital Association, thanked Dr. Barrow for her presentation and innovative ways to approach compliance.

Dr. Barrow concluded that small and big hospitals operate differently. Dr. Barrow added that when she first started she thought she would comply with USP 797 like a big hospital; however, she found that she had to get creative and think outside of the box to meet her small hospital's needs.

VII. RESULTS OF BOARD OF PHARMACY INSPECTIONS OF STERILE COMPOUNDING PHARMACIES AND IMPLEMENTATION OF SENATE BILL 294 (EMMERSON, CHAPTER 565, STATUTES OF 2013)

Ms. Herold and Supervising Inspector Dr. Ratcliff provided a presentation on the results of the sterile compounding inspections conducted between March and June 2014.

Below is a brief summary of the presentation. The entire presentation can be viewed following these minutes.

History

- Pre-1990
 - California has statutory law allows pharmacies to compound medications for prescriber office use
 - Regulations in place for “parenteral compounding”
 - Pharmacies can contract to do patient-specific parenteral compounding for another pharmacy
- Early 1990s
 - Regulations developed to define reasonable quantity that a pharmacy may compound for prescriber office use or anticipatory compounding based on prior dispensing of pharmacy

Sterile Injectable Compounding

- 2001-2013
 - May 2001: California community pharmacy compounds Betamethasone suspension due to manufacturing drug shortage, injuring 30, and killing 3
 - Board establishes specialty compounding license--with accreditation exemption alternative to licensure. Annual inspection for board licensees
 - Regulations developed, amended: All pharmacies compounding injectables must comply with requirements whether or not specially licensed

Early 2012

- Board again amends compounding regulations
- Board becomes concerned with substandard compounded products reaching California, low commitment from accrediting agencies to inspect and enforce board standards
- Drug shortages, especially of hospital medications, are a growing concern

Fall 2012

- NECC - The world changes for pharmacy, especially sterile compounding pharmacy
- Immediate inspections of large compounding facilities in CA, sometimes in conjunction with Federal Drug Administration (FDA)
- Compounding Committee reformed

2013

- Board sponsors legislation (SB 294, Emmerson)
 - Redefines sterile compounding to include inhalation, eye administration and injectable compounding
 - Eliminates accreditation as an alternative to board licensure
 - Inspections by board of California and nonresident pharmacies

More 2013 Law

- All entities shipping into California must comply with California provisions
- Recalls reported to board and MedWatch within 12 hours
- Report any discipline or accreditation issues to board

Early to Mid-2014

- Regulations for compounding and sterile compounding again under revision
- Board focuses on inspecting hospitals that will require board licenses July 1, as the accreditation exemption expires
- Board begins out-of-state inspections

Are Manufactured Medications Trouble Free?

- Pharmacies have been the focus of investigations for substandard compounded medications nationally; however, manufactured drugs are also generating serious issues regarding the quality of our medications:
 - From July 1, 2013 – March 17, 2014, the board released 273 recall notices from manufacturers or others on drugs being recalled at the pharmacy or patient level

Ms. Herold and Dr. Ratcliff reviewed the inspection results statistics, which can be viewed in the presentation following these minutes.

Ms. Herold concluded the presentation by showing pictures taken by inspectors during their visits to pharmacies. The pictures illustrated various violations of sterile compounding requirements and can be viewed in the presentation following these minutes.

Dr. Gutierrez asked if the board is prioritizing the out-of-state inspections by volume. Dr. Ratcliff responded that currently the board is prioritizing them by expiration date. When the inspectors receive their out-of-state assignments, they research the facilities to find out how large they are. Dr. Ratcliff noted that many of the inspections took over eight hours each to complete.

Mr. Law asked if the board can hire new inspectors to solely handle out-of-state inspections. Dr. Ratcliff responded that due to the sheer number of licensees, the board will need to redirect existing inspectors to help complete the inspections.

Mr. Schaad asked if when a facility received an FDA 483 they have to notify the board. Ms. Herold responded that the board looks for 483s and takes into account any prior FDA action. Mr. Schaad asked if the issuance of a 483 would prompt an inspection. Ms. Herold confirmed that depending on the findings it might.

The board recessed for a break at 10:57 a.m. and returned at 11:07 a.m.

VIII. DISCUSSION AND POSSIBLE ACTION TO INITIATE RULEMAKING TO ADOPT PROPOSED TEXT AT 16 CALIFORNIA CODE OF REGULATIONS SECTION 1735 ET SEQ, AN 1751 ET SEQ. RELATING TO PHARMACY COMPOUNDING

Dr. Gutierrez reported that after the last board meeting the board reviewed additional comments received and worked with the California Hospital Association to further modify the draft language. The language provided in the meeting materials is the latest version.

While there are some minor typos that will be addressed, Dr. Gutierrez reported that the work group focused on getting the content of the language right. Dr. Gutierrez added that when USP 800 is released it is expected that this language will be updated.

BJ Bartleson, from the California Hospital Association (CHA), thanked the board for their work on the language. She noted that there are two potential physical plant modifications that concerned the association. Dr. Bartleson reported that CHA is working on creating a grid to help their members better understand the requirements. She asked that the board continue to work with the association to further clarify the physical plant requirements.

Janette Haney, director of pharmacy at Mills Peninsula Hospital, commented that the grid that CHA is developing will help clarify the physical plant requirements and noted that during the 45-day comment period they would be submitting some minor comments.

Rita Shane, director of pharmacy services at Cedars Sinai Hospital, asked if there would be a comment period so they can address specific issues. It was confirmed there would be a 45-day comment period.

Katie Marconi, from Doctor's Hospital Manteca, thanked the board for their work on the language.

Motion: Initiate rulemaking using the language provided in the meeting materials, subject to the correction of the typos.

M/S: Gutierrez/Lippe

Support: 10 Oppose: 0 Abstain

President Weisser thanked the board, the staff and the various associations for their work on the compounding regulation language.

Dr. Gutierrez thanked Allen Schaad and Debbie Damoth for their work on the regulation.

X. LICENSING COMMITTEE REPORT

Chairperson Veale provided a report of the committee meeting held June 18, 2014.

Note: Several items from the June 18, 2014 Licensing Committee Meeting were heard during the June 26, 2014 board meeting.

Chairperson Veale noted that Greg Murphy, not Gregory Lippe, is on the Licensing Committee.

a. Discussion on Possible Development of a Policy Statement related to the Sale of Tobacco Products from Pharmacies, Pursuant to a Request from Pharmacists Planning Services, Incorporated

In February 2014, CVS announced that it would move to stop selling tobacco products from its stores in the fall. Chairperson Veale reported that at the June meeting, the committee heard a presentation from Pharmacist Planning Services Inc., on eliminating tobacco product sales from pharmacies.

Chairperson Veale noted that at the committee meeting the board's executive officer stated that the board does not have the statutory authority to restrict tobacco sales in pharmacies – such a move would require a legislative change. However, Ms. Herold noted that the board could create a policy statement regarding the adverse health effects of tobacco.

Chairperson Veale reported that the committee heard public comment in support of creating a policy statement. Steve Gray provided background on The California Pharmacist's Association's (CPhA) policy of supporting the restrictions of tobacco sales in any facility that houses a pharmacy and the American Pharmacist's Association' (APhA) policy which states that government should not allow a pharmacy that sells tobacco products to participate in government health networks (Medi-Cal, etc.). A representative of the California Society of Health System Pharmacists (CSHP) provided background into CSHP's policy supporting the elimination of tobacco sales from all California pharmacies and establishments that house a pharmacy. Chairperson Veale noted that a representative from the California Retailer's Association spoke in opposition to such a policy statement.

Dr. Gutierrez asked what would happen to a pharmacy in a large retail store or warehouse. Chairperson Veale responded that this is really a policy statement, rather than a requirement to eliminate the sale of tobacco and e-cigarettes.

President Weisser commented that while he agrees tobacco is harmful, he worries this might be a slippery slope. Tobacco and alcohol are both legal and both cause harm. He noted that he worries that different groups will come before the board to ask them to stop selling a legal product in pharmacies because it is unhealthy. Dr. Gutierrez and Mr. Lippe agreed that this could be a potential risk.

Mr. Law stated that he would like the board to take a stand as a consumer protection agency.

Dr. Wong commented that his pharmacies voluntarily stopped selling tobacco products years ago. He added that it should not be a requirement to stop selling, just a recommendation.

Ms. Butler stated that she fully supports the recommendation.

Chairperson Veale clarified that the board does not have the authority to require that pharmacies stop selling these products.

Bob Gordon, from the California LGBT Tobacco Education Partnership, stated that cigarettes are the only product that when used as directed will kill you. Dr. Gordon provided the board with a guide on tobacco-free pharmacies, noting that if the board wanted more of them he could provide them (it is not available electronically). Dr. Gordon reported that six years ago, San Francisco made the first ordinance in the United States to stop the sale of tobacco in pharmacies. The ordinance included locally owned pharmacies, as well as large chains. Dr. Gordon concluded by asking the board to support the motion.

A graduate student from Touro University student stated that the sale of tobacco products in pharmacies contradicts pharmacists' responsibility to help patients and it sends a message that tobacco is not dangerous.

Aglaia Panos, from the Marin County Pharmacists Association, reported that the tobacco sales in pharmacies have increased, in particular, the sale of e-cigarettes. She also noted the particular dangers that e-cigarettes pose to young people and the increase they have caused in nicotine poisonings.

Fred Mayer, from the Pharmacists Planning Service Inc., provided a letter to the board that contained recommendations from various Attorney Generals asking them to stop the sale of tobacco products in pharmacies. He asked the board to consider sending a similar letter to California's Attorney General.

Tim Gibbs, from the American Cancer Society, thanked the board for addressing this important issue. He reported that it is estimated that 34,000 Californian's will die each year from smoking related illnesses. Mr. Gibbs asked that the board approve the policy statement

Erin Reynoso, from the American Lung Association, thanked the board for considering the policy statement.

Jillian Hacker, from the California Society of Health System Pharmacists, offered their support for the elimination of the sale of tobacco products in pharmacies.

Joshua Brown, from the American Heart Association, noted that his association also supports the policy statement.

Mr. Law stated that while he agrees with the policy statement, since the board does not have jurisdiction he is not sure that this is the proper forum.

Dr. Gutierrez asked what will happen if the board adopts this policy statement. Ms. Herold answered that it would be announced in the newsletter and it would be reported on the board's web site. Ms. Herold added that the language for the announcement could be brought before the committees for vetting.

Committee Recommendation (Motion): Adopt a policy to recommend the elimination of tobacco and e-cigarette sales from California pharmacies.

Support: 9 Oppose: 0 Abstain: 1

Fred Mayer asked if the letter he provided could be voted on. President Weisser asked that that Public Education Committee review the letter and agendize the creation of the statement that will be put on the website for a future meeting.

b. Presentation on the Results of Continuing Education Audits of Pharmacists in California

Chairperson Veale reported that periodically, the board reviews statistics regarding the status of continuing education (CE) audits conducted on pharmacists who state under

penalty of perjury on their license renewals that they have earned 30 hours of CE as required. At the last committee meeting, Ms. Herold stated approximately 20% of those who are audited are not able to provide proof they have completed 30 hours of CE.

Ms. Hackworth asked how far back the audits go. Ms. Herold answered they are only allowed to go back four years when they conduct the audit.

Mr. Lippe stated that the board should consider making licensees fill out a form detailing all of the CE courses they completed.

Dr. Gutierrez stated that other states allow the uploading of certificates electronically.

Ms. Hackworth commented that the board should put an article in the newsletter about the CE requirements.

Chairperson Veale stated that the Licensing Committee should look at how other agencies handle reporting of CE at their next meeting.

The board asked if the BreZE system would allow CE to be uploaded. Ms. Sodergren responded that BreZE may offer some opportunities to improve the auditing process; however, until it is in place staff will not know its full functionality.

c. Discussion on Reporting of Intern Hours Earned for Interns in ACPE Accredited Schools

Chairperson Veale reported that at the June committee meeting, the committee considered staff recommendations to amend section 4209 BPC to specify that an intern pharmacist, who has graduated from an ACPE accredited school of pharmacy (on or after 1/1/16), shall be deemed to have complied with the 1,500 hours of pharmacy practice experience upon receipt of a certified transcript from the school of pharmacy which posts the PharmD degree, as well as recommended changes to 16 CCR section 1728 to incorporate the new statutory provisions. Chairperson Veale noted that existing provisions will remain for foreign-educated pharmacists who possess FPGEC certification, but need 1,500 hours of intern experience to qualify to take the CPJE.

Chairperson Veale stated that to effect these changes, the committee recommends that the board seek statutory changes to section 4209 BPC during the 2015 legislative session and to also pursue changes to the boards regulation at section 1728 of Title 16 CCR.

Chairperson Veale reported that the staff recommendations are as follows:

Staff Recommended Changes

For California pharmacist applicants who graduated after June 2016:

- (a) If not licensed in any state in the U.S.:
 - Accept a certified copy of a transcript from the ACPE-approved school of pharmacy identifying that the student has fulfilled all requirements and earned a doctor of pharmacy degree

OR

- Require a letter from the ACPE-approved school of pharmacy that the student has completed at least 1,500 hours of intern experience while completing the PharmD curriculum.
- (b) If licensed for one year in any state in the US – **no change** – accept licensure for one year as fulfilling the intern hours requirement.
- (c) If a graduate of a foreign school of pharmacy, possessing FPGE certification – **no change** – must submit intern hours on the intern hours affidavit forms. If hours earned outside California, must provide proof of licensure as an intern in that state and still require intern hours forms to total 1,500 hours. The state will not have to certify the forms nor collect the hours to transfer to California.

Chairperson Veale noted that the committee was leaning towards accepting a certified copy of a transcript from the ACPE-approved school of pharmacy rather than requiring a letter from the dean.

Ms. Sodergren asked to clarify if the board intended the transcripts from the school to fulfill all three intern hour requirements (completion of 1,500 hours, completion of 900 community pharmacy experience and certification of community and institutional experience). The board confirmed that the transcripts would fulfill all three.

Ms. Herold commented that staff would work with legal counsel to ensure that accepting transcripts would fulfill all three requirements without accepting a separate letter from the school.

The board chose to table this item to allow staff to work with the legal office to determine what documents would need to be submitted with the applications.

d. Review and Discussion of Questions on Applications to Collect Prior Conviction Information

Chairperson Veale reported that at the request of the DCA legal office, the committee in December 2013 began a discussion to revise the conviction questions on the board's individual applications. This activity was requested by the department in an effort to provide uniformity throughout the DCA boards and bureaus.

Chairperson Veale stated that unlike other professions, working in a pharmacy or drug wholesaler gives individuals direct access to dangerous drugs, including controlled substances. The board needs to determine how it will address prior convictions involving drugs.

Chairperson Veale reported that at the last meeting the committee discussed information and opinions from various attorneys regarding the proposed changes to the conviction question. The committee discussed whether or not, at some point, the board should develop a regulation to define those crimes which the board feels are substantially related to the duties and functions of a licensee.

Below is the proposed language to amend question number 7 on the pharmacy technician application and question number 19 on the pharmacist application. The language was created by the board's Attorney General counsel, Joshua Room.

Proposed Question:

Have you ever been convicted of, or pleaded guilty or nolo contendere/no contest to, any crime, in any state, the United States or its territories, a military court, or any foreign country? Include any offense felony or misdemeanor offense, and any infraction involving drugs or alcohol with a fine of \$500 or more. You must disclose a conviction even if it was (1) later dismissed or expunged pursuant to Penal Code section 1203.4 et seq., or an equivalent release from penalties and **disabilities** provision from a non-California jurisdiction, or (2) later dismissed or expunged pursuant to Penal Code section 1210 et seq., or an equivalent post-conviction drug treatment diversion dismissal provision or from a non-California jurisdiction. Failure to answer truthfully and completely may result in the denial of your application.

NOTE: You may answer "NO" regarding, and need not disclose, any of the following: (1) criminal matters adjudicated in juvenile court; (2) criminal charges dismissed or expunged pursuant to Penal Code section 1000.4 or an equivalent deferred entry of judgment provision from a non-California jurisdiction; and (3) convictions more than two years old on the date you submit your application for violations of California Health and Safety Code section 11357, subdivisions (b), (c), (d), or (e), or California Health and Safety Code section 11360, subdivision (b); and (4) infractions or traffic violations with a fine of less than \$500 that do not involve drugs or alcohol.

Chairperson Veale also noted that the committee discussed adding question number 2 from the pharmacy technician application to other personal license applications.

Mr. Law asked if the board could send any information to technician schools so that they can tell students what convictions would keep them from obtaining a license. Ms. Herold commented that for the most part the technician schools have an idea of what kind of convictions would result in a denial.

Dr. Wong commented that as most technician schools are for profit, they take any students no matter what. Ms. Hackworth agreed that it is a shame that students pay a lot of money for the education and then cannot obtain a license because of a conviction.

Mr. Schaad commented that creating a list of disqualifying convictions would save the board and students money. Chairperson Veale agreed and noted that the creation of a list is something that the Licensing Committee wants to address at future meetings.

Mr. Schaad also noted that the proposed language is a bit confusing.

Mr. Law asked if there was a way to see the number of license denials broken down by school. Ms. Sodergren responded that currently the system does not have a way to capture that information.

Committee Recommendation (Motion): Add question number 2 from the Pharmacy Technician Application (17A-5) to the Pharmacist, Intern Pharmacist, and Designated Representative Applications.

Support: 10 Oppose: 0 Abstain: 0

Dr. Gray from the California Society of Health System Pharmacists recommended that the board change the motion to apply to all personal license applications. The board agreed and modified the next motion accordingly.

Committee Recommendation (Motion): Amend question number 7 on the Pharmacy Technician application, question number 19 on the Pharmacist application and applicable questions on all individual licensing applications, as proposed.

Support: 10 Oppose: 0 Abstain: 0

e. Competency Committee Report

Chairperson Veale reported that effective April 1, 2014, the board instituted a quality assurance review of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE). The quality assurance review ended July 9, 2014 and the results were released thereafter.

1. Recruitment of New Members for the Board's Competency Committee

Chairperson Veale reported that the board is looking to recruit new members for the Northern Competency Committee, especially those who are specialized in institutional settings. Chairperson Veale encouraged practicing California pharmacists, especially who have been licensed within the last five years, to apply. She noted that applications must include a curriculum vitae, a cover letter describing the pharmacist's area of pharmacy experience or practice, and three letters of reference from pharmacists who are familiar with the pharmacist's work.

2. Job Analysis Design of the California Pharmacist Practice for the Practice Standards and Jurisprudence Examination (CPJE) for 2015-2020

Chairperson Veale stated that the committee has developed a job analysis survey to be used to complete an occupational analysis with the board's contracted psychometric firm. The survey was released to a random sample of pharmacists June 12, 2014. The information learned from this survey will determine if changes are necessary to the content outline of the CPJE. Pharmacists, who complete the job analysis survey, will be awarded three hours of CE credit. The board must approve the revised content outline at a future board meeting.

f. Licensing Statistics (July 1, 2014 – June 30, 2014)

Chairperson Veale reviewed the licensing statistics provided in the meeting materials. The board noted that there was a large increase in the number of hospital applications. Ms.

Herold stated that this could be due to a change of ownership that occurred. Ms. Sodergren stated that another factor could be that when the board conducted sterile compounding inspections it was determined that locations previously licensed as drug rooms needed to be licensed as hospital pharmacies.

g. Fourth Quarterly Report on the Committee's Goals for 2013/14

Chairperson Veale reported that the board is meeting the acceptance parameters for Success Indicators 2C – Review received deficiency items to determine application completeness within five working days of receipt and 2E – Update information changes to licensing records within five working days.

Chairperson Veale stated that the board is not meeting the acceptance parameters for the following Success Indicators

- 2A – Cashier All Revenue Received within three working days
- 2B – Review Initial Applications within 30 working days
- 2D- Issue licenses within 3 working days of completed application.

Ms. Herold commented that in these success indicators, board staff is working diligently to move towards the goal. She added that as new positions are filled and training is completed, additional progress will be made in these three areas.

The board recessed for a break at 12:30 p.m. and resumed at 1:29 p.m.

Note: Dr. Castellblanch arrived at 12:40 p.m.

XI. LEGISLATION AND REGULATION COMMITTEE

Note: There has been no meeting of the Legislation and Regulation Committee since April 2014. Chairperson Lippe provided a report for the Legislation and Regulation Committee as follows.

Part 1: Legislation Report

a. Status of Board-Sponsored Provisions

1. SB 960 (Morrell) Pharmacy Licenses: Letters of Admonishment

The board's provisions originally appeared in AB 2131 (Morrell), and sought to enact a separate statutory provision for a letter of reprimand for applicants (modeled after a Medical Board of California provision). Since that time Assembly Member Morrell became a senator, which resulted in a change in the bill's name from AB to SB. The bill also was amended to modify existing Section 4315 BPC to authorize the board to issue a letter of admonishment (currently authorized for licensees) also to an applicant, which would describe the nature and facts of an individual's violations. The section affords the individual the right to contest the LOA and specifies the process and timeframe for contesting the LOA, and would require that the LOA be purged three years from the date of issuance. The board voted to Support SB 960 at the April 2014 board meeting. On May 28, 2014 the bill was amended to specify that a LOA shall not be construed as a disciplinary action or discipline for purposes of licensure or the reporting of discipline for licensure.

Motion: Ratify the support position taken on June 13, 2014 by the board president and the committee chair.

M/S: Lippe/Veale

Support: 11 Oppose: 0 Abstain: 0

2. SB 1466 (Committee on Business, Professions, and Economic Development) Omnibus Provision Relating to Requirements for a Designated Representative

Senate Bill 1466, section 13, contains a board-sponsored provision to amend Section 4053 Business and Professions Code (BPC) to specify that a designated representative shall be at least 18 years of age.

Section 12 of the bill contains an amendment to section 4021.5 BPC to modify the definition of a “correctional pharmacy.” Currently, the definition applies to “state” correctional facilities, and the bill removes “state.” To implement the provision, the board will need to seek funding to modify the board’s licensing system, as correctional facilities that are currently licensed are fee exempt.

The board currently has a support position on this bill. There were no comments from the board or from the public.

3. SB 600 (Lieu) Repeal of Pedigree Requirements

Senate Bill 600 contains the board’s sponsored provisions to remove California’s e-pedigree requirements from the Business and Profession Code. This change would have eliminated possible confusion with federal law (the federal Drug Quality and Security Act) which preempted California’s requirement. The board’s provisions were amended into SB 600 on June 10. At that time, the bill also contained provisions to declare that drugs obtained outside of the licensed supply chain (regulated by the FDA) were deemed to be misbranded and provided for related penalties; these provisions have since been stricken. Board staff asked the board to take a support position on this bill.

Motion: Support SB 600.

M/S: Lippe/Veale

Support: 11 Oppose: 0 Abstain: 0

4. AB 2605 (Bonilla) Requirements for Third-Party Logistics Providers

The federal legislation enacted to establish standards for drug chain security contained provisions to establish national standards for wholesalers and to establish specialized regulation of third-party logistics providers (3PLs). The new federal law requires the FDA to establish regulation provisions regarding national standards for wholesalers and 3PLs over the next two years. If a state does not regulate 3PLs, the national registration will be required. The law specifically prohibits the regulation of 3PLs as wholesalers (which is exactly what California law currently does).

At the January Board Meeting, the board voted to secure legislation to implement a separate license category for third-party logistics providers. On April 23, 2014, Assembly Member Bonilla, Chair of the Assembly Committee on Business Professions and Consumer Protection, amended her Assembly Bill 2605 to carry the board's provisions. The bill has been amended twice since then and board staff continues to work with the author's office and stakeholders to refine the provisions. As reflected in the current language, a third-party logistics provider will have a "facility manager" in lieu of a designated representative, as the individual responsible for a facility's compliance with applicable laws.

The board president and chair of the committee established a support position on the bill following the publication of the board's provisions.

Motion: Ratify the support position taken by the board president and committee chair.

M/S: Lippe/Law

Support: 11 Oppose: 0 Abstain: 0

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

1. AB 186 (Maienschein) Professions and Vocations: Military Spouses: Temporary Licenses

AB 186 would require DCA licensing authorities, including the Board of Pharmacy, to issue a 12-month temporary license to an applicant, who is a military spouse or domestic partner, while the license is being processed so long as specified requirements are met.

Ms. Veale commented that she would not support this bill as it gives a free pass to someone who was not been vetted by the board. President Weisser and Mr. Lippe agreed.

Motion: Oppose AB 186.

M/S: Veale/Lippe

Support: 11 Oppose: 0 Abstain: 0

2. AB 1535 (Bloom) Pharmacists: Naloxone Hydrochloride

Assembly Bill 1535 will add section 4052.01 to the BPC to authorize a pharmacist to furnish naloxone hydrochloride (NH) pursuant to a standard procedure or protocol developed by the board and the Medical Board of California (MBC), in consultation with the California Pharmacists Association, the California Society of Addiction Medicine and other appropriate entities. The bill requires specific information to be included in the procedures or protocol, prohibits a pharmacist from allowing a person receiving NH to waive consultation and other requirements. The bill is co-sponsored by the California Pharmacist Association and the Drug Policy Alliance.

The most recent version of the bill authorizes the board to adopt emergency regulations to establish the standardized procedures or protocols.

Motion: Support AB 1535 as Amended June 24, 2014

M/S: Lippe/Gutierrez

Support: 11 Oppose: 0 Abstain: 0

3. AB 1702 (Maienschein) Professions and Vocations: Incarceration

Existing law establishes various eligibility criteria needed to qualify for a license and also authorizes the board to deny a license on the grounds that the applicant has been convicted of a crime substantially related to the qualifications, functions or duties of the business or profession for which application is made.

AB 1702 would provide that an individual who has satisfied any of the requirements needed to obtain a license while incarcerated, who applies for that license upon release from incarceration, and who is otherwise eligible for the license shall not be subject to a delay in processing the application or a denial of the license solely based on the prior incarceration. At its meeting held April 23, 2014, the board considered the introduced version of the bill and determined that the measure could limit the board's discretion when making a licensing decision and may add confusion as to what criteria the board could actually consider when making those decisions.

AB 1702 was amended on April 23 to specify that an application shall not be subject to delay in processing or a denial of the license based solely on the basis that all or some of the licensure requirements were completed while the individual was incarcerated. The April 23 version also stated that the bill shall not be construed to limit the board's ability to deny a license pursuant to Section 480.

Motion: Take no position on AB 1702.

M/S: Lippe/Gutierrez

Support: 11 Oppose: 0 Abstain: 0

4. AB 1727 (Rodriguez) Prescription Drugs: Collection and Distribution Program

Chairperson Lippe reported that AB 1727 has already chaptered and thus requires no action by the board.

5. AB 1841 (Mullin) Medical Assistants

Assembly Bill 1841 would authorize a medical assistant to hand out prepackaged prescription drugs, labeled in accordance with section 4170 (prescriber dispensing), to patients as part of the “technical supportive services” they provide in clinics that are issued a license by the board pursuant to Section 4180 BPC (nonprofit or free clinics) and Section 4190 BPC (Clinics). The language specifies that in every instance, prior to handing the medication to a patient, a “appropriate patient consultation regarding use of the drug” shall be provided by a licensed physician and surgeon, a licensed podiatrist, a physician assistant, a nurse practitioner, or a certified nurse-midwife.

16 CCR Section 171072(c) specifies the requirements for a patient consultation by a pharmacist. While the bill provides that the patient shall receive an appropriate consultation regarding the “use of the drug” – the bill does not require that the consultation cover precautions and relevant warnings, to include common severe side or adverse effects or interactions that the patient may encounter, or other information.

Mr. Law asked what the board can do if the medical assistant doesn’t give an appropriate consultation. Ms. Herold responded that the board can discipline the clinic permit, but not the individual because they are not licensed by the board.

President Weisser stated that by supporting this bill we endorse removing pharmacists from the dispensing of prescriptions and from providing consultations. Mr. Law agreed that the board should not encourage medical assistants to dispense and consult patients on medications.

Dr. Gutierrez commented that the board could oppose the bill, unless it is amended to strengthen the consultation requirements. Chairperson Lippe added that the language could be amended so that it holds them to the same consultation requirements as pharmacists.

Ms. Herold commented that there are two issues in this bill, who is consulting and who is doing the labeling.

Motion: Oppose AB 1841 unless amended to modify the labeling and consultation requirements.

M/S: Lippe/Law

Support: 11 Oppose: 0

6. SB 204 (Corbett) Prescription Drugs: Labeling

Senate Bill 204 would require the board to conduct surveys of pharmacists and electronic health record (EHR) vendors to evaluate the use of standardized directions on prescription

labels; to report the findings at its July 2016 Board Meeting, and to publish the findings on the board's website. The board has identified an estimated cost of \$50,000 to contract for the mandated surveys, which would come out of the board's Contingent Fund (license fees).

Dr. Castellblanch stated that the reason for standardized directions is that it has been shown in studies that one million medical errors a year are made because of unclear directions on labels. Standardized directions were created and promulgated by the board to address this issue. However, Dr. Castellblanch has heard that these directions are not actually being used. The survey would give the board the opportunity to determine if the standardized directions are being used in pharmacies.

Dr. Ratcliff commented that board inspectors are educating pharmacists on availability of the standardized directions. Dr. Castellblanch expressed his concern that the board inspectors are not enforcing their use.

Dr. Ratcliff commented that the requirements in 1707.5 are standards of practice for pharmacists and he estimated that probably 95 percent of pharmacies use standardized directions. Dr. Castellblanch disagreed as there are an estimated one million medical errors each year from unclear directions.

Dr. Castellblanch stated that he would like to see data that shows if the standardized directions are being used in pharmacies. Chairperson Lippe commented that this data could be gained from the board's inspectors rather than paying \$50,000 for the survey to be conducted. Dr. Castellblanch asked that the board inspectors report on this as to-date he has not seen this information.

President Weisser asked if a report from the board inspectors would provide the data that Dr. Castellblanch wanted. Dr. Castellblanch stated that it would, however, he did not feel that the board should take an oppose position. President Weisser stated that the reason he would oppose the bill is because it required the board to pay \$50,000 for information that it can obtain through its inspectors.

Ms. Herold commented that during the hearings held by the board on labeling, testimony was received from pharmacists who were concerned about changing in any way the directions for use written by the prescriber. They felt that in order to change the directions for use to fit the standardized directions for use, they would need to call the prescriber to get approval.

Motion: Oppose SB 204.

M/S: Lippe/Law

Support: 10 Oppose: 1 Abstain: 0

President Weisser directed that the board inspectors report on the use of standardized directions for use. Dr. Steve Gray commented that if a pharmacist is found not using the standardized directions for use, the inspectors should ask *why* they are not using them.

7. AB 2396 (Bonta) Convictions: Expungement: Licenses

Assembly Bill 2396 amends section 480 of the Business and Professions Code to prohibit a board within DCA from denying a license based solely on a criminal conviction that has been withdrawn, set aside, or dismissed by the court. As discussed by the board at the April 2014 Board Meeting, the enactment of AB 2396 would prohibit the board from using an expunged conviction as the sole reason for a licensure denial. Based on its concern that AB 2396 will eliminate the board's discretion in making licensure decisions in these cases, it voted to Oppose AB 2396.

The most recent amendment contains a technical amendment and does address the board's concerns, therefore the board did not change its oppose position.

8. AB 2603 (V. Manuel Perez) Controlled Substances: Permissive Lawful Possession

Assembly Bill 2603 amends section 11350 of the Health & Safety Code (HSC) to allow, under certain circumstances, an individual (other than the prescription holder) to possess a controlled substance.

In April 2014, the board opposed the introduced version of the bill – which allowed another person to possess the controlled substance if this person “intended” to deliver it to the prescription holder or “intended” to discard the controlled substance for the prescription holder.

The current version of the bill specifies that it is not unlawful to possess a controlled substance if both of the following apply: (1) the possession is at the direction or express authorization of the prescription holder and (2) the purpose of the possession is to deliver the prescription to the prescription holder or to discard the substance in a lawful manner.

The board did not change its oppose position.

9. AB 2757 (Bocanegra) Centralized hospital packaging pharmacies: medication labels

Assembly Bill 2757 is a “gut and amend” to amend sections 4128, 4128.4 and 4128.5 BPC to specify requirements for barcode and human-readable labels on drugs prepared by a hospital's centralized hospital packaging pharmacy.

The amendments would specify (in 4128.4) that a barcode shall be readable by ‘barcode administration software’ and that the software would verify it's the right medication, for the right inpatient, the right dose and the right route of administration.

Amendments to Section 4128.5 would specify the requirements of human-readable labels to require: the date the medication was prepared, the beyond use date, the established name of the drug, the quantity of the active ingredients, special storage or handling requirement, the lot number or control number, and the name of the centralized packaging pharmacy. This section further specifies that for quality control and investigative purposes, a pharmacist shall be able to retrieve the following information from using the lot number or control number: the components used in the drug product, the expiration date of each component and the NDC number.

Board inspectors have identified one suggested technical amendment for the board's consideration: to amend 4128.5(a)(4) to specify the quantity of "each" active ingredient.

Motion: Ratify the support position. Direct staff to work with the author to make the technical amendment.

M/S: Lippe/Veale

Support: 11 Oppose: 0 Abstain: 0

10. SB 1014 (Jackson) Pharmaceutical Waste: Home Generated

Senate Bill 1014 would require the Department of Resources Recycling and Recovery (CalRecycle) and the board to jointly develop regulations authorizing a voluntary program to collect and properly dispose of home-generated pharmaceutical waste. The program is to be based on the model guidelines that were developed in 2008.

In April, the board established a position of support if amended, to specify that the board be an equal partner in the development and implementation of any requirements for pharmacy drug take-back. Staff worked with the author, and on June 10, Senator Jackson amended SB 1014 to address the board's request. Thus, a letter of support was provided on June 12.

Ms. Herold reported that the Administration has encouraged the board, CDPH and CalRecycle to work together to amend the language. The intent is that within 18 months of the DEA releasing their requirements for drug take-back of controlled substances, the board will promulgate take-back regulations. Cal Recycle and Public Health will assist, however, the board would be responsible for creating the regulations. Ms. Herold asked the board to support the bill.

Motion: Ratify support SB 1014 as proposed to be amended.

M/S: Lippe/Butler

Support: 11 Oppose: 0 Abstain: 0

11. SB 1039 (Hernandez) Pharmacies: Furnishing Drugs

Senate Bill 1039 will expand what a pharmacy technician can perform in an acute care health facility licensed pursuant to Health and Safety Code section 1250(a). At the April Board Meeting, the board established a support if amended position and sought to address discrepancies with Title 22 in the language.

Staff worked with the author's office and stakeholders to address the board's concerns. The bill has been amended several times to include an amendment that the pharmacist be responsible for the duties performed under his or her supervision by a technician, adds Section 4119.6 to the BPC to authorize an intern pharmacist to stock, replenish and inspect the emergency pharmaceutical supplies container and emergency medical system supplies of a licensed general acute care hospital; and specify the facility's authority to administer, dispense or furnish dangerous drugs and dangerous devices to inpatients or patients upon discharge pursuant to preprinted or electronic standing orders, protocols, etc.

Based on recent amendments that addressed the board's concerns, the board president and committee chair established a position of Support.

Motion: Ratify the support position taken by the board president and committee chair.

M/S: Lippe/Murphy

Support: 11 Oppose: 0 Abstain: 0

12. SB 1258 (DeSaulnier) Controlled Substances: Prescriptions: Reporting

Chairperson Lippe reported that SB 1258 died in the Appropriations Committee, so no action or discussion is needed from the board.

c. Other Legislation Being Tracked by Board Staff

1. AB 1743 (Ting) Hypodermic Needles and Syringes

Existing law, until January 1, 2015, authorizes a pharmacist or physician to furnish 30 or fewer hypodermic needles and syringes for human use to a person 18 years of age or older. AB 1743 would extend these provisions to 2021.

The introduced version deleted the sunset date all together, and the board supported the bill. The current version of the bill appears to address the technical cross references to the Health and Safety Code, but now includes a sunset date of 2021.

Motion: Support the current version of AB 1743.

M/S: Lippe/Murphy

Support: 11 Oppose: 0 Abstain: 0

2. AB 2147 (Melendez) State Government Internet Web site: Information Practices

AB 2147 died in the house of origin; there was no action or discussion from the board.

3. AB 2418 (Bonilla) Health Care Coverage: Prescription Drug Refills

Assembly Bill 2418 would allow patients to opt out of their health plan's mandatory mail-order program if they prefer to obtain their prescription drugs from a community pharmacy; would streamline prescription medications by placing a patient's medications on the same refill schedule; and would allow for early refills of covered ophthalmic products at 70 percent of the predicted days of use. The bill is sponsored by the California Pharmacists Association and the California Healthcare Institute.

The board currently has a support position on the bill. Ms. Veale and Dr. Gutierrez commented that this seems to be more of a business decision and would like to change the board's position from support to neutral. Ms. Herold commented that the bill allows the consumers to choose to use a local pharmacy rather than a mail order pharmacy.

Ms. Butler noted that she would support patients getting refills on their eye drops sooner. Dr. Wong commented that his experience with mail-order pharmacies has not been positive and he would support patients being able to opt out.

Paige Talley, from RTP Consulting, commented that the bill has been amended to eliminate the mail order opt-out for patients whose drugs cost more than \$1,200.

Brian Warren, from the California Pharmacists Association, stated that amending the bill with the \$1,200 limit was done to address the cost issues in the bill. He added that the bill allows the consumer to decide if he or she wants to use a local pharmacy or a mail order pharmacy.

Ms. Veale commented that the board should not be telling insurance companies how to run their business. Dr. Gutierrez agreed.

Motion: Change the board's position from support to neutral.

M/S: Veale/Gutierrez

Support: 3 Oppose: 7 Abstain: 1

4. AB 2058 (Wilk) Open Meetings

The Bagley-Keene Open Meeting Act requires that all meetings of a state body, be open and public, and that all persons be permitted to attend and participate in any meeting of a state body, subject to certain conditions and exceptions. AB 2058 would amend the definition of a “state body” to exclude an advisory body with less than 3 individuals, except for certain standing committees. This bill may impact the board’s Organizational Development Committee, in that it is a “standing” committee, not an advisory committee. To make this committee a public meeting would have a fiscal impact to the board of approximately \$10,000 annually.

Ms. Herold reported that if this bill should become law, she would be unable to meet with the Organizational Development Committee to discuss emergency issues this committee which is comprised of the board president and vice president. The committee meets to discuss items such as pending litigation, personnel issues and emerging issues that cannot always be discussed in open meetings.

Motion: Oppose AB 2058.

M/S: Lippe/Hackworth

Support: 11 Oppose: 0 Abstain: 0

Part 2: Regulation Report

a. Board-Approved – Undergoing Administrative Review

At the October 2013 Board Meeting, the board voted to modify the patient-centered prescription label requirements at section 1707.5 (a) (1) to require that only the four items listed in section 1707.5 (a) (1) be clustered into one area of the label that comprises at least 50 percent of the label and to require these items to be printed in 12-point sans serif typeface.

At the January 2014 Board Meeting, the board approved a motion to initiate these changes in a rulemaking to amend section 1707.5 to Title 16 of the California Code of Regulations. The rulemaking was noticed on April 11, 2014, and the 45-day public comment period concluded on May 26, 2014.

At the June 2014 Board Meeting, the board voted to move forward with the rulemaking file and approved the draft responses to the comments received. The rulemaking file has been completed by staff and has been provided to the department for approval. Ms. Herold provided a brief overview of the rulemaking process.

b. Board-Approved – Awaiting Notice

1. Combined Rulemaking – Proposal to Amend Title 16 California Code of Regulations Sections 1702, 1702.1, 1702.2 and 1702.5 Related to Renewal Requirements

At the July 2013 board meeting, the board voted to approve the text to amend sections 1702, 1702.1, 1702.2, and 1702.5 to Title 16 of the California Code of Regulations relating to renewals. Staff is preparing the required notice documents and will be noticing these proposals as one combined rulemaking.

There were no comments from the board or from the public.

2. Combined Rulemaking – Proposal to Amend Title 16 California Code of Regulations Sections 1732.05, 1732.2, and 1732.5 related to Continuing Education

The board previously approved a 45-day public comment period for three proposals related to continuing education. Due to the significant changes in pharmacy law as a result of SB 294 (Emmerson, Chapter 565, Statutes of 2013) and SB 493 (Hernandez, Chapter 469, Statutes of 2013) with regard to the changes to compounding and the addition of the advanced practice pharmacist, board staff recommended to the Legislation and Regulation Committee to revisit the three continuing education regulation proposals. At the January 2014 Legislation and Regulation Committee meeting, the committee reviewed the board-approved language and deemed this language meets the board's requirements.

Dr. Wong asked if board members could receive continuing education credit for attending board meetings. Michael Santiago, DCA legal counsel advised the board that this would be a conflict of interest.

3. Proposal to Amend Title 16 California Code of Regulations Section 1703 Related to "Section 100" Regulatory Actions

At the October 2013 Board Meeting, staff proposed language to amend Title 16 California Code of Regulations to delegate to the executive officer the authority to initiate a rulemaking to adopt "changes without regulatory effect." At the October 2013 Board Meeting, the board voted to direct staff to initiate the formal rulemaking process and to issue the amended text as discussed at this meeting for a 45-day public comment period. If no negative comments were received, staff would be directed to take all steps necessary to complete the rulemaking process, including the 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 before completing the rulemaking process; and adopt the proposed regulation at Section 1703 as described in the text notice. Staff is preparing the required notice documents and will be noticing these proposals as one combined rulemaking.

There were no comments from the board or from the public.

The board recessed for a break at 3:02 p.m. and resumed at 3:16 p.m.

XII. DISCUSSION AND POSSIBLE ACTION ON REQUESTS FOR WAIVER OF CALIFORNIA BUSINESS AND PROFESSIONS CODE SECTION 4118 PERTAINING TO LICENSURE AS A CENTRALIZED HOSPITAL PACKAGING PHARMACY, CALIFORNIA BUSINESS AND PROFESSIONS CODE SECTIONS 4128 ET SEQ., FROM LOMA LINDA UNIVERSITY MEDICAL CENTER

President Weisser recused himself due to his relationship with Loma Linda University.

Dr. Gutierrez reported that at the June 2014 Board Meeting a waiver of California Business and Professions Code section 4118 had been granted for Loma Linda's Medical Center. At that time the representative from Loma Linda indicated that another waiver would be required for their Heart and Surgical Center. This additional waiver was agendized for the July 2014 Board Meeting.

Dr. Gutierrez asked if an inspection had been completed on the Heart and Surgical Center. Dr. Ratcliff confirmed and stated that there were no problems found during the inspection.

The representative from Loma Linda reported that they are working with their software team to come into compliance with the board's statutory requirements. He added that for now, all the requirements appear on the label but are not imbedded in the barcode.

Motion: Approve a five-year waiver for the Loma Linda University Heart and Surgical Center that as long as the required labeling elements appear on the label and the lot number is provided on the label and the required data elements are otherwise retrievable, waive the requirement that the data elements in section 4128.4 be retrievable at the patient's bedside by way of a barcode.

M/S: Lippe/Veale

Support: 10 Oppose: 0 Abstain: 0

Note: President Weisser recused himself from this vote.

XIV. PRESCRIPTION MEDICATION ABUSE SUBCOMMITTEE

Chairperson Castellblanch provided a report of the meeting held May 28, 2014.

President Weisser reported that at the May committee meeting he had the honor of recognizing a community pharmacist for his outstanding patient care. Dr. John Robertson, PharmD of Ramona, a pharmacist at Sav-On pharmacy inside Ramona's Albertsons supermarket, saved a patient's life by going to his home to check on him when the patient failed to pick up his prescription medication and didn't answer his phone. With the aid of sheriff's deputies, Dr. Robertson found the man collapsed inside his home where he had fallen two to three days earlier and was unable to get up. Ms. Hackworth noted that she spoke to Dr. Robertson after the incident and was impressed by his humility.

1. Update on Review of Prescription Drug Abuse Materials Currently Available on the Board of Pharmacy's Website.

Chairperson Castellblanch reported that there are materials, links and videos on the board's website page on prescription drug abuse prevention. He said materials are available for teens, college students, parents and educators; however, he noted that according to the CDC the main group affected by the epidemic is middle aged men. The website materials came mostly from government agencies with a goal of providing materials to people who need the information.

Chairperson Castellblanch also reported that a Prescription Opioid Misuse and Overdose Workgroup has been formed by the Department of Public Health and is chaired by the director of Public Health. The workgroup is made up of representatives from various state agencies and meets monthly. The goal of the group is to unify a focused policy that can be articulated by the state agencies in efforts on opioid abuse education and prevention. Dr. Castellblanch noted that the board's executive officer and public information officer attend the meetings on the board's behalf and report back to the subcommittee.

2. Summary of Presentation on Prescription Drug Abuse Prevention Materials by Rabia Atayee, PharmD, Assistant Professor of Clinical Pharmacy, UCSD School of Pharmacy; and Nathan Painter, PharmD, Associate Clinical Professor, UCSD School of Pharmacy

Chairperson Castellblanch reported that Dr. Atayee and Dr. Painter presented information for both health care professionals and patients/consumers on medication abuse. Some of the websites they recommend are the Medicine Abuse Project, which is geared to consumers and parents; Aware RX, which has a heavy focus on parents; a link to DEA Drug TakeBack; and Wake UP Now, which focuses on high school-age students and allows them to share their information on use and misuse of drugs. Dr. Atayee also indicated that health care professionals can find information at Ohio State University's GenerationRX, which provides tools for prescribers or pharmacists; the National Institute on Drug Abuse for current trends and health effects; and the White House Office of Drug Control for national strategies.

Chairperson Castellblanch asked that these materials be reviewed by legal counsel and placed on the board's website as soon as possible.

Chairperson Castellblanch stated that during the meeting, the representatives from UC San Diego expressed the value of the CURES system and reported on an education module they created to educate their students and faculty on the CURES system.

The committee discussed difficulties with the current CURES system and the frustration with the lack of funding and staffing. A letter was sent to the Attorney General expressing the board's concerns.

Ms. Herold reported that the information provided by Dr. Atayee and Dr. Painter were in fact recently placed on the website along with a "red flags" video filmed by the NABP.

3. Review of Educational Curriculum Materials for Teachers Developed by Purdue Pharma

Purdue Pharma provided a grant to the National Educator Association Health Information Network to create two books on opioids which are available without charge to educators. Chairperson Castellblanch reported that due to a potential conflict of interest, the board would not be placing the materials on its website; however, the materials were forwarded to the Department of Education.

4. Summary of Discussion About Use of/Education About Naloxone as Overdose Antidote

Chairperson Castellblanch reported that the subcommittee received valuable information on Naloxone, which is used in cases of opioid overdose and acts as an antidote. It neutralizes the effects of opioids, allowing drug users to continue breathing during an overdose.

5. Summary of Report of the Medical Board of California's Prescribing Task Force

The Medical Board's task force met in February and June 2014 in Sacramento to finalize revisions to the Medical Board's pain management guidelines. These guidelines have not been updated since the 1990s. Dr. Castellblanch reported that he had attended the June meeting and he was unsure if the Medical Board is heading in the right direction with the guidelines, in particular with the guidelines for "at risk" levels for opioid dosage.

Chairperson Castellblanch concluded that the next subcommittee meeting would be September 29, 2014 in downtown Sacramento.

XIII. SB 493 IMPLEMENTATION COMMITTEE

President Weisser provided a report of the Meeting held June 4, 2014.

1. Summary of Elements of SB 493 (Hernandez, Chapter 469, Statutes of 2013)

President Weisser stated that SB 493 creates a number of new opportunities for pharmacists to provide direct care to patients. He added that there are essentially two levels of additional services authorized – one for all pharmacists, the second to create a new licensure category of advanced practice pharmacist to provide additional duties.

2. Overview of Use of "Advanced Practice Pharmacists" in Other States

President Weisser reported that the board is aware that at least three states have some experience with a version of advanced practice pharmacists. These are New Mexico, North Carolina and Montana.

President Weisser stated that during the meeting it was noted that the programs in other states rely heavily on the oversight of the Medical Board, while in California, SB 493 gives the Board of Pharmacy far more autonomy.

There were no comments from the board or from the public.

3. Summary of Identification of Materials Where Board Guidance is Envisioned

President Weisser reported that Senate Bill 493 allows pharmacists to practice at the full scope of their knowledge and experience and increases their involvement in direct patient care.

The law provides that the following three items are areas where pharmacists who possess the minimum requirements for providing the services may do so without specific board licensure:

1. Initiate and Administer Immunizations Pursuant to Recommended Immunization Schedules by the Federal Advisory Committee of Immunization Practices
2. Prescription Medications not Requiring a Diagnosis that are Recommended by the CDC for Travel Outside the US
3. Ordering and Interpreting Tests to Monitor and Manage Drug Therapies

President Weisser noted that in the interest of patient safety, the board may wish to develop guidance or fact sheets to ensure all pharmacists who provide such services are fully aware of and compliant with the requirements. He added that during inspections, the board will monitor to ensure those pharmacists who provide these services are appropriately qualified to do so.

President Weisser reported that at the June committee meeting a number of comments and questions were discussed. President Weisser briefly reviewed some of the questions and discussion items from the meeting; the entire list of questions can be viewed in the board meeting materials and in the minutes from the June committee meeting. These comments and questions will be used to create future committee agendas where they will be discussed further.

4. Summary of Discussion on the Requirements for Pharmacists Who Furnish Self-Administered Hormonal Contraceptives and the Development of Draft Protocols

President Weisser reported that during the meeting, the committee discussed the requirements for the development of a protocol for self-administered hormonal contraception. These requirements include:

- Public collaboration with Medical Board of California, American Congress of Obstetricians and Gynecologists, the California Pharmacists Association and other appropriate entities
- A patient self-screening tool to identify risk factors based on the current U.S. Medical Eligibility Criteria (USMEC) for Contraceptive Use developed by the CDC as part of the protocol
- Referral of the patient to patient's primary care provider, or if the patient has no provider to nearby clinics if a self-administered hormonal contraceptive is not recommended.
- Development of a fact sheet for women on indications and contraindications for use of the drug, the appropriate method for using the drug, and need for medical follow up. Again, collaboration with the CA Department of Public Health, American

Congress of Obstetricians and Gynecologists and the CA Pharmacists Association in developing the fact sheet is required. Alternatively, provisions of an existing publication developed by nationally recognized medical organizations may fulfill this requirement.

President Weisser stated that staff proposes that a series of at least two public meetings be scheduled to include the required groups and any other interested parties to develop the protocols, the self-assessment questionnaire and the fact sheet. The format and scheduling of these meetings will be discussed at the next SB 493 Committee Meeting.

5. Summary of Discussion on the Requirements for Pharmacists Who Furnish Nicotine Replacement Products and Development of Draft Protocols

President Weisser Reported that SB 493 provides that a pharmacist may furnish nicotine replacement products approved by the FDA for use by prescription in accordance with standardized protocols. Implementation of this provision requires:

- Certification of the pharmacist in smoking cessation therapy by an organization recognized by the board
- Development of a protocol developed and approved by this board and the Medical Board of California with other “appropriate entities”
- The pharmacist maintain records of all prescription drugs and devices furnished for at least three years
- The patient’s primary care provider is notified of any drugs or devices furnished, or information is added to a shared patient record. If the patient has no primary care provider, the pharmacist provides the patient with a written record and advises the patient to consult a physician of the patient’s choice
- The pharmacist completes one hour of CE on smoking cessation therapy biennially.

President Weisser stated that as with the hormonal contraception protocol, staff recommends that separate meetings be held for various stakeholders.

6. Summary of Discussion on Application Requirements of the Advanced Practice Pharmacist License

a. Board of Pharmacy Specialties Certification Programs

President Weisser reported that at the February 2014 Licensing Committee Meeting, the board heard a lengthy presentation by the Board of Pharmacy Specialties on their certification programs. The Board of Pharmacy Specialties (BPS) has developed eight pharmacy practice areas for which it has developed certification programs. The BPS literature provides that certification of pharmacists promotes the recognition and value of specialized training, knowledge and skills in pharmacy.

b. Other Certification Programs (e.g., Commission for Certification in Geriatric Pharmacy)

President Weisser reported that at the committee meeting Tom Clark, from the Commission for Certification in Geriatric Pharmacy (CCGP), provided the committee with a presentation on their program.

At the committee meeting it was noted that the language in SB 493 states that the certification program must be recognized by ACPE or the Board of Pharmacy. However, ACPE does not recognize certification programs. President Weisser reported that the committee determined that in the future a legislative change may be needed to clarify the language or consider recognizing NCCA as an appropriate accreditation body.

c. Other Programs Envisioned or Under Development

At the committee meeting, President Weisser asked the public if there was anyone who would like to discuss other programs. There were several programs brought to the attention of the committee by members of the audience including the Clinical Lipid Specialist Exam, the Certified Diabetes Educator and the American Academy of HIV Medicine.

President Weisser reported that these programs and others would be discussed at future committee meetings.

7. Updated on the Development of Elements of Other Certification Programs

President Weisser reported that the committee members do not want to have multiple programs petitioning the committee and should instead focus on creating objective criteria that programs must meet in order to be considered.

President Weisser reported that at the committee meeting members of the public provided the committee with examples of various certification programs that are already available. It was also requested that the board consider the use of an Objective Structured Clinical Exam (OSCE). These exams are hands-on and are used in schools of pharmacy and in other medical professions.

8. Summary of Discussion on Renewal Requirements of the Advanced Practice Pharmacist License

President Weisser stated that the license expiration of the advance practice pharmacist license will be linked to the renewal or the underlying California pharmacist license.

Renewal of the APP license will require an additional 10 unit of CE in one or more areas relevant to the pharmacist's specialty. President Weisser noted that the board's staff plans to audit a high percent of APP renewals for full completion of both the 30 units and the additional 10 units.

President Weisser concluded that the committee has much to discuss and many legal questions that need to be considered. His goal is that the committee will be able to implement the requirements in SB 493 by January 2015. President Weisser also thanked the various stakeholders for their work and continued participation in the implementation of SB 493.

Dr. Wong commented that this is a great opportunity for pharmacists and he wants to be sure that the board handles implementation correctly. President Weisser agreed.

XIV. ENFORCEMENT AND COMPOUNDING COMMITTEE

Note: There has been no meeting of the Enforcement and Compounding Committee since the April 23-24, 2014 Board Meeting. Dr. Gutierrez provided a report on the Enforcement and Compounding Committee as follows.

1. Future Committee Meeting Dates

Dr. Gutierrez noted that the committee would need to change the September 30, 2014 date. Board staff offered to work with the members to reschedule the meeting. Dr. Gutierrez noted that there was also a meeting scheduled for December 17, 2014.

2. Fourth Quarterly Report on the Committee's Goals for 2013/14

Dr. Gutierrez stated that with all the focus on sterile compounding and staffing issues, some of the committee goals have not been met; however, staff is working to address the backlog of cases and investigations.

3. Enforcement Statistics for July 2013 – June 2014

Dr. Gutierrez briefly reviewed the statistics provided in the meeting materials.

XV. COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

Note: There has been no meeting of the Communication and Public Education Committee since the April 23-24, 2014 Board Meeting. In Ryan Brooks absence, Rosalyn Hackworth provided the Communication and Public Education report.

1. Future Committee Meeting Dates

Ms. Hackworth reported that the committee would be meeting on September 18 and December 10, 2014.

2. Update on Outreach Activities

Ms. Hackworth briefly reviewed the board's outreach activities. The complete list of the outreach actives can be found in the board meeting materials.

Dr. Gutierrez clarified that the July 9, 2014 meeting that she attended with Ms. Herold was the California Hospital Association's Medication Safety Committee.

Dr. Castellblanch commented that the committee will be discussing the possible re-design of the Notice to Consumer Posters at future committee meetings.

XVII. Discussion and Possible Action on a Request from Keck Graduate Institute School of Pharmacy for Recognition by the Board Under Section 16 CCR Section 1719 for Purposes of issuing Intern Licenses

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

President Weisser explained that there are three levels to full ACPE accreditation status for new schools of pharmacy: pre-candidate status, candidate status and full accreditation. A school may be granted candidate status once the school has produced its first class of graduates. At this point, section 1719 allows the board to issue intern licenses to current and future students. However, before possessing candidate status and while students are moving through the program at a new school, the school may have pre-candidate status with ACPE. This means that the school is progressing to meet the ACPE accreditation standards, but has not yet completed the process nor graduated its first class. In such cases, the board must recognize the school for purposes of issuing an intern license.

President Weisser noted that ACPE does not award pre-candidate status to new schools that are not adequately progressing towards full accreditation. The ACPE confirmed that Keck Graduate Institute possesses pre-candidate status and is moving through the steps required to ultimately secure ACPE full accreditation.

Dr. Kathy Webster, the founding dean of the Keck Graduate Institute School of Pharmacy, reported that they expect to have 80 students starting August 18, 2014.

Motion: Approve the request from Keck Graduate Institute School of Pharmacy for recognition by the Board under Section 16 CCR Section 1719 for purposes of issuing intern licenses

M/S: Gutierrez/Veale

Support: 11 Oppose: 0 Abstain: 0

ADJOURNMENT FOR THE DAY

The board adjourned for the day at 4:30 p.m.

Thursday, July 31, 2014

President Weisser called the meeting to order at 8:35 a.m. and conducted a roll call. Board members present: Stanley Weisser, Victor Law, Rosalyn Hackworth, Ramon Castellblanch, Amy Gutierrez, Lavanza Butler, Deborah Veale, Allen Schaad and Greg Lippe.

Note: Albert Wong arrived at 8:40 a.m. and Gregory Murphy arrived at 9:50 a.m.

XVIII. ORGANIZATIONAL DEVELOPMENT COMMITTEE

Note: There has been no formal meeting of the organizational development committee since the April 23-24, 2014 board meeting; however, several ad hoc teleconference meetings were convened to discuss items that required immediate attention. President Weisser provided a report on the Organizational Development Committee as follows.

1. Future Board Meeting Dates

President Weisser announced the future board meeting dates.

- October 28-29, 2014 – Southern California
- January 27- 28, 2015
- April 21-22, 2015
- July 28- 29, 2015
- October 28-29, 2015

2. Budget Update/Report

a. Budget Report for 2014/2015

President Weisser reported that the new budget year began July 1, 2014. The board’s spending authorization for the year is \$19,414,000, which is a seven percent increase from the prior year.

President Weisser briefly reviewed the chart below, which highlights budget change proposals secured for FY 2014/15. These changes account for a significant portion of the increase in authorized expenditures.

Cures – Combating RX Drug Abuse	AGPA (1.0); Research Program Specialist (1.0); Inspector (5.0); Sup. Inspector (1.0)
Enforcement Workload	AGPA (1.0); SSA (1.0)
SB 294 – Sterile Compounding	AGPA (1.0); OT (T) (1.0); SSA (1.0); Inspector (4.0)
SB 493 – APP	AGPA (1.0); OT (T) (0.5); SSA (0.5); Inspector (1.0)
Total Positions	20

Dr. Castellblanch asked if it was possible to determine the amount of funding the board had provided to the CURES program in 13/14. Ms. Herold responded that the board provides \$92,000 for ongoing maintenance of the system and in fiscal year 13/14 and 14/15 was required to provide an additional \$400,000 for the development of the new computer system over a two year period. Ms. Herold added that she would provide the exact figures at the next meeting.

Mr. Law asked if the DOJ reports back on how they spend the money we provide. Ms. Herold responded that previously the DOJ has not been required to; however, with the co-governance the board has been given, she hopes that these numbers will be available.

b. Budget Report for 2013/2014

President Weisser reported that fiscal year 2013/14 ended June 30, 2014. However, the final FY 2013/14 numbers will not be available until the beginning of August 2014. A final budget report will be provided during the October Board Meeting.

President Weisser explained that based on projections through the end of the year, the board identified that it would exceed its authorized enforcement related expenditures,

including Attorney General and Office of Administrative Hearings expenditures. Budget bill language allowed programs within the Department of Consumer Affairs to submit a deficiency request to increase authorized expenditures for enforcement related costs. (Redirection from other budget line items was not possible.) President Weisser reported that board staff, in collaboration with the AG's Office and the DCA Budget Office, prepared the deficiency notice seeking an additional \$1.742 million in authorized expenditures which was approved in Executive Order No. E 13/14, issued on April 7, 2014.

c. Fund Condition Report

President Weisser reported that the board's fund condition illustrates that the board may need to pursue another fee increase to sustain operations.

President Weisser stated that prior to a fee increase, a fee audit must be completed, similar to the one completed several years ago in advance of our 2008 fee bill. Board staff will begin working with an outside firm to determine the true costs to deliver application and renewal services, which will serve as the foundation for any changes to the board's current fee schedule.

d. Update on BreEZe, DCA's New Computer System

Ms. Sodergren reported that board staff discovered critical functionality that was not detailed in the original contractual requirements and that is essential to the board's ability to deploy BreEZe. Board staff is working with DCA and the vendor to determine the most efficient and economical path forward.

President Weisser thanked Ms. Sodergren and Ms. Herold for their work on the BreEZe system to ensure that the board gets a product that will meet its needs.

Dr. Gutierrez commented that she is concerned that using a system that does not meet the board's needs can negatively impact the board's budget.

Mr. Lippe asked who the manufactures of the system. Ms. Sodergren responded that Iron Data owns the system and contracts with Accenture for software interfaces.

Ms. Sodergren concluded that she anticipates having more information on the BreEZe project at the October board meeting.

e. Board Member Reimbursement and Mail Vote Information

President Weisser briefly explained the mail vote process and directed the board and the public to view the statistics provided in the meeting materials.

Dr. Wong asked if the board members could receive notification of the outcomes of the cases that they vote on. Ms. Herold responded that staff would report back on the outcomes of the votes.

Ms. Hackworth noted that it would be helpful if board staff notified members if they are missing votes on cases so that board members can respond by either voting or with an

explanation of why they are not voting. Ms. Veale noted that she has found that some of her votes get stuck in her email outbox causing her to miss one or two votes.

Holly Strom, former board member, asked when the BreZE system is scheduled to go live. Ms. Herold responded that they are still in the design phase; the expected implementation date is December 2014. She added that the board's main concern is getting the system to meet the board's needs. Dr. Strom asked if the board could choose to keep their current system. Ms. Herold responded that this would most likely not be possible.

3. Personnel Update

a. **Board Member Update**

President Weisser reported that the board currently has one public member vacancy. This position was previously held by Shirley Wheat who left her position as a board member after concluding her term in May.

b. **Board Staff Update**

Ms. Herold briefly reported on the board's staffing changes. She congratulated Christine Acosta and Antony Ngondara for their promotion to supervising inspectors.

Dr. Castellblanch asked if the hiring freeze had been lifted. Ms. Herold responded that the freeze had been lifted a few years ago.

Dr. Gray from CSHP asked Ms. Herold if she can provide an update on the current number of inspectors. Ms. Herold responded that the board has eight supervising inspectors who oversee forty inspectors. She noted that Dr. Ratcliff is the lead of the supervisors.

Ms. Veale asked how many of the inspectors completed the sterile compounding training. Ms. Herold responded that all of the current inspectors received the training.

Ms. Hackworth asked if employees designated as temporary are given the opportunity to become permanent. Ms. Herold responded that if the board has a position open they can apply for it.

4. Review of Board Comments Submitted on a Proposed Federal Rescheduling of Hydrocone From Schedule III to Schedule II

President Weisser reported that during the April 2014 Board Meeting, the board voted to submit comments on a proposed federal scheduling of hydrocodone from a Schedule III to Schedule II controlled substance. On April 28, 2014, the board sent a letter to the DEA with comments in support of the rescheduling hydrocodone from Schedule III to Schedule II.

Mr. Law asked if the board ever received a response to the letter sent to the DEA. Ms. Herold responded that the board never receives a response; however, she knows that the letters are read.

XIX. EXECUTIVE OFFICER'S REPORT

1. Update on the Activities of the Medical Board of California by Executive Director Kimberly Kirchmeyer

Ms. Kirchmeyer reported that the Medical Board's Prescribing Task Force held a meeting on February 19 and June 19 to discuss the revisions to the board's prescribing guidelines. These guidelines were posted on the Medical Board's website and emailed out to all individuals on their task force parties list. The meeting had representatives from the prescribing and dispensing communities, law enforcement and other regulatory boards, including Dental Board, Board of Pharmacy, Physician Assistant Board and Nursing Board. The group overall thought that the guidelines needed to be broad enough to cover all scenarios that may occur. Ms. Kirchmeyer noted that at the end of the meeting, everyone was offered an opportunity to go back and review the guidelines and provide their comments. The next meeting will be held in September, with the goal of having the revised guidelines reviewed at the October Board Meeting.

Ms. Kirchmeyer reported that on July 17-18 a representative from the Department of Public Health, Ms. Herold and herself traveled to Washington D.C. to represent California at a meeting hosted by the Department of Health and Human Services entitled "Advancing Policy and Practice: A 50 State Working Meeting to Prevent Opioid-Related Overdose." Ms. Kirchmeyer reported that there was valuable information provided at the meeting.

Additionally, Ms. Kirchmeyer reported that she and Ms. Herold continue to attend meetings with the California Department of Public Health's Opioid Overdose Workgroup. The group is made up of state agencies, including other boards under the DCA, several units within the Department of Health Care Services, the Department of Education, County Local Health Officers, the Emergency Medical Services Agency, and the Department of Justice and will be adding others in the future. Ms. Kirchmeyer stated that at the last meeting, it was recommended that the Medical Board's prescribing guidelines be the kickoff for this group and they plan to do a large press conference as soon as the guidelines are approved. The release of the Medical Board's guidelines will be the catalyst for all of these agencies to put their public outreach plans into play.

Ms. Kirchmeyer provided that the Medical Board will be conducting free CME on extended release/long acting opioid prescribing on September 19 at the LAX Hilton. Ms. Veale asked if the event was only for doctors. Ms. Kirchmeyer responded that they would give first priority to doctors, then open it to other health care providers.

Dr. Castellblanch commented that Workers Compensation is also creating guidelines on pain treatment. He reported that they had established 80 mL morphine equivalent daily dose as the "red flag level." Dr. Castellblanch asked if the Medical Board had created a similar mL limit. Ms. Kirchmeyer responded that they are still consulting with their experts, but right now they are leaning towards 100 mL.

Note: Greg Murphy arrived at 9:50 a.m.

Mr. Law asked how often the Medical Board gets information from the CURES system on their doctors. Ms. Kirchmeyer responded that currently they check CURES when a complaint is received. She noted that in July, they hired an employee who will be proactively searching CURES, rather than waiting for a complaint to be received.

Dr. Gutierrez commented that the data provided from the meeting in Washington DC was very interesting, especially the information on how much Florida has done to address their opioid problem. Ms. Kirchmeyer and Ms. Herold agreed and added that Florida was in such bad shape that they could only improve. Ms. Kirchmeyer commented that when Florida improved, the bad players move to other states.

Dr. Castellblanch commented that the Board of Pharmacy has sent a letter to the Attorney General expressing their concern about the lack of funding for the CURES system. Ms. Kirchmeyer responded that they have not sent a letter; however, they discuss CURES at all of their meetings.

President Weisser asked what percentage of their licensees are registered in CURES. Ms. Kirchmeyer responded that about 11% are registered. Ms. Herold noted that about 25% of pharmacists are registered.

Ms. Herold commented that at the 50 States Meeting she found that other states are far beyond California in regards to the development and use of prescription monitoring programs. Ms. Veale asked if there was any discussion on a national drug monitoring program. Ms. Kirchmeyer responded that Ms. Herold expressed the need for a national interoperable system during the meeting. Dr. Castellblanch and Ms. Veale noted that there are existing systems that could potentially work on a national level.

Dr. Gutierrez asked if at the 50 States Meeting the need for treatment was discussed. Ms. Kirchmeyer responded that she and Ms. Herold presented this as one of their “top three important items” at the meeting. Dr. Castellblanch commented that it is concerning that many insurance providers do not cover treatment options.

2. Formation of the California Department of Public Health’s Opioid Overdose Work Group

Ms. Herold provided a brief report of the California Department of Public Health’s Opioid Overdose Work Group that she and Ms. Kirchmeyer attended. Ms. Herold noted that regular reports would be given at the Prescription Medication Abuse Subcommittee meetings.

3. A Six-Hour CE Program is Planned For September 3 in Santa Barbara on Prescription Drug Abuse, Corresponding Responsibility and Preventing Pharmacy Thefts, which will be co-sponsored by the Los Angeles Office of the Federal Drug Enforcement Administration

Ms. Herold asked the board to approve six hours of continuing education credit for pharmacists who attend the September 2 and 3, 2014 training being presented by the board and the DEA. She also noted that another event would be held in the San Fernando Valley in the future.

Motion: Approve 6 units of continuing education for the September 2 and 3, 2014 DEA and Board of Pharmacy Joint training.

M/S: Veale/Gutierrez

Support: 11 Oppose: 0 Abstain: 0

4. Information on the Development of Corresponding Responsibility Brochure

The board viewed the updated brochure on corresponding responsibility developed by board staff. Ms. Herold noted that this would be placed on the board's website and would be provided to the Medical Board.

5. Duty Inspector

Ms. Herold reported that in response to the board's request to have an inspector on duty to answer the public's questions, that in October there will be an inspector on duty two to three hours a day three days a week to respond to inquiries. She emphasized that staff will not be providing legal advice. Ms. Herold concluded that a report will be provided to the board in January.

6. NABP .pharmacy prefix

Ms. Herold reported that NABP found that 97 percent of the 10,000 web sites they investigated were illegitimate and potentially harmful to patients. To combat this, the NABP is creating a .pharmacy domain so that consumers know that when they are on a .pharmacy web site, they are dealing with a licensed pharmacy. Ms. Herold concluded that she has been appointed to the workgroup and will continue to work on the implementation of this vital consumer protection project. Mr. Law asked that once the program is in place the board publicize it to consumers.

XX. FORUM OF PATIENT-CENTERED PRESCRIPTION LABELS

At the conclusion of the Executive Officer's Report, the remainder of the board meeting was dedicated to an informational forum on Patient-Centered Prescription Labels. The board heard presentations from invited speakers and the public on patient-centered prescription labels.

Below are summaries of each speaker's presentation to the board. All PowerPoint presentations given at the meeting have been provided immediately following these minutes. The archived video of the day's presentations can also be viewed at:

<http://www.youtube.com/watch?v=fTa4EXIzwo&feature=youtu.be>

1. Donna Bohannon, R.Ph, CPPS, Scientific Liaison for the U.S. Pharmacopeial Convention

Need for Standards

- Medication misuse results in more than one million adverse drug events per year. (IOM 2007)
- The patient's best source (and often only source) of information is the prescription container label.
- Prescription container labels must fulfill professional obligations of prescribers and pharmacists by providing all pertinent information on safe medication use.

- USP created an expert panel to create a universal prescription label standard for format/appearance and content/language.

Patient Centered Label

- Patient-directed information must be organized in a way that best reflects how most patients seek out and understand medication instructions.
- Prescription container labeling should feature only the most important patient information needed for safe and effective understanding and use.

Differences Between USP Standards and California Standards For Patient Centered Labels

- USP Standard
 - Critical Information at the top of the label
 - Minimum 12-point font
 - Patient name
 - Drug name and strength
 - Brand **and** generic
 - Explicit instructions
 - Placement of less critical information
- California Regulation
 - Clustered items occupy 50% of the label space
 - Patient name
 - Drug name and strength
 - Brand or generic
 - Directions for use
 - Condition or purpose

Simplify Language – USP vs. California

- USP Standard
 - Clear
 - Concise
 - No medical jargon
 - Sentence case
- California Regulations
 - Case not specified

Instructions For Use – USP vs. California

- USP Standard
 - Use explicit text to describe dosage/interval instructions
 - Separate dose from timing
 - Use numbers for dose (1)
 - Specifics for time periods
 - Consistent use of the same terms
 - Avoid vague instructions
- California Regulation
 - Use explicit text to describe dosage/interval instructions
 - Separate dose from timing

- Use numbers for dose (1)
- Specifics for time periods
- Consistent use of the same terms
- Fifteen specific phrases

Purpose for Use – USP vs. California Regulations

- USP Standard
 - Use explicit text to describe dosage/interval instructions
 - Separate dose from timing
 - Use numbers for dose (1)
 - Specifics for time periods
 - Consistent use of the same terms
 - Fifteen specific phrases
- California Regulation
 - One of four required elements
 - Prescriber discretion

Limited English Proficiency – USP vs. California Regulations

- USP Standard
 - Patient's preferred language
 - Instructions in English as well as preferred language
 - High quality translation process
- California Regulation
 - Use explicit text to describe dosage/interval instructions
 - Separate dose from timing
 - Use numbers for dose (1)
 - Specifics for time periods
 - Consistent use of the same terms
 - Fifteen specific phrases

Recommendations for Visual Impairment

- Follow patient-centered prescription container label standards
- Provide alternative access to label information
- Enhance communications on available options
- Provide service or direct patient to alternative access
- Follow best practices for alternative access format

Dr. Castellblanch asked Dr. Bohannon if USP had already created standardized directions for use that are easy to understand. Dr. Bohannon responded that that they have developed guidelines for directions, but they are not explicit because they wanted to allow states to be innovative.

Dr. Gutierrez asked if a medical record number should be included in the patient centered section of the label. Dr. Bohannon responded that the USP guidelines are used in community settings and do not apply when the medication is being administered by a health care professional in a clinic or hospital.

Dr. Castellblanch asked if there are any USP guidelines for non-English speakers. Dr. Bohannon responded that whenever possible patients should be provided their label in the language they are most comfortable with. However, she noted that it should also be provided in English so that caregivers and emergency personal can also read the label.

2. Donna Horn RPh, DPh, Director Patient Safety- Community Pharmacy Institute for Safe Medication Practices (ISMP)

Label Purpose

- Patients' best source (and often only source) of prescription medications is the prescription container label
- Obligated to include most essential information needed to understand
 - how to take safely and appropriately to adhere to the prescribed medication regimen

ISPM Supports Efforts of the CA BOP

- Specifically, we support
 - Condition or purpose on label
 - Physical description of the dispensed medication
 - Recommend that color and odor be added for liquids
 - Use of standardized dosing
 - Frequency based on: morning, noon, evening, bedtime
 - Provide and facilitate the use of the patient's native language
 - Website translations

Look of the Label

- Agree to minimum of 12-point font
 - For patient-centered elements including the patient directions (per current research and guidelines)

Items to Consider

- Prohibiting the term "as directed"
- Pharmacy name, address, phone, etc., should be at the bottom of the label
 - Uppermost should be patient name and date of birth
- Print brand and generic name if medication is written for brand and dispensed generically
- Directions must use metric dosing

More to Consider

- Avoid the use of all potentially dangerous abbreviations and dose expressions
 - Spell out the word Units
 - Properly spaced commas, i.e., 5,000
- PWL in a consistent location
- Horizontal text only

USP and Others' Recommended Guidelines

- Bolding,
- Justification (left-justified)
- Sentence case and spacing
- Contrast
- Black print
- Non-glossy paper

Dr. Castellblanch asked for the definition of the acronym “PWL.” Dr. Horn explained that it is an acronym for “prescription warning label.”

Dr. Horn noted that, originally, ISMP did not think that the drug manufacturer was important information for the patient. However, they are reconsidering this view as the information would be helpful in the case of a recall or if the patient knows they are allergic to a certain manufacturer’s drug. Ms. Veale asked if it should be in 12-point font in the patient centered label portion, or somewhere else on the label in smaller font. Dr. Horn responded that it should be in smaller font.

3. Larry Mokhiber, MS, MSHS - New York Board of Pharmacy

Mr. Mokhiber reported that on March 30, 2013, New York implemented the Safe Rx law, which included provisions to assist limited english proficient (LEP) individuals who need interpretation and translation services when filling prescriptions at pharmacies. The law also required the Commissioner of Education to develop rules and regulations to provide more patient-friendly prescription labels for all patients.

Mr. Mokhiber reported that during implementation, numerous meetings were held to allow stakeholders to provide feedback and work on solutions to various issues.

Mr. Mokhiber explained that the law applied to pharmacies that had eight or more commonly owned locations, this exempted many independent pharmacies. However, he said many independent pharmacies in ethnically rich areas still choose to provide translation services.

Mr. Mokhiber stated that the New York Board used census data to determine what languages translations should be provided. After reviewing the data, it was determined that all pharmacies (as defined by the law) must provide translations in at least Chinese, Italian, Russian and Spanish (free of charge). Mr. Mokhiber added that in addition to the translation, the label information must also be provided in English. While the board mandated that translations be provided in the four languages, Mr. Mokhiber noted that they have found many pharmacies provide translations in additional languages to meet the needs of their customers.

Mr. Mokhiber stated that on March 27, 2015, all prescriptions in New York will become electronic. There will be a way for the prescriber to note which language the patient speaks so that the pharmacy will know as soon as the prescription is received what language the label will need to be provided in.

Mr. Mokhiber reported that translation services can be provided by pharmacy staff or a third-party vendor. Mr. Mokhiber added that the pharmacy will not be held liable for any harm caused by the translations of a third party vendor, as long as they entered into the contact reasonably and in good faith.

Mr. Mokhiber stated that all pharmacies must prominently display a sign stating that translations services are available in the four required languages.

Mr. Mokhiber reported that the law allows pharmacies to request a waiver if they can demonstrate that implementation was unnecessary or burdensome in relation to the services offered. There was much concern that the board would be overwhelmed with waiver requests; however, Mr. Mokhiber stated that no waiver requests had been received to date.

Mr. Mokhiber explained that prescriptions being delivered by mail in New York are held to the same requirements as those dispensed in pharmacies.

Mr. Mokhiber reported that there have been no complaints of non-compliance received by the board.

Mr. Mokhiber noted that another element of the Safe Rx Law was for the board to make a recommendation on what critical items should be displayed prominently on all labels. It was determined that the patient name, directions for use and drug name must be the most predominant items on the label. These three items must be in 12-point font and can be bold or in any color.

Dr. Castellblanch asked if there have been any liability issues in regards to translations. Mr. Mokhiber responded that he meets quarterly with the New York Chain Pharmacy Association and to his knowledge there have been no liability issues.

Dr. Castellblanch asked if there are any qualifications that third party translation vendors must meet. Mr. Mokhiber responded that the pharmacies have been given the responsibility of contracting with a reputable vendor.

Dr. Castellblanch asked how consumers are notified of their right to translation. Mr. Mokhiber explained that every pharmacy must have a poster (written in Chinese, Italian, Russian and Spanish) prominently displayed that states that translation services are available at no cost. Dr. Castellblanch asked if there are any size requirements for the poster. Mr. Mokhiber responded that they did not regulate the size, just that it be prominently displayed at *all* locations where prescriptions are dropped-off, picked-up or paid for. He added that to date they have not received any complaints about unclear signs.

Ms. Veale commented that the board has 15 commonly used directions for use on its website which have been translated. She asked if New York has considered doing something similar to this. Mr. Mokhiber responded that this was not recommended during their stakeholder meetings. He noted that they did discuss the use of universal signs for direction for use; however, they choose not to mandate their use.

Mr. Law asked if a pharmacy would be in violation if they did not provide translations in all the mandated languages, even if 90% of their customers spoke Chinese. Mr. Mokhiber responded that they would be in violation - assuming they met the law's definition of pharmacy (eight or more commonly owned locations).

Ms. Veale asked if the translation had to be printed on the label. Mr. Mokhiber clarified that the translations have to be provided in writing, but they can be provided on a separate sheet as long as it includes all the information that would be provided on the label.

Mr. Law asked to clarify if chains of less than eight pharmacies are exempt from these requirements. Mr. Mokhiber confirmed that.

Ms. Veale asked to clarify if translations must be provided both verbally and in writing. Mr. Mokhiber confirmed that.

Dr. Castellblanch asked if the board has any data on whether written translations are more commonly provided on the label or on a separate sheet. Mr. Mokhiber responded that he did not have this data.

Dr. Castellblanch asked if there was any data on the cost of third-party translation services. Mr. Mokhiber responded that he knows some pay a flat rate, others pay on a per-call basis and large chains often utilize their bilingual staff.

Dr. Wong asked if a pharmacy was required to have a member of staff working that could provide the translations. Mr. Mokhiber explained that the translation could be provided by a third party vendor if the pharmacy did not have staff who spoke the language.

Dr. Wong expressed his concern with the liability for a pharmacy employee (not a third party vendor) who mistakenly provided an incorrect translation. Mr. Mokhiber clarified that pharmacies would not be held liable if they contracted with a third party vendor.

4. Michael Wolf, PhD, MPH – Professor at Northwestern University

Risk for Safety, Non-Adherence

- Many adults misunderstand prescription labeling and make dosing errors
 - 75% can't identify prescription indication for use = non-adherence, poorer clinical outcomes
 - 52% misinterpret auxiliary warning information
 - 54% demonstrate improper dosing on common 'sigs'
 - Misunderstanding and improper dosing linked to non-adherence, 20% greater risk of readmission

California Requirements

- Emphasize (via font size, color, bold, white space)
 - patient name
 - drug name, dosage
 - directions for use
 - indication, if given

- Above should comprise 50% of label
- Universal Medication Schedule (UMS) recommended, ‘when appropriate’
- Translations or interpreter services minimally required (not specified to label translation)

Directions for Use – Standardizing Instructions

- Universal Medication Schedule (UMS) proposed
 - Eliminate prescribing and dispensing variability
 - Help patients organize and consolidate multi-drug regimens
 - Use recognizable ‘pill box’ schema - morning, noon, evening, bedtime
 - Explicit time intervals better interpreted vs. times per day, hourly intervals, or even explicit times
 - Use graphic aid to reinforce dosing schedule

Lost in Translation

- Evidence of need for proper translations is very strong
 - Services are inconsistent and/or highly inadequate
 - Lack of adequate services a cause of non-adherence and error
 - A matter of equity

“Concordant RX”

- CA Endowment-sponsored project
- Developed UMS directions in 5 languages (Spanish, Chinese, Russian, Korean, Vietnamese)
- Efficacy Trial among 200+ consumers (SF, Chicago)
- ConcordantRx labels improved:
 - proper use by 25%
 - regimen consolidation by 32%

Recommendations

- Provide explicit guidance towards improved directions for use - consider UMS
 - not ‘when appropriate’
 - pill form only (for now)
 - no graphic requirement
- Require the provision of written language translations on prescription container labels
 - require proof of a valid means for accurate written translations
 - offer ConcordantRx instructions as one option for pharmacies who want them

Considerations

- Work with CA Medical Society/Board on standardizing ‘sigs’ and providing indication
- Take a pragmatic view of what you are asking for (space considerations, inclusion of English and translated instructions, room for indication)
- Expand regulatory requirements beyond container label - coordinate a system of Rx information
- Recognize that action on evidence can only improve upon the current, problematic practices

Dr. Gutierrez asked if Dr. Wolf would recommend the use of graphic aids. Dr. Wolf responded that studies have found that graphic aids do not improve patient understanding or adherence (when the patient is taking only one medication). However, they are still studying if graphic aids help patients who are taking more than one medication.

Dr. Castellblanch asked if there is a liability issue if pharmacies choose to use the directions created in the Concordant Rx study. Dr. Wolf responded that the study showed that using the Concordant Rx translated directions was beneficial to patients. He noted that he is not endorsing solely the use Concordant Rx, rather the use of *validated* translation services.

Mr. Law asked if medical students are being taught ways to write prescriptions so the directions are easier for patients to understand. Dr. Wolf responded studies found that 94% of the time doctors simply use the default directions provided by their software. They are working to modify the software so that it will default to more patient friendly directions.

5. William Shrank, MD, MSHS – CVS

Dr. Shrank commented that he is pleased to see that California is taking the lead on improving prescription labels and added that the nation is watching how California handles the issues surrounding labels and translations.

Dr. Shrank stated that there is little debate that the labels matter and makes a difference in patient care. It important to remember that medication non-adherence is a significant barrier to the management of chronic disease and our ability to improve the quality of life for patients.

Dr. Shrank commented that patients today receive a multitude of information including the label, black box warnings, medication guides, manufacturer information, etc. Dr. Shrank urged the board to consider how all this information can work together to give the patient a clear, unified message about their prescription.

Dr. Shrank reported that in his time working with CVS he has seen how the company is working towards optimizing their labels to encourage medication adherence and improved patient safety.

Dr. Shrank commented that the board's main challenge is determining how prescriptive they should be in their label and translation requirements. He added that the board needs to balance the need for consumer protection while allowing for innovation by pharmacies. Dr. Shrank encouraged the board to allow pharmacies to petition the board for exemptions if they have an innovative way to improve labels.

One of the items the board has discussed is the inclusion of the manufacturer name on the label when a generic is prescribed. Dr. Shrank commented that in the case where a patient has been taking a medication for years and only knows it by the generic name, the inclusion of the manufacture name would only cause confusion. On the other hand, if someone is taking a medication and it suddenly switched to a generic, the inclusion of the manufacturer name would be very helpful. Dr. Shrank concluded that the board needs to make sure that

they do not disorient patients by requiring manufacturer to be on the label. Rather, it should be up to the health care provider to determine if its inclusion will help the patient.

Another item the board has discussed is the inclusion of the condition or purpose on the label. Dr. Shrank commented that he has been very vocal about the benefits of having the condition or purpose on the label. It has been shown that many patients do not know why they are taking their medications. If patients know why they are taking a medication, they are more likely to take their medication. Dr. Shrank noted that prescriptions should not be held from being dispensed if the pharmacist cannot get in touch with the prescriber to determine the condition.

President Weisser commented that in California, all pharmacists are required to provide a consultation. In his opinion the information on the label is important, but it must be coupled with a verbal consultation. Dr. Shrank agreed with President Weisser and noted that CVS is always looking for ways to promote pharmacists as an important member of the health care team. Dr. Shrank noted that he feels that consultations should also include members of the patient's family and caregivers.

Mr. Lippe noted that he finds it helpful when pharmacies provide information on what a pill looks like and notification on when a pills appearance has changed. Dr. Shrank agreed that this information is important and should be provided both on the label and during the consultation.

Mr. Law was pleased to hear that CVS is looking for ways to make pharmacists more available to patients.

Dr. Wong asked if CVS has any plans for translated labels. Dr. Shrank responded that CVS already has the ability to provide translations and could provide any information the board desired on their services.

7. Maureen Schanck, PharmD – NABP Professional Affairs Manger

Recommendation #1

- Critical Information for Patients- Should be emphasized (highlighted or bold), in sans serif font (such as "arial"), minimum 12-point font and should never be truncated.
 - Example: ABCDE Vs ABCDE

Examples of Critical Information

- Patient name
 - legal name of the patient; or
 - if patient is an animal, include the last name of the owner, name of the animal and species
- Directions for use
 - directions for use as indicated by prescriber and medication purpose/indication, if included on the prescription drug order
 - language should be simplified, avoiding unfamiliar words and medical jargon; when applicable, use numeric instead of alphabetic characters

Recommendation #2

- Important information must appear on label, but should not supersede critical information.

Examples of Important Information

- Pharmacy Name- or dispensing practitioner's entity name
- Pharmacy Telephone Number
- Prescriber Name
- Format -"Prescriber: [prescriber name]"
 - "Fill Date"-
 - Format- "Date filled: MM/DD/YY"
- Prescription Number
- Drug Quantity
- Number of Remaining Refills
- Written or graphic product description
- Auxiliary information
- Any cautions or provisions required by state or federal law

Recommendation #3

- The following information may also appear on the prescription label
 - Bar codes
 - Pharmacy address
 - Store number

Additional NABP Comments

- Boards may want to consider supporting legislation which contains this type of language for incorporation into their State Food and Drug Act, so that it shall apply to all persons who dispense drugs, including practitioners who prescribe and administer as well as dispense drugs.
- Information traditionally included on the patient label must continue to be maintained and safeguarded by the record-keeping system. Boards of pharmacy should require that record-keeping systems prohibit any alteration or modification of these data unless an appropriate audit trail and justification exists. Record-keeping systems should also prohibit any deletion of information, except in accordance with state and federal requirements for data management and retention.
- Boards of pharmacy should recognize that some pharmacies "do business as" a name other than the corporate
- Phone number of the dispensing pharmacy, recognizing that a central fill pharmacy may be involved in the filling process; boards of pharmacy should not require more than one telephone number on the label.
- "Fill date" and "use by" date should be the only dates appearing on the prescription label. Other dates often found on labels, such as the original and expiration dates of the prescription drug order can be misunderstood by patients and clutter the label with unnecessary information.

- Auxiliary information, including auxiliary labels, should be evidence based, standardized, and demonstrated to complement the prescription label.

Mr. Wong commented that the pharmacy phone number and prescription number should not be typed too small on the label, as it is often difficult for patients to find. Dr. Schanck responded that she would take this note back to NABP.

Ms. Herold asked if there were any pending recommendations from the NABP. Dr. Schanck commented that they recently updated their guidelines to direct pharmacists to use metric measurement for liquid dosing whenever possible.

8. Michelle Tenerelli – Clinical Director for Rite Aid

Dr. Tenerelli reported that Rite Aid already includes the manufacturers' name and pill description on their prescriptions.

Dr. Tenerelli noted that Rite Aid has found that some medications have very long directions for use. They would like to see the board allow patients to receive a supplemental direction sheet rather than trying to fit the directions for use in the 50% portion of the label.

Dr. Tenerelli reported that Rite Aid is currently working to improve their translation services. Dr. Tenerelli stated that they currently can provide instructions in 12 different languages (the information is printed on a supplementation sheet). She noted that currently Spanish is the only language in which auxiliary information can be printed; however, they are working with a vendor to increase the languages available.

Dr. Tenerelli explained that Rite Aid does not let their pharmacists provide written translations; they use a third-party vendor. She clarified that if a pharmacist speaks the language they can verbally provide the consultation, but still must use the vendor for the written translation.

Dr. Gutierrez asked if Rite Aid is looking for ways to encourage pharmacist and patient interaction. Dr. Tenerelli responded that they have modified their workflow so that pharmacists have more opportunities to talk with patient and spend less time doing tasks that other pharmacy staff can complete. She added that they are providing training to all their pharmacists to help them improve their consultation skills.

Dr. Castellblanch asked if Rite Aid had already secured a third-party vendor for all their translation services and asked if it was a significant cost burden. Dr. Tenerelli confirmed that they contracted with a third party vendor. She could not speak to the cost, but stated that Rite Aid feels it is a necessary service to provide their patients.

At Dr. Wong's request, Dr. Tenerelli provided an overview of how Rite Aid's written translation software functions.

9. Anandi Law, B.Pharm., MS, PhD, FAACP, FAPhA – Professor at Northwestern University

Prescription Label

- Prescription labels serve as an immediate and important source of medication information for patients

- Prescription labels are used to communicate key information
 - Medication name
 - Dosage
 - Directions
 - Precautions

What is a Good Prescription Label?

- Easy to use
 - Simple
 - Convenient
- Without need for assistance
- Intended to supplement provider counseling
- Communicates to patient:
 - What is the medication
 - When to take the medication
 - How to take the medication
 - How much to take
 - WHY to take the medication

Some Facts About Prescription Labels

- Differences in prescription label formats and instructions among pharmacies
- Patients often do not receive adequate medication counseling from health care providers (e.g. physicians, pharmacists)
- Vulnerable populations show difficulty in understanding prescription and auxiliary labels.
 - Elderly
 - People with low health literacy
 - People with low English proficiency (LEP)

Impact of Misunderstanding Prescription Labels

- Institute of Medicine (IOM) report in 2006 cited prescription labeling as “the cause of a large proportion of outpatient medication errors and adverse drug events.”
- Misunderstanding prescription label instructions has led to inadvertent patient-initiated errors in med use
 - Under or overdosing
 - Preventable adverse drug reactions
 - Emergency room visits
 - Hospital admissions
 - Morbidity and mortality
 - Economic burden in healthcare system
- 63% of patients misunderstand one or more dosage instructions on the prescription label
- 12% of emergency room visits are drug related
- 1.5 million preventable adverse drug events occur every year
- Medication errors and adverse drug reactions result in an estimated annual cost of \$50 billion

The Study

- Study purposes
 - To determine the effect of an educational intervention on change in prescription label comprehension among older adults who use prescription medications
 - To compare change in comprehension with 2 prescription labels:
 - Currently existing label
 - Redesigned patient-centered label
- Sampling and Setting
 - Conducted at 5 community senior centers in Southern California
 - Participants were all older than 55, taking two or more medications, and spoke English
- Study participants were broken into two groups, those that received the currently used labels and those that received the redesigned labels. In those two groups, some participants were simply given the label with no instructions; others were given the labels and received simple pharmacist consultations.

Key Messages

- Prescription labels need to be simple, easy to use and understand, given as a routine part of self-care.
- Certain populations consistently find it difficult to read and understand existing prescription labels, leading to adverse health outcomes and economic burden on the health system.
- The redesigned prescription label was favored over current labels by all stakeholders
- Simple education significantly improved prescription label comprehension in their sample of older adults for patients using their redesigned prescription labels
- Participants showed better prescription label comprehension with the redesigned prescription label than with the current prescription label both before and after educational intervention

Recommendations

- Manufacturer's name should be listed – not necessarily in the main area of the label
- Brand name of generic equivalent should be included under drug name
- Purpose/Condition should be a general requirement – 91% of 143 participants in their research indicated they would want it to help manage medications by category, distinguish between medications and reduce confusion.
 - Also helps pharmacists counsel in most cases
 - Does not have to be clinical indication – just lay language
 - Privacy is an issue, but it can be left to consumers to opt out
 - A panel of experts was asked to modify indications into lay language
- Translations on labels
 - Table of administration times
 - Name of drug and directions translated
 - 2010 study revealed 68% of 552 California pharmacies that were interviewed indicated they provide multilingual labels.

- Issues
 - Literacy in one's own language
 - Pharmacists' lack of understanding in language
 - Unreliable translations
 - Pictograms are ethnically nuanced

Ms. Veale asked if the study found that education improved patient understanding, even if they were assigned the current labels. Dr. Anandi Law confirmed that education improved patient understanding no matter what label was used; however, there was a greater increase in understanding for those who had the redesigned label.

Dr. Anandi Law reported that studies show that 80% of the time any leaflet that a patient is given will be thrown away without being read.

President Weisser asked what should be done with illiterate patients who will not be able to understand the label no matter what language it is provided in. Dr. Anandi Law responded that a verbal consultation would need to be used to educate the patient to the best of the pharmacist's ability.

Dr. Wong asked where a foreign language translation would be provided on the redesigned labels. Dr. Anandi Law responded that currently, they are conducting a study where the labels are translated into Korean. However, in the study the labels only appear in Korean, the information is not also provided in English. Dr. Anandi Law commented that she is not sure that both languages could fit on the label and noted that having both may actually confuse the patient.

10. Linda Neuhauser DrPH, MPH – Professor, School of Public Health University of California, Berkeley

Medications and Patient Communication

- Majority of adverse drug events (ADEs) are related to poor communication
- Half of patients take medications incorrectly
- Patients forget/misunderstand half of verbal instructions
- Medication adherence is related to communication
- Vulnerable populations: low health literacy and limited English proficient (LEP)
 - Less than 20% of California consumers are LEP
 - Vulnerable populations increasing in California:
 - Increase in minority populations
 - ACA enrollment
 - Increase in Medicaid enrollment (25%)
 - Population is aging
 - Shorter clinical encounters

Dr. Castellblanch noted that the board should consider if its regulations address liability for translations.

Dr. Castellblanch asked if Dr. Neuhauser knew who had authority over the additional medication information leaflets that patients are given. Dr. Neuhauser responded that the

FDA oversees that information. She reported that she worked with the FDA on improving the clarity of this information.

Dr. Castellblanch asked if each state still had control of labeling requirements. Dr. Neuhauser confirmed that; however, she noted that the FDA may use their authority to supersede the states as the number of adverse drug events continue to increase.

Dr. Neuhauser stated that New York created the Safe Rx law in response to a civil rights complaint against pharmacy chains.

Dr. Wong asked if it was known how many adverse drug events were caused by a language barrier. Dr. Neuhauser responded that this data was not available; however, she felt that a study would be relatively simple to conduct.

Dr. Wong commented that if a doctor does not write the purpose on the prescription the pharmacist is not allowed to put it on the label. Dr. Neuhauser suggested that the board work with the medical associations to change the practice of doctors not including purpose on their prescriptions.

Dr. Neuhauser commented that patients will often choose not to take a medication because they do not understand the importance of the medication or are confused on how it should be taken.

11. Sarah De Guia – California Pan-Ethnic Health Network

Sarah De Guia reported that there are between six and seven million limited English speakers in California. She added that 1.5 million limited English speakers will become eligible for health care under the Affordable Care Act.

Ms. De Guia stated that a survey showed that limited English speakers were more than twice as likely to have difficulty understanding their prescription labels.

Ms. De Guia explained that her organization has found that limited English speakers do not presume that translations services are available, they instead make due by using family and friends. She added that not all limited English speakers live with someone or near someone who can translate for them.

Ms. Veale asked if they do not know that translations are available or just do not feel comfortable asking. Ms. De Guia responded that they have found that both scenarios are occurring. She suggested that pharmacies collaborate with the doctor so that they know the patient needs a translated label before they even arrive in the pharmacy (some health systems have electronic networks where primary language can be indicated).

Ms. De Guia reported a presidential executive order requires that any entity that receives federal financial assistance is required to ensure that limited English speakers have the ability to access the healthcare services. She clarified that these entities include both public and private businesses. Ms. De Guia also noted that federal law states that oral translations cannot take the place of written translations.

Ms. De Guia encouraged the board to create a protocol for pharmacists so that when a limited English speaker enters their pharmacy they know what they need to do and who they need to call to provide care for the patient. She also asked that the board continue to meet with stakeholders to look at ways they can improve the translations services available.

Ms. De Guia introduced Dr. Dave Margolis, chief resident in medicine at the University of California, San Francisco. Dr. Margolis provided the board with valuable insight into how he provides care to limited English speaking patients. He noted that he knows what pharmacies provide both written and verbal translations and he sends limited English speakers to these pharmacies whenever possible.

Dr. Margolis shared his experience with a patient whose primary language was Spanish. To aid the patient Dr. Margolis attached a hand written note to the pill bottle with directions for use in Spanish. A few weeks later the patient ended up in the hospital. It was discovered that when he had refilled the medication the new pill bottle did not have the directions for use in Spanish because the pharmacy he went to did not provide translation services. This resulted in the patient taking the pills incorrectly and being admitted to the hospital due to a dangerously low heart rate.

Next, Ms. De Guia introduced Hee Po Pak, a 93 year old consumer from the Los Angeles area. Ms. Pak provided testimony in Korean with the use of a translator. Ms. Pak explained to the board the difficulty that many of her elderly friends have in obtaining their prescriptions. They often travel very long distances to Korea Town to obtain their medication because they are not comfortable going to their local chain pharmacies.

Dr. Castellblanch asked if it is difficult for Ms. Pak to receive translated labels. She responded that pharmacies in Korea Town will provide labels in Korean, so she and her friends are willing to travel farther to these pharmacies.

Ms. Veale asked Ms. De Guia if she had any data showing if providing translations on the label or as a supplemental sheet was more effective. Ms. De Guia responded that she did not have any data, but noted that in New York translations are allowed to be provided on a supplemental document.

Mr. Law noted that when a pharmacy signs up with Medicare they are required to indicate what languages are spoken by pharmacy staff.

Dr. Castellblanch asked how limited English speakers find a pharmacy that can provide services in their language. Dr. Gutierrez commented that many clinics know what pharmacies provide services in various languages. Ms. Pak responded that there is a Korean Yellowbook and often doctors will recommend Korean pharmacies.

Mr. Law commented that currently the board requires translation services to be available verbally, but does not require labels to be translated.

Ms. Herold asked Dr. Margolis if he would have a problem with a pharmacist changing the prescription label to say "take one in morning and one in evening" if he had written "BID" on the prescription. Dr. Margolis responded that he would not have any problem with the

pharmacist using their professional judgment to make this change to better serve the patient. Dr. Margolis commented his electronic prescribing system has hundreds of options for directions. Ms. Herold commented that pharmacists seem to be hesitant to use their education and professional judgment to modify directions for use to make the instructions for taking medication clearer.

12. Public Comments

Sujen Sun, a pharmacist, commented that it is particularly difficult to interpret veterinary directions for use. Dr. Ratcliff responded that veterinarians use completely different abbreviations; it is something that pharmacists just have to learn as they go.

Dr. Steve Gray, representing himself, commented that medical schools do not provide any education on how to write a prescription, he encouraged the board to work with the Medical Board and medical associations to change this. He also commented that purpose and condition is important information, and should be included on the label. He encouraged the board to clarify that its inclusion is allowable under the law. Dr. Gray added that if pharmacists don't know what a prescription is for, then they will be unable to provide a quality consultation. President Weisser agreed.

Mandy Lee, from the California Retailers Association, stated that CRA does not oppose the use of translations services. She added that CRA members know the important role that translations play in the health of patients. Ms. Lee noted that many of their members already provide services above and beyond what is required.

Ms. Lee recommended that the board look at ways to better publicize the availability of translation services currently available. Dr. Castellblanch agreed that the board needs to improve consumer education.

Dr. Wong asked how many languages their members offer. Ms. Lee responded that it varies by company.

Dr. Wong asked if CRA members need a regulation to be in place in order to provide translation services. Ms. Lee responded that they would not; as they would respond to the market and the needs to of the patients they serve in order to remain competitive.

Brian Warren, representing the California Pharmacist Association, commented that a similar meeting should be held in the future so that more stakeholders can attend (such as the Medical Board). Mr. Warren encouraged the board to ensure that as they move forward in the regulation process they make decisions based on evidence.

Al Carter, representing Walgreens, reported that Walgreens started the process of providing translations in 2002. He reported that Walgreens uses both employees and a third party vendor to provide verbal translations. Mr. Carter asked the board to consider technology limitations to provide written translations. Mr. Carter also provided the board with a brief report on the ways that Walgreens is expanding their translation services.

Ms. Veale commented that she is happy to see that chain pharmacies are working on improving labels and translation services.

Dr. Castellblanch asked if Walgreens had any opposition when the New York Safe Rx law was being created. Mr. Carter responded that Walgreens was already providing many of the services required by the New York law.

Dr. Wong commented that if pharmacies are already providing the services in response to the market, a regulation should not be required. Dr. Castellblanch disagreed.

Dane Hutchings, with the California Grocers Association, commented that mandated translations on labels may pose a risk as the pharmacist may not understand what the label says. Mr. Hutchings agreed with earlier presenters on the need for liability protection for pharmacists who provide translations.

Dr. Castellblanch asked what the board's next step would be. President Weisser responded that the Communication and Public Education Committee would be taking the information gained at this meeting to further discuss labels and translations and make recommendations to the full board.

It was noted the next Communication and Public Education Committee Meeting would be held September 18, 2014 in Sacramento.

President Weisser adjourned the meeting at 3:30 p.m.