California State Board of Pharmacy
1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

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

DATE: October 28-30, 2015

LOCATION: Department of Consumer Affairs
1st Floor Hearing Room
1625 North Market Blvd.
Sacramento, Ca 95834

BOARD MEMBERS PRESENT:
Amy Gutierrez, PharmD, President
Deborah Veale, RPh, Vice President
Victor Law, RPh, Treasurer
Stanley Weisser, RPh
Gregory Lippe, Public Member
Allen Schaad, RPh
Albert Wong, PharmD (10/29/15 and 10/30/15)
Rosalyn Hackworth, Public Member (10/28/15 and 10/29/15)
Lavanza Butler, RPh (10/28/15 and 10/29/15)
Ricardo Sanchez, Public Member
Ryan Brooks, Public Member (10/28/15)
Gregory Murphy, Public Member

BOARD MEMBERS NOT PRESENT: Ramon Castellblanch, Public Member

STAFF PRESENT:
Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Laura Freedman, DCA Staff Counsel
Joshua Room, Supervising Deputy Attorney General (10/29/15 and 10/30/15)
Laura Hendricks, Staff Analyst
Lori Martinez, Staff Manager
Michael Ignacio, Supervising Inspector

Note: The webcast of this meeting may be found at:
http://www.pharmacy.ca.gov/about/meetings.shtml

Wednesday, October 28, 2015

Call to Order **10:06 a.m.**

I. Call to Order and General Announcements

President Gutierrez called the meeting to order at 10:06 a.m. Board members present: Ryan Brooks, Stanley Weisser, Lavanza Butler, Rosalyn Hackworth, Amy Gutierrez, Greg Murphy, Allen Schaad, Victor Law, Deborah Veale, Ricardo Sanchez and Greg Lippe.

II. Update from the Department of Consumer Affairs (DCA)

Director Awet Kidane gave an update of the DCA's recent activities, including the creations of the new Medical Marijuana Bureau.

Director Kidane announced that the second phase of BreEZe is going smoother than the first phase.

Director Kidane thanked Ms. Herold for her work on the implementation of the CURES 2.0 system.

Director Kidane reported that the DCA legal department would provide a presentation on the North Carolina State Board of Dental Examiners v. Federal Trade Commission United States Supreme Court Ruling at the April board meeting.

III. Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings

Note: The board may not discuss or take action on any matter raised during this public comment section that is not included on this agenda, except to decide whether to place the matter on the agenda of a future meeting. [Government Code Sections 11125, 11125.7(a)]

John Cronin thanked board staff their exceptional customer service while processing a wholesale application for his client.

Roger Morgan, founder of the Take Back America Campaign, and Bishop Allen spoke on behalf of Fred Meyer against the use of medical marijuana. The board noted that it does not have jurisdiction over medical marijuana and recommended that the speakers meet with the DCA to discuss the new Medical Marijuana Bureau.

IV. Approval of the September 15, 2015 and September 30, 2015 Board Meeting Minutes

Motion: Approve the September 15, 2015, and September 30, 2015, board meeting minutes.

M/S: Weisser/Hackworth

Support: 10 Oppose: 0 Abstain: 1

Name	Support	Oppose	Abstain	Not Present
Brooks			x	
Butler	x			
Castellblanch				x
Gutierrez	x			
Hackworth	x			
Law	x			
Lippe	x			
Murphy	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong				x

V. Recognition and Celebration of Pharmacists Licensed In California for 50 Years

The board recognized Rosalie Mc Ilroy, Gary W. Gray, Richard Wolfe, Gary Reeder, Ronald E. Grady and Vince Sue for 50 years of service as pharmacists.

VI. Licensing Committee

a. Pharmacy Technician Requirements Assessment

1. Pharmacy Technician Accreditation Commission (PTAC) Information

Chairperson Weisser explained that currently the law creates several pathways to licensure as a pharmacy technician, including the completion of a training program that meets one of the following criteria:

- Training program is accredited by the American Society of Health-System Pharmacists (ASHP)
- Training program is provided by a branch of the federal armed services
- Course provides a training period of at least 240 hours of instruction covering specified areas of pharmacy practice.

Chairperson Weisser stated that in 2013, the new Pharmacy Technician Accreditation Commission (PTAC) was launched. The PTAC is a collaboration of the ASHP and the Accreditation Council for Pharmacy Education (ACPE) and is tasked with assuring and advancing the quality of pharmacy technician education and training programs.

Chairperson Weisser reported that the committee heard a presentation on the PTAC by Dr. Peter Vlasses, Executive Director of the ACPE. Chairperson Weisser noted that following the presentation the committee discussed various components of pharmacy technician training programs, expressed concerns with the timing of background checks that are conducted (after program costs have been incurred by students).

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

2. National Changes to the Pharmacy Technician Certification Board (PTCB)

Chairperson Weisser explained that currently the law creates several pathways to licensure as a pharmacy technician including certification by the Pharmacy Technician Certification Board (PTCB).

Chairperson Weisser reported that the Pharmacy Technician Certification Board (PTCB) starting implementing changes to the certification program in 2014 and will continue through 2020. He noted that the changes are designed to advance pharmacy technician qualifications by elevating PTCB's standards for certification and recertification. Chairperson Weisser reviewed the changes to the PTCB as provided below.

Certification Changes:

- Completion of an ASHP-accredited pharmacy technician education program by 2020

Recertification Changes:

- One hour of medication safety continuing education (CE) by 2014. This is in addition to the one hour of law CE currently required.
- Twenty hours of pharmacy technician-specific CE by 2015. As part of this implementation, PTCB will gradually reduce the number of hours that can be earned via college/university coursework as well as the number of hours that can be earned through in-services.

Chairperson Weisser stated that the committee was concerned that the PTCB would not be implementing criminal background checks as part of their program.

Mr. Brooks stated that the board had previously discussed notifying all pharmacy technician schools that their students may not be licensed if they have a criminal background. Chairperson Weisser responded that the schools are well aware of the criminal background checks conducted by the board; however they have a financial incentive to enroll students even if they have a criminal background.

Chairperson Weisser stated that the board is creating a video on the application process which would include information on criminal background checks.

Ms. Hackworth and Mr. Brooks again stated their concern that students are not notified about problems with their criminal background until after they have paid for the training programs.

b. Pharmacy Technician Licensure Requirements and Practice and Possible Changes

Chairperson Weisser briefly reviewed the definition of a pharmacy technician as defined in Business and Professions Code Section 4038 as well as the general requirements for an applicant seeking licensure as a pharmacy technician.

Chairperson Weisser explained that Title 16 CCR 1793.7 establishes the requirements for pharmacies employing pharmacy technicians and includes provisions that the supervising pharmacist is fully aware of all activities of a pharmacy technician under his or her direct supervision. Chairperson Weisser noted that this section provides that a pharmacist shall be responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk to patients.

Chairperson Weisser reported that at several meetings the board has discussed different facets of the pharmacy technician program. He added that board has discussed its desire to raise the bar to qualify for licensure as a pharmacy technician, and has also expressed concern with the training programs that are accepting students with criminal backgrounds, who likely will not become licensed.

Chairperson Weisser stated that the board requested that the committee consider the possibility of creating different types of pharmacy technician licensure (i.e., hospital, compounding, community, etc.). Chairperson Weisser stated that following the board's direction, the committee discussed the existing licensure requirements and noted that while the educational requirements for pharmacists have changed, the pharmacy technician requirements have not.

Chairperson Weisser reported that the committee heard comments from the public in support of increasing the knowledge of pharmacy technicians, but not necessarily by increasing the statutory minimum educational requirements.

Chairperson Weisser stated that the committee made the following recommendation to the board:

Committee motion: Approve changes to the Pharmacy Technician requirements as follows:

Amend Business and Professions Code section 4202 to require that all new applicants seeking licensure as a pharmacy technician meet one of the following educational requirements:

1. Be required to have two years (60 college credits) or an associate degree, and successful completion of a pharmacy technician training program accredited by the PCAB, and be PTCB certified at the time of application.
2. Military training.
3. Graduation from a school of pharmacy recognized by the board.

In addition to reviewing the qualifications for initial licensure Ms. Veale asked the Licensing Committee to consider requiring pharmacy technicians to maintain a current PTCB certification in order to renew their license.

Ms. Veale expressed concern with requiring pharmacy technicians to complete 60 college credits prior to applying for licensure. Mr. Law responded that the board sees a large number of discipline cases for pharmacy technicians, by elevating the qualification requirements the pharmacy technicians will have more invested into their licensure and will be less likely to violate pharmacy law. Mr. Law also noted that the salary for pharmacy technicians has been increasing.

Mr. Sanchez agreed with the need to elevate the qualification standards for pharmacy technicians.

Ms. Veale agreed that there are a significant number of disciplinary cases; however she questioned the correlation between a college degree and the lowering of discipline.

Ms. Herold reported that staff reviewed pharmacy technician licensees over a four year period and found that of those technicians who had been disciplined, over 80 percent had qualified for licensure by completing a training program. Ms. Herold added that she would provide more detailed statistics at the next Licensing Committee Meeting.

Ms. Veale stated that the board will always see more disciplinary cases for pharmacy technicians simply because there are more pharmacy technicians licensed in California than pharmacists and interns.

President Gutierrez stated that as pharmacists take on a larger role in the care of patients, technicians will be relied on more. She added that she would like to see different levels of pharmacy technician licensure, similar to the new APP pharmacist license.

Mr. Brooks stated that he would like the board to consider if raising the qualifications will create the unintended consequence of creating a pharmacy technician shortage. President Gutierrez agreed that the possibility of creating a shortage is something that the board needs to discuss when considering raising the qualification standards.

Mr. Schaad expressed his concern that requiring college education may eliminate many people from qualifying for licensure and may create a shortage. Ms. Butler agreed with Mr. Schaad's statement.

Mr. Schaad and Ms. Hackworth stated that they would like the board to require schools to provide information on criminal background disqualification *prior* to enrolling students.

The board asked staff to provide more detailed statistics on pharmacy technician qualification methods and discipline at the next Licensing Committee meeting.

Chairperson Weisser asked if the board would like to vote on the committee recommendation or if they would like to table the motion so that the committee could review more statistics and discuss the topic further.

The board tabled the committee motion.

Mr. Brooks asked the committee to consider if education level correlates to the likely hood of discipline.

President Gutierrez asked the committee to obtain testimony from chain drug stores on their pharmacy technician training programs and the changing landscape of the practice of pharmacy.

Dr. Steve Gray commented that this topic is being discussed at national meetings and encouraged the board to get stakeholders involved in the discussion and look at what other states require for pharmacy technician requirements.

Brain Warren from CPhA stated that their organization will be forming a workgroup to study pharmacy technician job duties. Chairperson Weisser volunteered to represent the board in the workgroup.

Pat Whalen on behalf of National Healthcareer Association (NHA) stated that their organization has conducted a workforce study for pharmacy technicians and he would be presenting the findings at the next Licensing Committee Meeting.

Angie Manetti, representing the California Retailers Association, supported the board's decision to table the motion and allowing retailers to provide information on their training program to the committee. Mr. Law asked CRA to provide the average pay for pharmacy technicians in chain drug store at the next Licensing Committee meeting. Chairperson Weisser asked CRA to report on any criminal background checks that chain drug stores conduct on pharmacy technicians. Ms. Manetti stated that she would gather the requested information for the next Licensing Committee.

A pharmacy technician training instructor thanked the board for their in-depth discussion and stated that if the board decides to require 60 hours of college education they should require it to be in a subject related to the practice of pharmacy.

Mr. Law asked the Licensing Committee to continue the discussion on pharmacy technician duties and qualifications at the next Licensing Committee Meeting.

Motion: Direct the Licensing Committee to gather statistics and information on pharmacy technician qualification methods and discipline and invite stakeholders to participate in the discussion.

M/S: Law/Butler

Support: 11 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks			x	
Butler	x			
Castellblanch				x
Gutierrez	x			
Hackworth	x			
Law	x			
Lippe	x			
Murphy	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong				x

The board recessed for a lunch break at 12:15 p.m. and resumed at 12:45 p.m.

c. <u>Pharmacy Technician Application Requirements Video</u>

Chairperson Weisser reported in the past the committee has discussed the deficiency rates of pharmacy technician applications. Over the years the board has tried various approaches to reduce the deficiency rates, to include updating the application form and instructions, including a fact sheet with the application, and maintaining a Frequently Asked Questions link on the board's web site.

Chairperson Weisser stated that to further these efforts board staff has been working with the department to develop a video on how to complete a Pharmacy Technician Application. He added

that the script has been finalized however there currently is no timeline for completion of the video as the department video team is currently working on other projects.

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

d. North American Pharmacist Licensure Examination Changes

Chairperson Weisser explained that the NAPLEX examination is developed and administered by the National Associations of Boards of Pharmacy (NABP). On July 12, 2015, the NABP announced plans for enhancements across all of the NABP examination and assessment programs, including the NAPLEX.

Chairperson Weisser reported that in November 2015 a new NAPLEX competency statement and a revised passing standard will be implemented. He added that the NAPLEX will make a progressive transition to a new administration model in 2016 after which the NAPLEX will increase in length from 185 items to 250 items.

Chairperson Weisser concluded that additional changes to the NAPLEX scoring are being evaluated as well; however, there is no proposal yet for state boards of pharmacy to consider.

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

e. Accreditation Council for Pharmacy Education Updates of Curriculum Requirements for Pharmacists

Chairperson Weisser explained that the Accreditation Council for Pharmacy Education (ACPE) is the national agency for the accreditation of professional degree programs in pharmacy.

Chairperson Weisser reported that during its January 2015 meeting the ACPE Board of Directions announced its approval of new *Accreditation Standards and Key Elements for the Professional Program in Pharmacy Leading to the Doctor in Pharmacy Degree ("Standards 2016").* In its press release the ACPE noted the following:

> "Standards 2016 are employed for quality assurance so graduates of pharmacy education programs are practice-ready and team-ready and therefore, prepared to directly provide patient care in collaboration with other healthcare providers. Standards 2016 articulate the expectations of ACPE, the academy, the practice communication, and the U.S. Department of Education and are solidly based on evidence and experience."

Chairperson Weisser stated that the new standards and guidance will become effective July 1, 2016 and will be used in accreditation reviews beginning September 2016.

Chairperson Weisser reported that at its recent meeting, the committee heard a presentation from Dr. Peter Vlasses, Executive Director, ACPE, on the new standards.

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

f. Implementation of Pharmacy Curriculum Outcomes Assessment to be Used by Schools of Pharmacy

Chairperson Weisser reported that on June 23, 2015, the NABP released updated information about the status of implementation of the Pharmacy Curriculum Outcomes Assessment (PCOA) to all schools and colleges of pharmacy. It its release, the NABP indicates that administration of the PCOA at or near the end of the didactic curriculum will be at no cost. However if a school chooses to schedule a second administration for students the current fee of $75.00 will apply.

Chairperson Weisser stated the according to the NAPB, the PCOA provides a valid and reliable assessment of student competency in four board science domains:

- Biomedical science
- Pharmaceutical science
- Social/Behavioral/Administrative science
- Clinical science

Chairperson Weisser explained that although this assessment tool is not new, it will now be integrated into all colleges and schools of pharmacy consistent with ACPE standards. He added that the PCOA will be adjusted moving forward to conform to all of the new ACPE standards.

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

g. Competency Committee Report

Chairperson Weisser reported that effective August 1, 2015, the board instituted a quality assurance review of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE). He explained that this means that there was a delay in the release of all CPJE examination scores. This process is done periodically to ensure the reliability of the examination. Chairperson Weisser reported that the board released the quality assurance review the week of October 12, 2015.

Chairperson Weisser reported that the Competency Committee held its annual meeting in August as well as workgroup meetings in September and October to fulfill examination development related duties.

Chairperson Weisser stated that examination scores for the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE) and North American Pharmacist Licensure Examination (NAPLEX) are released twice a year, generally in spring and fall.

Chairperson Weisser reviewed the Semi-Annual CPJE statistical report for April 1, 2015, through September 30, 2015, which reflects the overall pass rate for the CPJE was 84.7%. The pass rate for graduates from the California Schools of Pharmacy was 92.6%. The overall pass rate for the NAPLEX was 96.4%.

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

h. Pharmacy Application Requirements

Chairperson Weisser reported that at its recent meeting, senior manager, Carolyn Klein, gave a presentation on pharmacy application requirements. He noted that the presentation was an overview of how a community pharmacy application is processed by the board, and included items that are common deficiencies.

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

i. Status of Implementation of Legislation (AB 2605) Regarding Third-Party Logistics Providers

Chairperson Weisser reported that Effective January 1, 2015, the board implemented licensing Third-Party Logistics Providers in state and out of state as well as Designated Representatives-3PL based on the recent change in federal legislation that expressly states 3PLs cannot be licensed as wholesalers but as a unique licensure class.

Chairperson Weisser stated that in December 2014, the board received its first nonresident Third-Party Logistics Provider application. Chairperson Weisser reported that the board issued its first nonresident Third-Party Logistics Provider and Designated Representative – 3PL licenses in February 2015.

Chairperson Weisser reported that the board is continuing to educate applicants and other states about the requirements for these three new license categories. Chairperson Weisser added that on April 17, 2015, the board issued a subscriber alert on "Guidance for Third-Party Logistics Providers Currently Licensed as Drug Wholesalers" in order inform consumers and licensees of the new law and to provide guidance on the licensure requirements.

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

j. Licensing Statistics

Chairperson Weisser reported that as of September 30, 2015, the board has 139,554 licensees, including almost 43,300 pharmacists and almost 74,700 pharmacy technicians. He directed the board and the public to review the meeting materials for more detailed statistics.

The board commended licensing staff for working to decrease application processing times to less than 30 days.

k. Future Committee Meeting Dates

Chairperson Weisser reported that the Licensing Committee has established the following dates for future meetings:

January 6, 2016
March 30, 2016
May 26, 2016
September 21, 2016

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

VII. Organizational Development Committee

a. Budget Update/Report

1. Final Budget Report for 2014/2015

President Gutierrez reported that fiscal year 2014/15 ended June 30, 2014. President Gutierrez noted that the final budget numbers were not available until the beginning of August 2015. She highlighted the board's expenditures and revenue as provided below.

- Expenditures: $19,611,614
- Maximum spending authority for year: $20,598,708 (includes $1.4 million Attorney General augmentation)
- Revenue Collected (as of July 2015): $18,951,500

Ms. Herold noted that a significant amount of the board's licensing revenue came from a buyout of a major chain pharmacy.

President Gutierrez explained that 58 percent of the board's expenditures were attributed to personnel; and 19 percent was related to enforcement and 13 percent was attributed to prorata. She added that revenue for the year came primarily from application and renewal fees, 88 percent; with citation and fines accounting for 8 percent.

2. Budget Report for 2015/2016

President Gutierrez reported that the new budget year began July 1, 2015. The board's spending authorization for the year is $19,770,000 which is a 3 percent increase from the prior year.

President Gutierrez explained that based on preliminary first quarter information, the board has expended $4,629,287 and taken in $5,132,000 in revenue.

Budget charts detailing revenue and expenditure information for the first quarter of the fiscal year were provided in the board meeting materials.

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

3. Fund Condition Report

President Gutierrez explained that the information below reflects the estimated fund condition with the additional revenue from the approved fee increase:

2014/15	$11,741,000	7.1
2015/16	$ 8,577,000	5.1
2016/17	$ 5,118,000	2.7
2017/18	-$ 1,391,000	-0.8

President Gutierrez stated that as the fund condition reflects, the board will need to pursue a fee increase to sustain operations. She explained that as a precursor to making such a determination a fee audit is underway, similar to the one completed several years ago in advance of the board's 2008 fee bill.

b. DCA Fee Audit and Possible Statutory Changes to Board Fees

President Gutierrez reported that the board secured a contract with a company to conduct an independent audit of the board's fee structure to determine the costs to deliver services. Unfortunately, after consultation with the DCA's budget office, it was clear that the board is unable to use the draft information provided by the contractor.

President Gutierrez explained that the DCA's budget office would complete the necessary independent assessment and provide written recommendations on the appropriate fees necessary to ensure the board receives full recovery for the costs it incurs to deliver services.

President Gutierrez reported that board staff is working with the budget office to evaluate the current fee structure based upon the cost to deliver the services. She added that it is the intent to bring draft legislation to the November board meeting for members to consider restructuring our fees to address the current structural imbalance in our budget.

Taylor Schick, DCA budget officer, and Robert De los Reyes, DCA budget manager, updated the board on the fee assessment. Mr. Schick explained that the budget office is zero basing the board's budget by completing time taking for each function completed by board staff. The time tasking will then be used to determine the cost of delivering the service. He added that overhead costs, such as administrative staff, will also be factored into the cost. Mr. Schick explained that the board's enforcement cost would mostly be applied to renewal fees, as discipline is typically taken against current licensees.

President Gutierrez asked if the board would reassess the fees in the future if technology streamlines the board's processes. Mr. Schick explained that the board would need to conduct ongoing fee assessments to account for changes in the board's licensee population and improvements in technology.

Ms. Herold thanked the DCA budget office for their work on the fee analysis.

c. Board's Current Strategic Plan and Progress

President Gutierrez reported that the board's Strategic Plan for 2012-17 was developed in 2011-12. The board used a consultant in concert with board staff and then board president Weisser to develop the strategic plan. She stated that at the May 2012 board meeting, the board unanimously voted to approve the Strategic Plan for 2012-17.

President Gutierrez explained that a review of the board's Strategic Plan for 2012-17 was conducted by assessing the current relevance of the plan's responsibilities, strategic objectives, and performance measures/success indicators for each of the five board committees.

President Gutierrez stated that board staff is offering for consideration several additions and modifications to the current Strategic Plan to ensure that it accurately reflects the priorities and focus of the board.

Note: A copy of the board's Strategic Plan incorporating the proposed changes (indicated in red) was provided in the board meeting materials.

Ms. Sodergren explained that the proposed changes include updates to the work each committee has completed since the Strategic Plan was finalized in 2012.

Motion: Approve the changes to the Strategic Plan as provided in the board meeting materials, with the correction of the Sunset date.

M/S: Veale/Weisser

Support: 11 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks	x			
Butler	x			
Castellblanch				x
Gutierrez	x			
Hackworth	x			
Law	x			
Lippe	x			
Murphy	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong				x

d. Future Strategic Planning - Presentation on The Department's Strategic Planning Services

Dennis Zanchi, Organizational Development Manager with the DCA SOLID Training and Planning Unit, provided the board with an overview of the strategic planning process.

Mr. Zanchi provided the board with a handout illustrating the timeline for completing the board's strategic plan. The handout has been provided immediately following these minutes.

Ms. Herold explained that the board staff would begin the background work on the strategic plan in January and at the April board meeting eight hours would be dedicated to completion of the plan.

e. Formation of a Committee to Hear Petitions for Reinstatements, Early Termination or Modification of Penalty

President Gutierrez explained that Business and Professions Code Section 4309 sets forth the

requirements for a person whose license has been disciplined by the board to petition the board for reinstatement of a revoked license or to petition the board for a modification of penalty, including early termination of the probationer period. She added that subdivision(c) of this section allows for a petition to be heard in three ways:

1. Board members sitting with an administrative law judge
2. A committee of the board sitting with an administrative law judge
3. The board may assign the petition to an administrative law judge

President Gutierrez explained that currently, petitions hearings are held in conjunction with board meetings and are presided over by an administrative law judge. There are many times when petitioners must wait several board meetings before having their petitions heard because of other board business. She noted that when possible the board typically dedicates about four to five hours each meeting for this purpose.

President Gutierrez reported that during its January 2014 Board Meeting, the board considered a recommendation to change its policy to have petitioners heard by a committee of the board sitting with an administrative law judge. At that time the board did not approve the change. President Gutierrez stated that members at the time noted their preference was to continue to have the full board hear petitioner requests and indicated their preference to schedule additional meetings to hear petitions.

President Gutierrez explained that since that time the board has heard 16 petitioner requests, 14 of which were heard during special board meetings. She added that despite these additional meetings, the board currently has 12 petition requests pending.

President Gutierrez stated that she is recommending a change in the board's policy to allow for more timely consideration of petitioners. The three options provided below were presented to the board for consideration and discussion.

Option 1: It is the board's policy that, for purposes of hearing petitions for reinstatement of a license or petitions for reduction of penalty, including modification or termination of probation, a third day shall be added to all quarterly board meetings which shall be used for this purpose. Board members available shall attend the additional day and the hearings will be presided over by an administrative law judge. A quorum of the board will not be required to hear petitions, however all board members will have the opportunity to vote on the decision made when a quorum of the board is not present.

Option 2: It is the board's policy that, for purposes of hearing petitions for reinstatement of a license or petitions for reduction of penalty, including modification or termination of probation, a third day shall be added to all quarterly board meetings which shall be used for this purpose. Board members available shall attend the additional day and the hearings will be presided over by an administrative law judge. A quorum of the board will be required to hear petitions.

Option 3: It is the board's policy that, for purposes of hearing petitions for reinstatement of a license or petitions for reduction of penalty, including modification or termination of probation, board meeting shall occur every two months to accommodate petitioner

requests.

The board discussed the pros and cons of each option.

Mr. Brooks stated that he would like the full board to continue to hear petitioners as the differing viewpoints result in meaningful discussion and quality decisions.

Mr. Brooks recommended that board hold one-day board meetings once per quarter with the sole purpose of hearing petitioners. Mr. Lippe agreed that holding one-day board meetings would be preferential over adding a third day to existing board meetings.

Mr. Weisser expressed support of forming a committee of the board to hear petitioners.

The board discussed the option of holding a one-day board meeting that could convert to a committee meeting if a quorum could not be reached. Ms. Freedman stated that she would work with staff to properly agendize the meeting to allow for this option.

President Gutierrez asked staff to alternate scheduling meeting in northern and southern California to accommodate petitioners.

Motion: Schedule one-day board meetings once per quarter to hear petitioners. If a quorum cannot be reached, the meeting will be converted to a committee meeting.

M/S: Brooks/Veale

Support: 11 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks	x			
Butler	x			
Castellblanch				x
Gutierrez	x			
Hackworth	x			
Law	x			
Lippe	x			
Murphy	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong				x

f. <u>Board's Mail Vote Policy and Procedures</u>

President Gutierrez reviewed that the board's current policy for mail votes including the following:

If two votes are cast before the deadline to hold a case for discussion, the case is set

aside and not processed (even if seven votes have been cast on the decision). Instead the case is scheduled for discussion during closed session at the next board meeting. Under board policy when a member wishes to hold a case, the reason for the hold must be provided on the mail ballot. This allows staff the opportunity to prepare the information being requested.

President Gutierrez reported that at the last board meeting the board approved new mail ballots in an attempt to clarify the mail voting procedures.

President Gutierrez stated that the board's policy should be changed as provided below. The board agreed with her recommendation.

> If two votes are cast before the deadline to hold a case for discussion, the case is set aside and not processed (even if seven votes have been cast on the decision). Instead the case is scheduled for discussion during closed session at the next board meeting. Under board policy when a member wishes to hold a case, the reason for the hold ~~must~~ should be provided on the mail ballot. This allows staff the opportunity to prepare the information being requested.

Mr. Brooks thanked staff for their responsiveness in answering questions on mail votes.

President Gutierrez noted that if the board has questions on stipulated settlements they can ask Ms. Sodergren, and for questions on all other decisions they can call Ms. Freedman.

Ms. Butler asked when it was decided that two members could hold a decision. Ms. Herold explained that this has been board policy for a number of years, she added that the board could elect to change this policy. Ms. Freedman stated that the majority of boards use the two member hold policy. She explained that holding a decision is intended to facilitate a discussion on the matter during closed session.

Motion: Modify the board's mail vote policy as provided below.

> If two votes are cast before the deadline to hold a case for discussion, the case is set aside and not processed (even if seven votes have been cast on the decision). Instead the case is scheduled for discussion during closed session at the next board meeting. Under board policy when a member wishes to hold a case, the reason for the hold ~~must~~ should be provided on the mail ballot. This allows staff the opportunity to prepare the information being requested.

M/S: Law/Butler

Support: 11 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks	x			
Butler	x			
Castellblanch				x
Gutierrez	x			

Hackworth	x			
Law	x			
Lippe	x			
Murphy	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong				x

g. Presentation on the Disciplinary Process

DCA Counsel Laura Freedman provided the board with a presentation on the disciplinary process. The information presented by Ms. Freedman is provided immediately following these minutes.

h. Policy Regarding Waivers of Statutory Provisions in a Declared Emergency and Possible Revisions

President Gutierrez reported that on September 15, 2015, the board held an Emergency Board Meeting in response to the wildfires in Lake and Napa counties.

President Gutierrez explained that in light of the recent use of the policy it is being brought to the board for evaluation and assessment to determine if changes to the policy are necessary. She stated that she would like the Enforcement Committee to evaluate the policy and report their recommendation to the full board. The board agreed with President Gutierrez's recommendation.

i. Board Member Reimbursement and Mail Vote Information

President Gutierrez reported that the reimbursement and mail vote information were provided in the meeting materials.

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

j. Personnel Update

The board reviewed the personnel update as provided in the board meeting materials.

k. Future Board Meeting Dates

President Gutierrez announced the following board meeting dates.

- November 11, 2015, Irvine, CA
- February 2-3, 2016, location to be determined
- April 27-28, 2016, location to be determined
- July 27-28, 2016, location to be determined
- October 26-27, 2016, location to be determined

The board recessed to a break at 3:15 p.m. and resumed at 3:37 p.m.

Note: Mr. Brooks returned at 3:35 p.m.

VIII. Communication and Public Education Committee

Note: Agenda item "a" was presented by Ms. Hackworth as Ms. Veale recused herself due to her relationship with CVS Health.

a. Request for Waivers of Requirements for Patient-Centered Labels as Provided in California Business and Professions Code Section 4076.5(d) from: Coram CVS/Specialty Infusion Services

Ms. Hackworth explained that the statutory requirements for patient-centered labels contain a provision that allows the board to provide a waiver from the requirements in certain circumstances.

Ms. Hackworth reviewed that the provisions that provide the waiver from section 4076.5(d) as provided below:

> (d) The board may exempt from the requirements of regulations promulgated pursuant to subdivision
> (a) prescriptions dispensed to a patient in a health facility, as defined in Section 1250 of the Health and Safety Code, if the prescriptions are administered by a licensed health care professional. Prescriptions dispensed to a patient in a health facility that will not be administered by a licensed health care professional or that are provided to the patient upon discharge from the facility shall be subject to the requirements of this section and the regulations promulgated pursuant to subdivision (a). Nothing in this subdivision shall alter or diminish existing statutory and regulatory informed consent, patients' rights, or pharmaceutical labeling and storage requirements, including, but not limited to, the requirements of Section 1418.9 of the Health and Safety Code or Section 72357, 72527, or 72528 of Title 22 of the California Code of Regulations.
> (e) (1) The board may exempt from the requirements of regulations promulgated pursuant to subdivision (a) a prescription dispensed to a patient if all of the following apply:
> (A) The drugs are dispensed by a JCAHO-accredited home infusion or specialty pharmacy.
> (B) The patient receives health-professional-directed education prior to the beginning of therapy by a nurse or pharmacist.
> (C) The patient receives weekly or more frequent followup contacts by a nurse or pharmacist.
> (D) Care is provided under a formal plan of care based upon a physician and surgeon's orders.
> (2) For purposes of paragraph (1), home infusion and specialty therapies include parenteral therapy or other forms of administration that require regular laboratory and patient monitoring.

Ms. Hackworth explained that the board has heard several requests from entities over the years, but has never approved a waiver.

Ms. Hackworth stated that the board received a waiver request from Coram CVS/Specialty Infusion Services. She reported that at the October 2015 Communication and Public Education Committee, Ms. Lauren Berton, Director of Pharmacy Regulatory Affairs, CVS Health, which includes Coram CVS Specialty Infusion Services, and Patricia Igarashi, Pharmacist and Branch Manager in Hayward, California presented Coram CVS Specialty Infusion Services' request for waiver grant an exemption to Business and Professions Code section 4076.5 (e) (2) and California Code of Regulation section

1707.5.

Note: A copy of Coram CVS/Specialty Infusion Services' request for waiver and presentation was included in the board meeting materials.

Ms. Hackworth reported that the committee inquired further about the processes used by Coram CVS/Specialty Infusion Services and the exemption sought.

Ms. Hackworth noted that Mr. Brooks requested Coram brings a sample TPN bag to the full board meeting. Ms. Lauren Berton, Director of Pharmacy Regulatory Affairs for CVS Health, provided samples of their TPN bags to the board as requested by Mr. Brooks at the committee meeting.

The board clarified that CVS Health is requesting that the font on their TPN bags be in 10 point font.

The board asked if other home health clinics use 10 or 12 point font. Supervising Inspector Anne Hunt reported that inspector see a both font sizes being used. Ms. Herold stated that she expects the board to receive more waivers in the future.

Mr. Weisser stated that as the patient receives training from healthcare providers he would approve the waiver to allow 10 point font on the label. Ms. Brooks agreed with Mr. Weisser.

Robert Stein, from KGI School of Pharmacy, recommended the board promulgate regulations that would specifically exempt these entities from the font size requirements.

Mr. Brooks asked why the committee only approved the waiver for two years. Ms. Hackworth explained that as this is the first waiver that the committee has approved and therefor the committee intended the two year waiver to serve as a pilot program.

The board asked the Communication and Public Education Committee to consider drafting a regulation that would either exempt these entities from the font size requirement or at least streamline the waiver process.

Committee Recommendation (Motion): Recommend to the board that Coram be granted a two year conditional waiver and Coram be required to self-report complaints to the board.

Support: 10 Oppose: 0 Abstain: 1

Name	Support	Oppose	Abstain	Not Present
Brooks	x			
Butler	x			
Castellblanch				x
Gutierrez	x			
Hackworth	x			
Law	x			
Lippe	x			
Murphy	x			
Sanchez	x			
Schaad	x			

Veale			x	
Weisser	x			
Wong				x

b. Survey Questionnaire with Regard to Patient Consultation Released in July 2015 and Possible Revision for Future Use

Chairperson Veale reported that at the July Board Meeting, the board reviewed the results of a short questionnaire made available to the public via Survey Monkey regarding patient consultation. Over 1,000 individuals responded to this survey.

Note: A copy of initial survey and results were provided in the board meeting materials**.**

Chairperson Veale stated that during the discussion on the results of the survey, there were questions raised about the quality of the questions themselves. The board asked that the committee take a look at the questionnaire and see if it could be improved.

Chairperson Veale reported that at the October 2015 Communication and Public Education Committee, the committee decided that the survey was a good place to start but preferred improving the survey prior to taking action and inquired as to the resources within the Department of Consumer Affairs.

Chairperson Veale explained that the committee expressed concern that survey did not clearly illustrate *why* consultation is not regularly performed, and whether the issue involves additional education, training, or staffing problems. The committee was not comfortable making statutory or regulatory changes regarding consultation solely based on the survey.

Chairperson Veale stated that the committee decided to bring the conversation to the full board for more discussion.

Ms. Hackworth noted that the committee discussed the need to improve the wording of the questions on the next survey to improve the results.

The board discussed the issues that can impede consultation, including staffing levels and pharmacy technicians screening patients.

The board discussed the possible statutory and regulatory changes based on the results of the survey including stronger discipline for lack of consultation, limiting the number of prescriptions filled and changing the pharmacist to pharmacy technician ratio.

Ms. Herold asked the board if they would like the committee to formulate survey questions to bring before the board for approval. The board asked that the committee consider the use of survey experts when formulating the new survey.

Dennis McAllister, member of the Arizona Board of Pharmacy, explained that their board elected to eliminate the pharmacy to pharmacy technician ratio and they have seen an improvement in consultation rates.

William Culver, president of the Indiana Board of Pharmacy, recommended that the board collaborate with schools of pharmacy to draft the survey.

Robert Stein, with KGI School of Pharmacy, recommended the board collect information on how the patient refuses consultation (i.e. verbally or via signature pad).

The board asked the committee to continue their work on the survey.

The board recessed to closed session at 4:25 p.m. to handle a time-certain item. The board resumed open session at 5:11 p.m.

Note: Mr. Murphy left the meeting at 5:10 p.m.

c. Request to Augment Information on the Board's Website Regarding the State's Emergency Contraception Protocol

Chairperson Veale explained that for a number of years, California has had a protocol that allows pharmacists to provide emergency contraception to patients who request it. The protocol was developed by a group of sponsors for the enabling legislation, vetted and approved by the board and the Medical Board.

Note: A copy of statutes and information regarding Emergency Contraception were provided in the board meeting materials.

Chairperson Veale stated that recently, the board received a request from Professor Sally Rafie, PharmD, BCPS, from UCSD's School of Pharmacy. In her request, Dr. Rafie provided information about components she believes would provide better information to pharmacists who provide emergency contraception and educational items for the public who may seek emergency contraception.

Chairperson Veale reported that at the October 2015 Communication and Public Education Committee Dr. Rafie joined the committee meeting via telephone call. The committee found Dr. Rafie's materials to be very informative and her ideas of placement to expose these protocol facts to both the pharmacists and the public very clear and helpful.

Chairperson Veale explained that the committee felt the first page of Dr. Rafie's handout was helpful; however, the committee was concerned that the second page displayed actual products that may be misconstrued as board endorsement or advertising.

Chairperson Veale reported that the committee requested Dr. Rafie send the board a letter from the Reproductive Health Technologies Project or from another group that has been a proponent of the protocol over the years, stating that distributing this information would be a beneficial step for the cause, and thereby further validate placing the information on the board's web site.

Committee Recommendation (Motion): Recommend to the board placing the information on the board's Web site provided the product brand names, pictures, and prices are deleted, and request a follow up with legal counsel on appropriateness.

Support: 10 Oppose: 0 Abstain: 0

	Support	Oppose	Abstain	
Brooks	x			
Butler	x			
Castellblanch				x
Gutierrez	x			
Hackworth	x			
Law	x			
Lippe	x			
Murphy				x
Sanchez	x			
Schaad	x			
Veale			x	
Weisser	x			
Wong				x

d. October is "Talk About Prescriptions Month"

Chairperson Veale reported that every October, the National Council on Patient Information and Education (NCPIE) promotes consumer education themes. This year, the theme is again "Talk About Your Medications Month." The goal is to "focus attention on the value that better medicine communication can play in promoting better medicine use and better health outcomes."

Chairperson Veale reported that in their press release, NCPIE states:

> The ultimate objective of any communication between patients and their healthcare providers is to improve the patient's health and medical care. Good communication is at the heart of good medicine. In fact, data have shown that patients reporting good communication with their health providers are more likely to be satisfied with their care, follow advice and adhere to the prescribed treatment. Of course, communication is a two-way street. Consumers need to be aware of the questions to ask, and healthcare providers in turn must be able to share medical information in a meaningful way that their patients are able to understand and act on. To that end, Talk About Your Medicines Month empowers both.

Chairperson Veale stated that there would be a press release written by and issued this month from the board's new Public Information Officer, Ed Selznick. She noted that a copy of the board's press release will be available as a handout at the next board meeting.

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

e. Redesign of the Board's Website

Chairperson Veale reported that board webmaster Victor Perez continues his work on redesigning the board's Web site to make it more user-friendly.

Chairperson Veale stated that the goal is to finish the work by the end of 2015.

Chairperson Veale explained that the committee Chair and Vice Chair will review the website prior to release.

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

f. .Pharmacy Domain and Options for the Board to Distribute Public Information

Chairperson Veale stated that the National Association of Boards of Pharmacy has established a .pharmacy (pronounced as "dot pharmacy") top level domain suffix system that will identify websites that comply with NABP's standards. She added that the committee will continue to discuss ways to promote the use of the .pharmacy domain.

g. Status of Final Report on the Activities of the Prescription Drug Abuse Subcommittee

Chairperson Veale reported that over the last two years, the board convened a Prescription Drug Abuse Subcommittee to deal with issues relating to prescription drug abuse. She added that seven subcommittee meetings were held.

Chairperson Veale explained that recently, Chairperson of the subcommittee, Ramón Castellblanch offered to write a report summarizing the major work of this subcommittee.

Chairperson Veale reported that Dr. Castellblanch will provide his report at the next committee meeting.

The board recessed to closed session at 5:22 p.m.

Thursday, October 29, 2015

Call to Order **9:06 a.m.**

IX. Call to Order and Establishment of Quorum

President Gutierrez called the meeting to order at 9:06 a.m. Board members present: Ricardo Sanchez, Allen Schaad, Stanley Weisser, Amy Gutierrez, Deborah Veale, Rosalyn Hackworth, Lavanza Butler, Victor Law, Albert Wong and Greg Lippe.

Note: Mr. Murphy arrived at 9:13 a.m.

X. Enforcement Committee

Part 1: Enforcement Matters

1. Update on the CURES 2.0 Prescription Monitoring Program

President Gutierrez explained that the California Department of Justice (DOJ) continues to work on

upgrades to the CURES system. On June 30, the DOJ had a "soft launch" of CURES 2.0 as the new system is called. She noted that since then the DOJ has been working to pilot test the new system and install upgrades that will permit conversion to the new, enhanced system.

President Gutierrez reviewed the update prepared in late June on the soft launch from the DOJ's press release as provided below:

> **CURES 2.0 Soft Launch and Phased Rollout**
>
> Update from July 1, 2015:
>
> The Department of Justice (DOJ) and the Department of Consumer Affairs (DCA) are pleased to announce that the state's new Controlled Substance Utilization Review and Evaluation System – commonly referred to as "**CURES 2.0**" – went live on July 1, 2015. This upgraded prescription drug monitoring program features a variety of performance improvements and added functionality.
>
> In order to ensure a smooth transition from the current system, CURES 2.0 will be rolled out to users in phases over the next several months, beginning with early adoption by a select group of users who currently use CURES and meet the CURES 2.0 security standards, including minimum browser specifications. DOJ is currently identifying prescribers and dispensers who meet these criteria and will contact and coordinate their enrollment into CURES 2.0. For all other current users, access to CURES 1.0 will not change and no action is needed at this time. For users and entities not currently enrolled in CURES, further notification will be provided in August as to the enrollment/registration process.
>
> Practitioners and health systems should begin to prepare for universal adoption of the system by January 2016, at which point all users will be required to meet CURES 2.0's security standards. If you have any questions please contact cures@doj.ca.gov.
>
> Thank you for your continued support of the CURES program.
>
> ***Note:*** CURES 2.0 users will be required to use Microsoft Internet Explorer Version 11.0 or greater, Mozilla FireFox, Google Chrome, or Safari when accessing the system.

President Gutierrez reported that Robert Sumner and Mike Small of the DOJ provided an update on the transition to the new CURES 2.0 system at the committee meeting. They advised the committee that CURES 2.0 should be available to all users by January 2016 and explained some of the barriers in transitioning to CURES 2.0. Mr. Sumner explained that there are 18,487 pharmacists registered with CURES, which is less than 50% of all licensed California pharmacists.

President Gutierrez reported that on October 11, 2015, Governor Brown signed a bill (AB 679, Allen) that will delay implementation of the CURES registration requirements for pharmacists and prescribers that was to take effect January 1, 2016. The new deadline is July 1, 2016.

Ms. Herold reported that approximately 50 percent of the board's licensees are enrolled in CURES. She added that the board included information on the CURES system and the registration due date in *The Script* newsletter.

Mr. Wong noted that he called the DOJ for help with CURES and he found their staff to be very responsive and helpful.

There were no comments from the public.

2. Update on the University of California, San Diego on Its Pilot Program to Permit Patients to Access Medications from an Automated Storage Device not Immediately Adjacent to a Pharmacy

President Gutierrez explained that at the Board of Pharmacy's April 2015 board meeting, the board approved an 18-month pilot study under the auspices of the UCSD School of Pharmacy. This study would permit UCSD and San Diego's Hospital staff and their families, who opt in, to retrieve their outpatient medications from an automated storage device located in a hospital, rather than going to a community pharmacy.

President Gutierrez noted that this study, which was originally scheduled to begin in June or July, 2015, has been delayed.

President Gutierrez reported that Dr. Hirsch delivered a presentation to the committee via phone on the implementation of the program, which she anticipates will start in December 2015.

Note: A copy of Dr. Hirsch's presentation was provided in the board meeting materials.

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

3. Enforcement Options for Patient Consultation Violations

President Gutierrez explained that nearly 25 years ago, the Board of Pharmacy promulgated regulations to require pharmacists to consult with patients when receiving a medication for the first time. The board included in the regulation additional occasions where a pharmacist must consult a patient, such as when the patient has questions or the pharmacist believes a medication warrants consultation.

President Gutierrez stated that California's requirement is for the pharmacist to consult the patient – not to offer to consult. When preparing the consultation rulemaking, the board emphasized that consultation was to be initiated by the pharmacist, and that any denial of the consultation must be made directly to the pharmacist, other staff (e.g., pharmacy technicians or ancillary staff) are not to screen for consultation by asking if the patient wanted to speak to the pharmacist or have questions about the medication.

President Gutierrez stated that over the years, the board has enforced the patient consultation requirement in various ways. Initially, it was one of the first violations for which the board used its citation and fine authority. In recent years, the board typically assesses fines of approximately $1,000 when it observes failure to consult during an inspection.

President Gutierrez noted that at the July board meeting, the board heard a report summarizing the results of a short Survey Monkey questionnaire conducted by the board involving patient consultation.

President Gutierrez reported that after discussion the Enforcement Committee asked the Communication and Public Education Committee to focus on consumer education and why patient consultation is important.

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

4. Proposed Regulation for Pharmacies and Clinics Aimed at Reducing Losses of Controlled Substances

President Gutierrez reported that at the July board meeting, the board approved initiation of a rulemaking to establish inventory requirements for controlled drugs for pharmacies and clinics. The regulation requires perpetual inventories of all federal Schedule II drugs, with a physical count every 90 days. President Gutierrez noted that the board will establish a list of one or several additional controlled drugs from Schedules III – V that are reported as frequently stolen to the board and/or DEA.

President Gutierrez explained that staff developed a list of the top non-Schedule III-V drugs reported lost or stolen to the board in the last year (provided below). She noted that based on the list, the board would require the inventory monitoring of Alprazolam and Promethazine with Codeine.

Top Ten: FY 2014 – 2015 CS Schedules III-V Losses by Quantity

Drug	**Quantity In Actual Dosage Equivalents** *mLs converted into 5mL dosage units
Alprazolam	160,169
Promethazine/Codeine	77,862*
Carisoprodol	38,579
Tramadol Hydrochloride	34,801
Acetaminophen/Codeine	27,903
Lorazepam	26,864
Zolpidem Tartrate	18,657
Diazepam	17,139
Clonazepam	14,628
Phentermine	10,820

President Gutierrez reported that board's staff also developed the following list of Schedule II controlled drugs reported lost or stolen within the last year (provided below).

Top Ten: FY 2014 – 2015 CS Schedule II Losses by Quantity

Drugs	**Quantity In Actual Dosage Equivalents**
Hydrocodone and Combos	402,377*
Oxycodone and Combos	73,756*
Amphetamine/Salts/Methamphetamine	26,368
Hydromorphone/Oxymorphone	20,885
Dex/Methylphenidate	19,212
Methadone	9,817

Fentanyl Citrate	6,822
Diphenoxylate/Atropine	4,130
Tapentadol Hydrochloride	2,062
Meperidine HCI	831

*total dosages (mLs converted into 5mL dosage units and added to solids)

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

5. Tracking of Automated Drug Delivery Devices in Use in California

President Gutierrez explained that pharmacies are able to operate automated dispensing machines or devices in various settings away from the licensed pharmacy. This includes:

- Skilled nursing homes and other health care facilities licensed under Health and Safety Code section 1250 (c), (d) or (k) (the devices are authorized under section 1261.6 of the Health and Safety Code, authority for pharmacies to do this in specific locations is specified in Business and Professions Code section 4119.1)
- Clinics licensed under section 4180 of the Business and Professions Code (the devices are authorized under section 4186) – these include licensed, nonprofit community or free clinics defined under Health and Safety Code 1204(a)(1), a clinic operated by a federally recognized Indian tribe or tribal organization referred to in Health and Safety Code section 1206(b), a clinic operated by a primary care community or free clinic operated on a separate premises from a licensed clinic and that is open no more than 20 hours per week as referred to in Health and Safety Code section 1206(h), a student health center clinic operated by a public institution of higher education such as college health center as referred to in Health and Safety Code section 1206(j).
- Hospitals may use Pyxis or Pyxis-type machines throughout a hospital to store medication under application of provisions in Title 22 that allow drugs to be stored in nursing stations. The Pyxis and like devices are considered secured storage units for drugs.

President Gutierrez reported that the board does not know how many of these devices are in use, where they are in use, or which pharmacies are responsible for the machines.

President Gutierrez stated that the demand for additional use of these devices is growing. As reported earlier at this meeting, a pilot study is underway that if proven valuable, would allow patients to pick up medication from devices not located in a pharmacy.

President Gutierrez reported that board staff suggests that a simple registration be established for pharmacies that operate these devices to identify their locations.

President Gutierrez reported that the committee heard comments from the public in support of having device locations in outpatient and retail settings and to differentiate between the two. It was suggested that the board consider a separate proposal to require licensure of drug delivery devices.

President Gutierrez concluded that the committee will continue to work towards creating a registration program for drug delivery devices.

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

6. Enforcement Statistics

President Gutierrez reported that the first quarterly report of the Enforcement Statistics and SB 1441 Program Statistics were provided in the board meeting materials for review.

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

Part 2: Compounding Matters

1. Medicare's Pharmacy Practice Expectations for Critical Access Hospitals

President Gutierrez explained that at the committee meeting time was set aside for a discussion of these practice guidelines for hospital pharmacies. She noted that the item was agendized for information only.

Note: documents and articles related to this agenda item were provided in the meeting materials.

There were no comments from the board or the public.

2. Warnings about Becton-Dickinson Syringes and Loss of Medication Potency from the Food and Drug Administration and Institute for Safe Medication Practices

President Gutierrez reported that several weeks ago, the FDA and Institute for Safe Medication Practices released warnings about the loss in potency detected for certain medications stored in 3mL, 5mL or perhaps additional larger Becton–Dickinson syringes.

Note: the two warnings and a copy of the Becton-Dickinson public notice were provided in the board meeting materials.

President Gutierrez explained that this item was added to the agenda so that the committee could discuss the situation, and make a determination as to whether the board needs to initiate additional actions or warnings to clinicians.

President Gutierrez stated that following the committee meeting, the board issued an updated subscriber alert with the following information:

> The board had received several questions about information contained in prior e-mail alerts about the loss of potency noted when medication is stored in B-D Syringes.
> We are therefore re-issuing a subscriber alert that contains the FDA's most recent update on this issue: http://www.fda.gov/drugs/drugsafety/ucm458952.htm.
> We also call to the reader's attention the FDA's statements in this update that provide:
> Hospital pharmacies and staff should:
>
> - Contact any outsourcers to determine if affected lots of BD syringes were used for compounded or repackaged products
> - Not administer compounded or repackaged drugs that have been stored in any of these syringes unless there is no suitable alternative available

Ms. Veale asked if there are any other plastic syringes that could cause a loss of potency if they are used for medication storage. Ms. Herold explained that BD owns a large portion of the market the issue was identified with their products. She added that she will be attending a 50-state FDA meeting and she would ask if there were other products that should not be used as storage devices.

Christine Vestal with Dyna Labs reported that they have been tracking the loss of potency in syringes and they have seen that other products also result in the loss of potency.

Dr. Wong asked if there is a certain amount of time that will cause the loss of potency. President Gutierrez responded that it depends on the medication. She noted that most hospitals dispense the medication within 24 hours.

3. Compounding for Prescriber Office Use

President Gutierrez stated that section 4052(a)(1) of the California Business and Professions Code provides that: Notwithstanding any other law, a pharmacist may furnish a reasonable quantity of compounded drug product to a prescriber for office use by the prescriber.

President Gutierrez explained that if the proposed compounding regulation changes take effect, pharmacies will be able to compound for prescriber office use, but not in quantities for prescribers to dispense to a patient.

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

4. Comments on the Food and Drug Administration's Guidance Document on Compounding Animal Drugs from Bulk Drug Substances

President Gutierrez reported that the board had previously expressed interest in submitting comments on the FDA's Guidance Document 230, *"Compounding Animal Drugs from Bulk Substances."*

President Gutierrez stated that the committee discussed this guidance document and the comments it wished to submit to the FDA and asked Ms. Herold to draft a response letter. She added that the comments are due November 16.

Note: the guidance document and the draft response to these questions were provided in the board meeting materials.

Ms. Herold briefly reviewed the draft response letter and asked the board for approval to submit it to the FDA.

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

Motion: Approve the draft response prepared by Ms. Herold. Direct staff to submit the response to the FDA.

M/S: Weisser/Sanchez

Support: 11 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch				x
Gutierrez	x			
Hackworth	x			
Law	x			
Lippe	x			
Murphy	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

5. Compounding Services Provided by Sterile Compounding Pharmacies and Outsourcing Facilities

President Gutierrez explained that the November 2013 enactment of the Drug Quality and Security Act (DQSA) created a new type of entity authorized to compound medications – the outsourcing facility. These generally large-scale production facilities are authorized to compound large quantities of medications for use by other entities. The medications must be prepared under current good manufacturing practices (or cGPMs), which are more stringent than compounding requirements for pharmacies, since many patients in multiple locations can receive these medications that are not usually linked to a patient-specific prescription.

President Gutierrez stated that the legislation essentially creates a new entity, with the results that there are three types of drug producers.

1. Manufacturers who are regulated by the FDA, and for facilities located in a specific state, often by a unit of the state's Department of Health (this occurs in CA). Manufacturers are required to perform extensive drug testing trials before receiving authorization to market a drug. Their physical plants are inspected by the FDA and must comply with rigorous cGMPs.

2. Outsourcers are regulated more like drug manufacturers and are regulated under cGMPs, but outsourcing facilities are exempted from performing drug approval testing like manufacturers must do for their products. In the future, the FDA has stated they plan on developing specific cGMP requirements for outsourcing facilities, but these specialized requirements are not yet available.

3. Pharmacies, which are authorized to compound pursuant to a patient-specific prescription, are regulated by state boards of pharmacy. Because pharmacies generally do not compound drugs in quantities the size of those produced by outsourcing facilities or manufacturers, pharmacies are regulated under lesser standards. Sterile compounding pharmacies, however, are generally regulated at a level closer to that of manufacturers and outsourcers because of heightened concerns about sterility, integrity, potency and quality of the compounded medication.

President Gutierrez reported that for a number of years, the board and other agencies have grappled with the issue of at what point does a pharmacy compounding medications in large quantities in anticipation of receiving a prescription, actually become a manufacturer because the pharmacy is compounding so much medication, or compounding not specific to received prescriptions. She noted that the board, the CA Department of Public Health and the FDA have all studied and discussed this issue in CA over the years, and similar discussions have gone on in other states and federally.

President Gutierrez stated that with the advent of outsourcing facilities, the issue is simplified;

- An outsourcing facility (aka a 503B facility) licensed by the FDA (and in the future by the CA Board of Pharmacy if located or shipping into the state), shall function under the supervision of a pharmacist and operate according to cGMPs, to produce compounded drug products for multiple entities without a prescription.
- A pharmacy (aka a 503A facility) may compound a medication pursuant to patient-specific prescription order or in very limited quantities based on normal dispensing patterns in anticipation of a prescription, and dispense pursuant to a patient-specific prescription.
- A specially licensed sterile compounding pharmacy may compound a sterile medication pursuant to a patient-specific prescription or in limited quantities based on normal dispensing patterns in anticipation of a patient-specific prescription, but dispense pursuant to a patient-specific prescription.

President Gutierrez explained that a pharmacy may compound medication or sterile medication for administration in a physician's office (but after implementation of California's new compounding requirements, not for dispensing to patient in 72-hour quantities).

President Gutierrez asked if the board inspectors have found that 503A facilities are issuing prescriptions that are not patient specific in violation of federal law. Ms. Herold responded that there have been a few pharmacies that have been found to be violating federal law.

A representative from Senator Stone's office stated that the Senator has been made aware of a gray area in the differentiation between a 503A and 503B facility. He stated that the Senator is concerned that the Board of Pharmacy is unnecessarily ceding control of these facilities to the FDA. The representative asked if the board could inspect all 503A and 503B facilities and only involve the FDA if the board finds a facility is violating federal law.

Ms. Herold explained that out of professional curtesy the FDA advises the board when they will be going into a pharmacy and allows the board inspectors to accompany them. Ms. Herold stated that the board cannot tell the FDA when they can or cannot inspect a pharmacy. Mr. Room added that these pharmacies are not only licensed with the board, they are also engaged in an activity that is regulated by federal law.

Ms. Herold reported that the FDA conducts these types of inspections all over the United States, not just in California. Ms. Herold offered to speak with Senator Stone regarding the subject of 503A and 503B pharmacies.

Supervising Inspector Michael Ignacio stated that the FDA uses UPS 797 when they inspect 503A pharmacies.

6. Review of Sterile Compounding Statistics Identified by the Board

President Gutierrez reported that at the committee meeting, Supervising Inspector Dr. Acosta provided an overview of the statistics compiled by the board from inspections and investigations of California-licensed compounding pharmacies from March 2015 to September 2015.

Note: a copy of Dr. Acosta's presentation is provided in the board meeting materials.

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

7. Future Committee Meeting Dates

President Gutierrez reported that the Enforcement Committee would meet on the following dates.

- December 14, 2015
- March 2, 2016
- June 1, 2016
- August 31, 2016

XI. Proposed Regulations to Amend Title 16 California Code of Regulations Sections 1735 et seq. and 1751 et seq., Relating to Compounding

President Gutierrez reported that the board will have the opportunity to discuss the regulation, the comments received and determine what course of action it wishes to pursue. Among its options:

1. Adopt the regulation as approved at the July 2015 Board meeting
2. Amend the regulation to address concerns expressed by staff and stakeholders and notice the modified text for a second 15 day comment period.

Dr. Ignacio provided an overview of the changes to the compounding regulation made in response to the comments received.

President Gutierrez explained that a revised USP 797 will become effective in approximately one year. She noted that the board's regulations would have to be updated when the new version takes effect.

President Gutierrez stated that staff and legal counsel are recommending opening the regulation up for a 15-day comment period so that stakeholders could provide comments on the updated language.

Ms. Herold thanked President Gutierrez, Mr. Schaad and board staff who all spent numerous hours reviewing the comments and updating the regulation. President Gutierrez thanked Supervising Inspectors Ignacio and Acosta as well as Mr. Room for their work in revising the regulation.

Brian Warren, representing CPhA, asked the board to consider holding the regulation until the revised USP 797 takes effect. He also noted that the physical remodels that will be required by hospitals will be extensive and asked the board to delay the effective date of relevant sections of the regulation to January 1, 2020. Mr. Warren also outlined additional changes that CPhA would recommend making to

the regulation. President Gutierrez asked CPhA to submit their comments during the next 15-day comment period.

Lori Hensik from Kaiser Permanente echoed the concerns raised by Mr. Warren regarding the extensive remodeling that will be required in hospitals. She asked the board to create a standardized waiver process so that hospitals can request extensions to allow for construction.

President Gutierrez stated that she would like hospitals to submit waivers to the board which include a project timeline and a deadline for compliance. Ms. Freedman and Mr. Room stated that a standard waiver for hospitals should be included in the regulation.

A representative from Mercy Hospital explained that extensive construction would be required for their hospital, and added that there are other agencies that also have to approve construction plans which can add significant time to the process.

Corbin Bennett from Kaiser reported that approximately half of their hospitals will need to be remodeled. He noted that the estimated cost for each hospital remodel is $ 1.5 million. Mr. Bennett stated that construction usually takes been 18 months and three years.

Ms. Freedman presented the language below as a possible way to include the construction waivers in the regulation language.

> *For any provision of the [newly amended regulations] that requires physical construction to a facility, to allow the facility time to make such physical changes, compliance may be waived by the board or its designee for a period of time to be determined by the board. Each facility shall request such a waiver. The request shall explain the section of the regulation requested to be made, provide a description of the physical changes that must be made and provide a timeline for making such changes.*

Ms. Freedman and Mr. Room stated that if the board agreed with the premise of including the construction waiver in the language, they would refine the language and determine what section of the regulation if should be included in. The board directed staff to refine the language and include it in the language being noticed for the 15-day comment period.

Dr. Judith Broz raised concerns with how the regulation could negatively impact disabled pharmacists. Ms. Freedman responded that the regulations were reviewed and modified in response to the comments submitted by Dr. Broz. However, she explained that the pharmacist-in-charge must be able to ensure that staff involved in sterile compounding completes adequate training to ensure that the medication is prepared safely for patients.

Motion: Modify the text as provided in Attachment 4 of the board meeting materials, to include the construction waiver. Delegate the authority to board staff to refine the waiver language and determine the appropriate section of the regulation in which to include the language. Notice the modified text for 15-day comment period.

M/S: Weisser/Hackworth

Support: 11 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch				x
Gutierrez	x			
Hackworth	x			
Law	x			
Lippe	x			
Murphy	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

The board recessed for a break at 11:35 a.m. and resumed at 11:41 a.m.

XII. Proposed Regulations for the Take Back of Prescription Medication

President Gutierrez reported that since the July 2015, board meeting, the board has continued to refine the proposed requirements for drug take back programs.

President Gutierrez explained that counties have established requirements to permit or require take back of unwanted pharmaceuticals from the public.

President Gutierrez stated that on September 26, the Drug Enforcement Administration (DEA) conducted another national Drug Take Back day. She added that the board released a subscriber alert and posted information about this collection day on the board's web site.

President Gutierrez reported that after discussion at the September 9, 2015, Enforcement Committee meeting the committee made the following recommendation: Direct staff to complete work on the proposed regulation, including the policy comments made by the committee, and bring the proposed regulation to the board for possible initiation of a rulemaking.

Ms. Herold reported that she has discussed the proposed language with various stakeholders to refine the language further. Ms. Herold briefly reviewed the changes made to the proposed language (as provided immediate following these minutes), including making the internal container safe for chemotherapy drugs.

President Gutierrez stated that the Enforcement Committee had decided to make pharmacy participation in take-back programs voluntary. Ms. Freedman and Mr. Room explained that there has been a recent legal opinion that gives the state the authority to preempt local ordinances; however the proposed regulation would need to be reviewed by legal counsel to determine if it would preempt local ordinances.

Mr. Lippe stated that many pharmacies may choose to participate because it could potentially increase their business.

President Gutierrez noted that the pharmacies will have to modify their DEA registration in order to participate in take-back programs, which will pose some liability risk for the pharmacies who participate.

Ms. Herold noted that the Enforcement Committee requested collection receptacles be locked when the pharmacy is closed. It was noted that the requirement for the receptacle to lock after business hours is a DEA requirement for all collection boxes.

Ms. Herold explained that in skilled nursing facilities a pharmacist must collect the drugs and the drugs cannot be transported back to the pharmacy, they must be appropriately disposed of at the skilled nursing facility.

Ms. Herold explained that only drugs dispensed to patients can be place in the receptacles. Un-dispensed, recalled or outdated drugs from the pharmacy cannot be place in the take-back receptacle for disposal.

A representative from Sharps Compliance briefly explained their company's mail-back and receptacle take-back programs. The representative also explained that if the internal container is labeled for chemo-therapy drugs the staff would then be required to follow chemo-therapy protocol which would include wearing protective garbs.

Brian Warren, CPhA, thanked the board for moving forward with the regulation and making it consistent with the federal requirements. Mr. Warren also stated that CPhA supports the board's current position of not mandating that all pharmacies participate in take-back programs. Mr. Warren noted that they are concerned with the requirement for pharmacists to log all mail back envelopes. Ms. Herold responded that this is a DEA requirement.

President Gutierrez noted that the language prohibits pharmacies that are on probation with the board from participating in take-back programs.

Angie Manetti with the California Retailers Association stated that CRA also supports the board's decision to make take-back participation voluntary.

Ms. Manetti stated that chemo-therapy drugs in the receptacle could potentially harm customers and the pharmacists collecting the drugs and therefore the regulation should address the need for protective garbs and ventilation systems. Mr. Schaad responded that as retail pharmacies already dispense chemo-therapy drugs, it would be unlikely that any additional contamination would occur due to the take-back programs.

Jennifer Snyder from the National Association of Chain Drug Stores, agreed with Ms. Manetti's comments.

Thomas Harris, from the City of Santa Rosa, stated that their city has not had problems with customers or pharmacists being harmed by chemo therapy drugs in take-back receptacles. He asked the board to remove the requirement that the container be labeled for chemo-therapy drugs. Mr. Harris stated that

he is concerned that some of the containers currently being used in Santa Rosa would not meet the standards in the draft language. Ms. Herold asked him to send her examples of the containers.

Jennifer Jackson, from the City of San Francisco, explained that the city of San Francisco has been conducting a pilot take-back program and they have collected approximately 60,000 pounds of waste. Ms. Jackson also stated that previously programs were allowed to sort and study the drugs that were disposed of, and it was found that chemotherapy drugs are rarely disposed of through take-back programs. Ms. Jackson asked the board to remove the statement that makes participation voluntary, she stated that local governments should be allowed to determine if programs should be mandated in their counties.

Bill Worrall, from the San Lois Obispo County Integrated Waste Management Authority, suggested requiring pharmacies to offer mail back envelopes with all dispensed drugs. He also expressed concern with labeling the receptacles as containing chemotherapy. Mr. Worrall noted that in their county pharmacies are mandated to provide take-back services, the pharmacy can choose to provide mail back envelopes or operate a receptacle.

Heidi Sanborn, director of the California Product Stewardship Council, invited the board members to visit pharmacies that are participating in take-back programs. She also described how take-back programs work in other countries.

Ms. Sanborn asked the board to remove the language making program participation voluntary in order to allow each county to determine what programs would be most appropriate for their community. Ms. Sanborn also explained that mail back programs work in some instances, however they can be expensive, especially when there are large quantities of drugs to dispose of after a patient has died.

A representative from Cal Recycle explained that labeling containers for chemotherapy will limit the facilities that will accept the waste.

President Gutierrez asked if there are enough reverse distributors in California to handle the take-back programs. Ms. Herold responded that the use of reverse distributors is a DEA requirement; therefor pharmacies must find a reverse distributor.

Dr. Gutierrez stated that the board could remove the chemotherapy labeling and simply require a medical waste bag. She asked if there is a thickness requirement for bags containing medical waste. Ms. Herold responded that she would research this and report to the board.

The board asked the Enforcement Committee to review the draft language at their next meeting and make changes based on the board's discussion.

Motion: Return the draft language to the Enforcement Committee for further review and refinement.

M/S: Weisser/Lippe

Support: 11 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch				x
Gutierrez	x			
Hackworth	x			
Law	x			
Lippe	x			
Murphy	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

Ms. Herold asked if the board would like to remove the chemotherapy requirement from the language. The board decided to remove the chemotherapy requirement; however they asked that she draft language to ensure that the liner used is appropriate for medical waste.

President Gutierrez asked the board if participation in take-back programs should be voluntary or mandated.

Mr. Lippe suggested that the board remain silent on the issue and made a motion to remove the language from the draft language.

Mr. Room clarified if the board remained silent it would allow local governments to mandate pharmacy participation in take-back programs. Ms. Herold added that up until now the board has maintained that take-back programs are voluntary.

Mr. Weisser and Ms. Butler expressed concern with pharmacies being mandated to participate in take-back programs.

Mr. Lippe did not receive a second for his motion to remain silent on mandating participation and the motion was tabled.

Heidi Sanborn stated that the Product Stewardship Council and local governments oppose the board making participation voluntary.

President Gutierrez explained that she is concerned that mandating participation might over burden pharmacies and pharmacists and take away from patient care.

Bill Worrall, from the San Lois Obispo County Integrated Waste Management Authority, stated that if the board makes participation voluntary many pharmacies will stop participating.

Angie Manetti with the California Retailers Association stated that CRA, asked the board to allow the pharmacies to choose if they want to participate in drug take-back programs. She added that in counties that currently mandate participation retail pharmacies do not host receptacles due to liability and space issues, instead they comply by providing take-back envelopes.

Jon Roth, representing the California Pharmacists Association, expressed CPhA's support of the board making take-back programs voluntary.

Ms. Veale stated that she would like the board to reconsider their prior motion to send the language back to the Enforcement Committee. She stated that she would like the board to move the language to 45 day comment period so that stakeholders can officially submit comments.

Motion: The board directed staff to remove the chemotherapy liner requirement from the language. Move the language as provided at the October board meeting (with the chemotherapy requirement removed) to 45-day comment period.

M/S: Veale/Lippe

Support: 11 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch				x
Gutierrez	x			
Hackworth	x			
Law	x			
Lippe	x			
Murphy	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

The board recessed for a break at 1:55 p.m. and resumed at 2:24 p.m.

XIII. Legislation and Regulation Committee

Part 1: Legislation Report

a. Board-Sponsored Legislation

1. AB 1073 (Ting) Prescription Drug Labels

Chairperson Lippe explained that Assembly Bill 1073 was approved by the Governor on October 11, 2015. The bill requires a pharmacist to use professional judgment to provide a patient with directions for use of a prescription, consistent with the prescriber's instructions.

Chairperson Lippe reported that AB 1073 also requires a prescriber to provide translated directions for use, if requested, and authorizes the dispenser to use the translations made

available on the board's website to comply with the requirement.

Chairperson Lippe stated that dispensers are not *required* to provide translated directions for use beyond what the board has made available. However, the bill does authorize a dispenser to provide his or her own translated directions for use to comply with the requirement. He noted that veterinarians are exempt from the requirement to provide translated directions for use.

Chairperson Lippe reported that the provisions of the bill go into effect on January 1, 2016.

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

2. SB 590 (Stone) Intern Licenses

Chairperson Lippe reported that Senate Bill 590 was approved by the Governor on August 7, 2015. The bill amends section 4209 of the Business and Professions Code to streamline the application process for graduates from an ACPE accredited school or school of pharmacy recognized by the board for purposes of confirming completion of the required pharmacy practice experience requirements.

Chairperson Lippe stated that the provisions go into effect on January 1, 2016.

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

3. SB 619 (Morrell) Outsourcing Facilities: Licensure

Chairperson Lippe stated that as reported at the July Board Meeting, Senate Bill 619 would have established the regulatory framework for licensure of outsourcing facilities that compound non-patient specific medications for administration to California patients.

Chairperson Lippe reported that the bill was held on suspense and died in Senate Appropriations in May. The proposal will need to be pursued in 2016 when the Legislature reconvenes.

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

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

1. AB 45 (Mullin) Household Hazardous Waste

Status: 2-Year Bill
Board Position: Oppose Unless Amended

Chairperson Lippe reported that AB 45 states that it is the intent of the Legislature to enact legislation that would establish various household hazardous waste collection programs, including curbside, door-to-door and residential pickup services as a principal means of collection such waste and diverting it from California's landfills and waterways.

Chairperson Lippe explained that this measure would require each jurisdiction that provides for residential collection and disposal of solid waste, including household pharmaceutical waste, to

increase its collection and diversion of such waste by 15% by July 1, 2020 unless otherwise specified.

Chairperson Lippe stated that board staff offered amendments to require the use of mail-back programs unless the jurisdiction complies with the provisions of federal law relating to the safe collection and disposal of such waste, but our amendment was not accepted. He added that board staff has continued to try to find a workable solution, and the board's Enforcement Committee has begun discussions on the matter.

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

2. AB 339 (Gordon) Health Care Coverage: Outpatient Prescription Drugs

Board Position: None

Chairperson Lippe explained that Assembly Bill 339 requires health plans and health insurers that provide coverage for outpatient prescription drugs to have formularies that do not discourage the enrollment of individuals with health conditions, and requires combination antiretroviral drug treatment coverage of a single-tablet that is as effective as a multitablet regimen for treatment of HIV/AIDS, as specified.

Chairperson Lippe stated that the bill places in state law, federal requirements related to pharmacy and therapeutics committees, access to in-network retail pharmacies, standardized formulary requirements, formulary tier requirements similar to those required of health plans and insurers participating in Covered California and copayment caps of $250 and $500 for a supply of up to 30 days for an individual prescription, as specified.

Chairperson Lippe reported that the provisions go into effect on January 1, 2016.

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

3. AB 486 (Bonilla) Centralized Hospital Packaging Pharmacies

Board Position: Support

Chairperson Lippe reported that Assembly Bill 486 provides an alternative method to maintain certain medication information that shall be readable at the patient's bedside, either via a barcode scan or human-readable, for unit dose medications prepared in a centralized hospital packaging facility. The provisions of the bill went into effect on September 2, 2015.

Chairperson Lippe explained that with the enactment of AB 486, centralized hospital packaging pharmacies no longer require waivers from the board regarding the labeling of unit dose medications packaged in these centralized pharmacies.

4. AB 1069 (Gordon) Prescription Drugs: Collection and Distribution Program

Status: 2-Year Bill
Board Position: Oppose Unless Amended

Chairperson Lippe reported that AB 1069 would expand the provisions under which a county established repository and distribution program allow the transfer of drugs to other counties (not just adjacent counties) and would allow for the advance repackaging of donated medications in advance of a prescription.

Chairperson Lippe explained that prior to the Legislative recess, board staff worked with the author's office to secure amendments to address many of the legal conflicts the measure initially contained. There are still some concerns with the bill in its current form.

Chairperson Lippe stated that currently, the bill would remove a pharmacist from several aspects of the redistribution program of prescription drugs; would allow a "participating entity" to transfer drugs like a distributor without appropriate licensure and control; and would permit what is currently unlawful repackaging and co-mingling of previously dispensed medications, including donated medications from various sources … all to the detriment of patient safety.

Chairperson Lippe reported that staff will continue to work with the author's office on this measure.

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

5. AB 679 (Allen) CURES

Board Position: Support

Chairperson Lippe reported that Assembly Bill 679 amended Health and Safety Code 11165.1 related to the requirement that prescribers and dispensers apply to the Department of Justice to obtain approval to access information contained in the CURES database regarding the controlled substance history of a patient under his or her care register for access to CURES by one of the following, whichever respective event occurs later:

- by July 1, 2016, or
- upon licensure, in the case of a pharmacist or
- upon receipt of a federal Drug Enforcement Administration registration, in the case of another health care practitioner authorized to prescribe, order, administer, furnish, or dispense controlled substances.

Chairperson Lippe explained that prior law required registration by January 1, 2016. He added that because the bill contained an urgency clause, the provisions went into effect on October 11, 2015.

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

c. Legislation Impacting Board Operations

1. AB 12 (Cooley) State Government: Administrative Regulations

Status: 2-Year Bill

Board Position: Oppose

Chairperson Lippe explained that Assembly Bill 12 would require state agencies and departments to review, adopt, amend, or repeal any application regulations that are duplicative, overlapping, inconsistent, or out of date by January 1, 2018. The measure also would establish notice and reporting requirements.

Chairperson Lippe stated that the board has determined that AB 12 would have a significant impact to its current operations. Given the complexity of the board's regulatory structure, board staff has concerns that the board would not be able to achieve compliance within the time allotted for completion of the review (2 years), without having a significant impact on other areas of the board's operations.

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

2. AB 85 (Wilk) Open Meetings

Chairperson Lippe reported that this bill was vetoed.

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

3. AB 1351 (Eggman) Deferred Entry of Judgment: Pretrial Diversion

Chairperson Lippe reported that this bill was vetoed.

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

4. AB 1352 (Eggman) Deferred Entry of Judgment: Withdrawal of Plea

Board Position: Oppose

Chairperson Lippe reported that Assembly Bill 1352 will allow a defendant who was granted deferred entry of judgment on or after January 1, 1997, after pleading guilty or nolo contendere to the charged offense, to withdraw his or her prior guilty plea and enter a plea of not guilty if the charges were dismissed after the defendant performed satisfactorily during the deferred entry of judgment period and the defendant shows that the plea may result in the denial or loss to the defendant of any employment, benefit, license, or certificate, including, but not limited to, causing a noncitizen defendant to potentially be found inadmissible, deportable, or subject to any other kind of adverse immigration consequence.

Chairperson Lippe explained that the amendments to the Penal code will significantly impact the Board's ability to prove in disciplinary proceedings that a licensee or applicant is engaged, or has been engaged, in illicit drug activities. He added that the bill is likely to increase the board's costs of prosecution or could lead to the dismissal of certain disciplinary charges, to the detriment of public safety.

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

d. Other Pieces of Legislation Impacting the Practice of Pharmacy, the Board's Jurisdiction or Board Operations

Chairperson Lippe reported that SB 464 was chaptered and will take effect January 1, 2016.

Chairperson Lippe explained that the bill will allow physicians, surgeons, nurse practitioners, midwifes, physician assistants and pharmacists to use a self-screening tool that will allow them to identify risk factors when providing self-administered hormonal contraception. He explained that the board has already been working in this area as it relates to SB 493.

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

Part 2: Regulation Report

a. Board Approved – Awaiting Review by Control Agencies

Chairperson Lippe explained that the items listed below are currently under review by various control agencies. He provided a brief status on each regulation as provided below. There were no comments from the board or from the public on any of the items.

1. Amendment of Title 16 California Code of Regulations (CCR) section 1793.5 Related to Pharmacy Technician Application

   Status: On October 8, 2015, the file was submitted to the Office of Administrative Law for final review.

2. Amendment of Title 16 CCR sections 1715 and 1784 to Update Self-Assessment Forms 17M-13, 17M-14 and 17M-26

   Status: As of September 25, 2015, the file was being reviewed by Agency. Once approved by Agency, the file will be submitted to the Office of Administrative Law for final review, pursuant to the Administrative Procedures Act.

3. Addition of Title 16 CCR Section 1746.1 Related to Self-Administered Hormonal Contraception

   Status: Board staff compiled the final rulemaking documents and submitted it to the Department of Consumer Affairs to begin the administrative review process on October 13, 2015. Once approved by the Department and Agency, the file will be submitted to the Office of Administrative Law for final review.

4. Addition of Title 16 CCR Section 1746.2 Related to Nicotine Replacement Products

   Status: Board staff compiled the final rulemaking documents and submitted it to the Department of Consumer Affairs to begin the administrative review process on the October 16, 2015. Once approved by the Department and Agency, the file will be submitted to the Office of Administrative Law for final review.

5. Addition of Title 16 CCR Section 1746.3 Related to Naloxone Hydrochloride (Non-Emergency)

Status: Board staff compiled the final rulemaking documents and submitted it to the Department of Consumer Affairs to begin the administrative review process on the October 16, 2015. Once approved by the Department and Agency, the file will be submitted to the Office of Administrative Law for final review.

b. **Board Approved – Recently Noticed**

1. Proposal to Add Title 16 CCR Section 1730 Related to Advanced Practice Pharmacist

Chairperson Lippe reported that at the June 2015 Board Meeting, the board approved proposed text to add Section 1730 to Title 16 of the California Code of Regulations related to Advanced Practice Pharmacist. Staff prepared the required notice documents and on July 31, 2015, issued the 45-day text.

Chairperson Lippe stated that the comment period ran from July 31 to September 14, 2015. In response the comments received, modifications were made to the text.

Chairperson Lippe reported that at the September Board Meeting, the board approved the noticing of modified text; the 15-day comment period began October 9, 2015 and ended October 23, 2015.

Staff manager Lori Martinez explained that many of the comments received were outside of the scope of the comment period.

Ms. Martinez stated that two of the comments received ask the board to modify section 1730.1(c)(1)(b) as provided below.

> (B) Completed the required number of hours of clinical services to patients, as specified in this subdivision and in Business and Professions Code section 4210 (a)(2)(C), which includes initiating, adjusting, **modifying or** ~~**and**~~ discontinuing drug therapy of patients; and

Mr. Warren from CPhA explained that the modification is intended to make the language consistent with the amendments previously made to 1730.1(c).

Motion: Modify section 1730.1(c)(1)(b) as provided below and notice it for 15-day comment period.

> (B) Completed the required number of hours of clinical services to patients, as specified in this subdivision and in Business and Professions Code section 4210 (a)(2)(C), which includes initiating, adjusting, **modifying or** ~~**and**~~ discontinuing drug therapy of patients; and

M/S: Weisser/Lippe

Support: 11 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch				x
Gutierrez	x			
Hackworth	x			
Law	x			
Lippe	x			
Murphy	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

Mr. Warren also asked the board to consider removing the requirement for the 1,500 experiential hours to be completed within a four-year time period. The board discussed Mr. Warren's comment and agreed that some pharmacists may have difficulty completing 1,500 hours in a four-year time period. The board decided to extend the time period to ten years.

Motion: Expand the timeframe for pharmacists to complete 1,500 hours of experience to ten years.

M/S: Lippe/Butler

Lori Hensik from Kaiser Permanente noted that there is a disparity between the time frame requirements for those completing experiential hours and those completing a residency program.

The board decided to discuss this further and asked staff to make copies of the regulation so that the board and the public could review the language during the discussion. The motion made by Mr. Lippe was tabled.

The board elected to move on to the next agenda item so that staff could make copies of the regulation language.

2. Proposal to Amend Sections 1732.05, 1732.2, and 1732.5 of Article 4 of Division 17 of Title 16 of the CCR Related to Continuing Education

Board staff explained that the language needed to be amended as to change the term "units" to "hours."

Ms. Herold recommended that the board change the effective date of the regulation from July 1, 2016 to July 1, 2018.

Motion: Modify the language to use the term hours. Change the effective date to July 1, 2018. Notice the modified text for 15-day comment period.

M/S: Veale/Butler

Support: 11 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch				x
Gutierrez	x			
Hackworth	x			
Law	x			
Lippe	x			
Murphy	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

3. Proposal to Add Title 16 CCR Section 1746.5 Related to Travel Medications

Chairperson Lippe reported that at the June 2015 Board Meeting, the board approved proposed text to add section 1746.5 to Title 16 CCR related to Travel Medications.

Chairperson Lippe stated that the 45-day comment period began on September 25, 2015 and will end on November 9, 2015.

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

4. Proposal to Amend Title 16 CCR Section 1744 Related to Drug Warnings

Chairperson Lippe reported that at the April 2015 Board Meeting, the board approved proposed text to amend section 1744 of Title 16 CCF related to drug warnings.

Chairperson Lippe stated that the 45-day comment period began on September 25, 2015 and will end on November 9, 2015.

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

5. Proposal to Add Title 16 CCR Section 1746.4 Related to Vaccinations

The board asked staff to make copies of the regulation language so that they could review it during the discussion.

The board elected to move on to the next agenda item so that staff could make copies of

the regulation language.

XIV. Consideration of Proposed Changes to the Board's Disciplinary Guidelines and Title 16 California Code of Regulations Section 1760

Chairperson Law reported that in early 2011, the board directed staff to restructure and update its Disciplinary Guidelines. Subsequent to this, in April 2011, the uniform standards required in B&PC section 315 were finalized. Over the course of the next year, the board initiated a rulemaking to update the disciplinary guidelines and incorporate the SB 1441 uniform standards as it deemed appropriate considering comments from counsel and staff on how best to proceed.

Chairperson Law stated that in addition to the standards themselves, the board also received opinions on what was required to implement the uniform standards. The board was provided a copy of a legal opinion from the Legislative Counsel Bureau, executive summary issued by the Office Of the Attorney General as well as an implementation memo from Doreatha Johnson, Deputy Director of Legal Affairs, DCA. Chairperson Law added that the opinions provided did not provide consistent guidance and as such the board requested a formal legal opinion from the Office of the Attorney General in January 2013. The board received a response to this request on April 8, 2015.

Chairperson Law reported that during the April 2015 board meeting, the board briefly discussed the new legal opinion and was advised that the new opinion provides for some discretion by the board. Chairperson Law noted that staff and legal counsel stated that they would review the new legal opinion and provide a more in depth report at the June 2015 board meeting.

Chairperson Law stated that during the June Board meeting, an ad hoc committee was established to allow a complete review of the proposed implementation strategy. Following the work of the ad hoc committee, during the July Board meeting, the board was presented with recommended changes to the guidelines.

Chairperson Law reported that as part of the public discussion on the proposal, the board heard concerns from the Department of Consumer Affairs Deputy Director of Legal Affairs Doreathea Johnson. Ms. Johnson stated that the language does not clearly define who the licensees are that will be subject to the uniform standards. Ms. Johnson requested that the board refer the matter back to committee.

Chairperson Law stated that despite Ms. Johnson's request, the board voted to initiate the 45-day comment period with the understanding that the DCA legal office would complete its review.

Chairperson Law reported that on September 4, 2015 the board initiated the 45-day comment period. Since that time the board received comments from counsel regarding the proposal as well as comments from two individuals.

Chairperson Law stated that based on the comments received from counsel, staff is recommending several changes to the section 1760 language as well as to the guidelines. He noted that the changes being presented for board consideration include non-substantive changes as well as substantive changes intended strengthen and/or clarify the understanding of the guidelines as well as to clarify the intent of some of the language.

Chairperson Law explained that staff is requesting that the board review the changes being presented in

the guidelines, consider the public comments received during the comment period as well as provide clarification on some policy issues.

Ms. Sodergren noted that the proposed changes to the disciplinary guidelines have been provided in the meeting materials, with the changes highlighted in double strikeout and underscore. She also noted that brief descriptions of all the proposed changes are provided in the meeting materials.

Ms. Sodergren briefly reviewed the proposed changes. She noted that no new terms were added; items were either clarified or consolidated to make the disciplinary guidelines more user friendly.

Chairperson Law explained that staff prepared policy questions for the board to review. Chairperson Law stated the each policy question must be discussed and voted on by the board. Below is a summary of each policy question and the vote by the board.

Policy Question: The guidelines currently provide optional language that allows the respondent to pay costs in a payment plan approved by the board or its designee, as long as full payment is completed no later than one year prior to the end of probation. Would the board like to convert this optional language into the standard term?

Motion: Convert this optional language into a standard term.

M/S: Veale/Lippe

Support: 11 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch				x
Gutierrez	x			
Hackworth	x			
Law	x			
Lippe	x			
Murphy	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

Policy Question: As currently drafted, a respondent that surrenders a license must reapply if a license is surrendered. Does the board wish to continue with this current policy or change it to treat it as for a petition for reinstatement?

Ms. Freedman noted that this was a policy question that she asked to be brought before the board. She

explained that other boards require licensees who have surrendered a license to petition the board for reinstatement. Mr. Room stated that he believes that the current process of reapplication is adequate.

Ms. Sodergren noted that staff is recommending that the board not change the current reapplication policy. She explained that reapplication ensures that staff can determine if the applicant has met the minimum qualifications.

Motion: Keep the board's current policy requiring licensees who surrender their license to reapply for licensure.

M/S: Hackworth/Gutierrez

Support: 11 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch				x
Gutierrez	x			
Hackworth	x			
Law	x			
Lippe	x			
Murphy	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

Policy Question: Current guidelines provide that a respondent pharmacist is automatically suspended if he or she fails to take the exam within 6 months of the effective date of the decision. The term also specifies that failure to pass within 6 month is a violation of probation. Does the board agree with this change, or should we revert back to the two different time frames.

Motion: Change the requirement to 6 and 12 months.

M/S: Lippe/Wong

Support: 11 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch				x
Gutierrez	x			
Hackworth	x			

Law	x			
Lippe	x			
Murphy	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

Policy Question: The board's current guidelines establish the requirement for remedial education, including a provision that at the request of the board, respondent may be required to take an approved examination to test respondent's knowledge of the course. The term further states that failure of respondent to receive a passing score on the exam will be considered a violation of probation. Does the board wish to reconsider this provision to specify that respondent shall take another course approved by the board in the same subject area if he or she fails the examination? Below is language to establish this requirement if the board elects to change its current policy on this issue. (Change is reflected in strikeout.)

Remedial Education

Following the completion of each course, the board or its designee may require the respondent, at [his/her] own expense, to take an approved examination to test the respondent's knowledge of the course. If the respondent does not achieve a passing score on the examination~~, this failure shall be considered a violation of probation. Any such examination failure shall require~~ that course shall not count towards satisfaction of this term. Respondent shall take another course approved by the board in the same subject area.

Motion: Approve the change as provided above.

M/S: Gutierrez/Butler

Support: 11 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch				x
Gutierrez	x			
Hackworth	x			
Law	x			
Lippe	x			
Murphy	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

Policy Question: The board's current guidelines include a term specific to intern pharmacist experience to require an intern to complete a training program under specified conditions. Does the board believe that this term is still appropriate? Staff notes that this term has not been used in at least the last seven years.

Motion: Remove this term.

Note: Ms. Hackworth was not present for the vote.

M/S: Wong/Lippe

Support: 10 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch				x
Gutierrez	x			
Hackworth				x
Law	x			
Lippe	x			
Murphy	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

Policy Question: As drafted, this term does not apply to pharmacy technicians, who by law must always perform duties under the direct supervision of a pharmacist in a pharmacy. Does the board want a pharmacy technician to be supervised only by a supervisor approved by the board? If so, the below language could be incorporated into the draft guidelines

Option (For Pharmacy Technicians Only)
Within thirty (30) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, the name of a pharmacist licensed by and not on probation with the board, to serve as respondent's practice supervisor. As part of the documentation submitted, respondent shall cause the proposed practice supervisor to report to the board in writing acknowledging that her or she has read the decision in case number [insert case number], and is familiar with the terms and conditions imposed thereby, including the level of supervision required by the board or its designee. Respondent may have multiple supervisors approved by the board if necessary to meet respondent's work requirements.

Any of the following shall be considered a violation of probation: failure to timely nominate either an initial or a replacement practice supervisor; failure to cause the practice supervisor to timely report to the board in writing acknowledging the decision, terms and conditions, and supervision level; practicing in the absence of an approved practice supervisor after lapse of the nomination period; and/or failure to adhere to the level of supervision required by the board or its designee. If any of these obligations or prohibitions is not met, respondent shall be prohibited from practice as a [insert license type] and may not resume such practice until notified by the board or its designee in writing.

Motion: Incorporate the language above into the disciplinary guidelines. Fix the typo in sentence two to correct "her or she has read…" to "he or she has read…"

Note: Ms. Hackworth was not present for the vote.

M/S: Gutierrez/Veale

Support: 10 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch				x
Gutierrez	x			
Hackworth				x
Law	x			
Lippe	x			
Murphy	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

Policy Question: The model language for both the revocation and surrender of a premises license includes optional language that requires a respondent to arrange for the continuity of patient care and specifies how that should be done. Does the board believe that this optional language should be included in all orders calling for the revocation or surrender of a license?

Motion: Make this a standard term.

Note: Ms. Hackworth was not present for the vote.

M/S: Gutierrez/Veale

Support: 10 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch				x
Gutierrez	x			
Hackworth				x
Law	x			
Lippe	x			
Murphy	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

Chairperson Law explained that in addition to the policy questions raised by board staff, comments were received from stakeholders during the comment period.

Note: the comments received were provided in the board meeting materials.

Ms. Sodergren noted that one of the comments received asked the board to define "geographic area." Staff explained that during the first meeting with their probation monitor the "geographic area" is clearly defined for the probationer.

Ms. Sodergren and Mr. Room stated that the board should consider if they want to require all probationers to notify the board when they leave the defined "geographic area," or if it should only be a term for probationers who are required to complete drug testing.

Motion: Only require probationers who must complete drug testing to notify the board if they are leaving the defined geographic area.

M/S: Veale/Lippe

Note: Ms. Hackworth was not present for the vote.

Support: 9 Oppose: 0 Abstain: 1

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler			x	

Castellblanch				x
Gutierrez	x			
Hackworth				x
Law	x			
Lippe	x			
Murphy	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

Chairperson Law asked Mr. Room if the board should modify the proposed language in response to the comment that stated that the terms “knowingly” and “willfully” are vague and ambiguous. Mr. Room and Ms. Freedman responded that he would not change the proposed language in response to this comment.

The board reviewed the comment submitted by Megan Harwood and decided not to modify the proposed language in response to the comment.

Motion: Approve the proposed language incorporating the changes made by the board in response to the policy questions and comments received.

M/S: Gutierrez/Veale

Note: Ms. Hackworth and Ms. Butler were not present for the vote.

Support: 9 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler				x
Castellblanch				x
Gutierrez	x			
Hackworth				x
Law	x			
Lippe	x			
Murphy	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

The board recessed for a break at 4:20 p.m. and resumed at 4:30 p.m.

Motion: If no comments are received during the 15-day comment period, adopt the language as noticed and delegate to the executive officer the authority to make technical or non-substantive changes as may be required to complete the rulemaking file.

M/S: Gutierrez/Weisser

Support: 9 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler				x
Castellblanch				x
Gutierrez	x			
Hackworth				x
Law	x			
Lippe	x			
Murphy	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

The board returned to the previous regulation agenda item: <u>Proposal to Add Title 16 CCR Section 1730 Related to Advanced Practice Pharmacist</u>

Mr. Room explained that earlier in the meeting the board was asked by a representative from Kaiser to discuss why the board is placing a 10-year limit on experimental hours, when the residency program does not have a time limit.

The board did not modify the language based on the comment made by Kaiser.

The board returned to the motion previously made by Mr. Lippe.

Motion: Expand the timeframe for pharmacists to complete 1,500 hours of experience to ten years.

M/S: Lippe/Butler

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler				x
Castellblanch				x
Gutierrez	x			
Hackworth				x
Law	x			
Lippe	x			

Murphy	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

Motion: Move the language as modified at the October board meeting to 15-day comment period.

M/S: Lippe/Ricardo

Support: 9 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler				x
Castellblanch				x
Gutierrez	x			
Hackworth				x
Law	x			
Lippe	x			
Murphy	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

The board returned to the previous regulation agenda item: <u>Proposal to Add Title 16 CCR Section 1746.4 Related to Vaccinations</u>

Staff manager Lori Martinez reported that at the June 2015 Board Meeting, the board approved proposed text to add section 1746.4 to Title 16 CCR related to Vaccinations. The 45-day comment period began on July 24, 2015 and ended on September 7, 2015. She added that in response the comments received, the board approved modifications to the text and authorized a 15-day comment period. The 15-day comment period began on October 8, 2015 and ended October 22, 2015.

Staff manager Lori Martinez reviewed the comment submitted regarding the notification of the patient's prenatal care provider as follows.

> (d) Notifications: The pharmacist shall notify the patient's primary care provider of any vaccines administered to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. Primary care provider notification must take place within 14 days of the administration of any vaccine. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall advise the patient to consult an appropriate health care provider of the

patient's choice. Notification to the prenatal care provider of immunizations provided to pregnant women must take place within 14 days of the administration of any vaccine**, if the prenatal care provider is known or was provided by the pregnant patient.**

The board agreed with the comment regarding notification of prenatal care providers. Ms. Herold recommended simplifying the language as follows. The board agreed with Ms. Herold's recommendation.

(d) Notifications: The pharmacist shall notify the patient's primary care provider of any vaccines administered to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. Primary care provider notification must take place within 14 days of the administration of any vaccine. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall advise the patient to consult an appropriate health care provider of the patient's choice. **If known,** notification to the prenatal care provider of immunizations provided to pregnant women must take place within 14 days of the administration of any vaccine.

Motion: Modify the language as follows.

(d) Notifications: The pharmacist shall notify the patient's primary care provider of any vaccines administered to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. Primary care provider notification must take place within 14 days of the administration of any vaccine. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall advise the patient to consult an appropriate health care provider of the patient's choice. **If known,** notification to the prenatal care provider of immunizations provided to pregnant women must take place within 14 days of the administration of any vaccine.

M/S: Gutierrez/Lippe

Support: 8 Oppose: 0 Abstain: 1

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler				x
Castellblanch				x
Gutierrez	x			
Hackworth				x
Law	x			
Lippe	x			
Murphy	x			
Sanchez	x			
Schaad	x			
Veale			x	

Weisser	x			
Wong	x			

Ms. Martinez reviewed the comment submitted by Lori Hensic as provided below.

> (f) Documentation: For each vaccine administered by a pharmacist, a patient **vaccine administration** ~~**medication**~~ record shall be maintained in an automated data processing or manual record mode such that the required information under title 42, section 300aa-25 of the United States Code is readily retrievable during the pharmacy or facility's normal operating hours. A pharmacist shall provide the patient with a vaccine administration record, which fully documents the ~~**initiation and administration of any**~~ vaccine**s administered by the pharmacist**. An example of an appropriate vaccine administration record is available on the Board of Pharmacy's website.

The board agreed with the comments submitted by Ms. Hensic.

Motion: Modify the language as provided below.

> (f) Documentation: For each vaccine administered by a pharmacist, a patient **vaccine administration** ~~**medication**~~ record shall be maintained in an automated data processing or manual record mode such that the required information under title 42, section 300aa-25 of the United States Code is readily retrievable during the pharmacy or facility's normal operating hours. A pharmacist shall provide the patient with a vaccine administration record, which fully documents the ~~**initiation and administration of any**~~ vaccine**s administered by the pharmacist**. An example of an appropriate vaccine administration record is available on the Board of Pharmacy's website.

M/S: Lippe/Veale

Support: 9 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler				x
Castellblanch				x
Gutierrez	x			
Hackworth				x
Law	x			
Lippe	x			
Murphy	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

Ms. Martinez reported that the San Diego County Pharmacists Association asked the board to delay implementation as the Immunization Registry is not currently fully functional. Ms. Martinez indicated that the immunization registry is a free software database and comes with free training. The system requirements are high speed internet. Additionally, the registry accepts file transfer via "flat file" which is the same system that CURES uses. As pharmacies report to CURES, they have the ability to report to the immunization registry. The board did not modify the language based on the comment.

Motion: Move the text as modified at the October Board Meeting for 15-day comment period.

M/S: Law/Wong

Support: 9 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler				x
Castellblanch				x
Gutierrez	x			
Hackworth				x
Law	x			
Lippe	x			
Murphy	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

Motion: If no comments are received during the 15-day comment period, adopt the language as noticed and delegate to the executive officer the authority to make technical or non-substantive changes as may be required to complete the rulemaking file.

M/S: Gutierrez/Weisser

Support: 9 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler				x
Castellblanch				x
Gutierrez	x			
Hackworth				x
Law	x			
Lippe	x			
Murphy	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			

Wong	x			

XVI. *Sternberg v. California Board of Pharmacy*

a. Publication of Court of Appeal Case (California's 2nd District Court of Appeal Case No. B255862; Filed August 6, 2015)

Mr. Room explained that recently the board prevailed in a State Court of Appeal case involving a pharmacist-in-charge who appealed the board's disciplinary decision involving substantial controlled substances losses during his tenure as pharmacist-in- charge. The final decision from this court provides a number of substantial findings and determinations involving the role of a pharmacist-in-charge.

Note: a copy of the decision was provided in the board meeting materials.

Mr. Room stated that to further educate pharmacists about the findings of the court with respect to the role of pharmacists-in-charge, and to ensure the board's ability to rely on this decision's findings in future disciplinary matters, the executive officer, with President Gutierrez's consent, requested the publication of the decision.

Mr. Room explained that among the conclusions in the Sternberg decision:

1. *Sternberg* interpreted Business and Professions Code ("Code") sections 4036.5, subdivision (c), 4081, and 4113, to hold that "imposing strict liability [under those Code sections] is consistent" with prior appellate decisions interpreting other licensing statutes. This holding reaffirmed the principle applied in *Margarito v. State Athletic Commission* (2010) 189 Cal.App.4th 159, 168-169, that strict liability is an appropriate basis for license discipline when a licensing statute does not contain "qualifying language such as 'knowingly' or 'intentionally.'" This holding also reaffirmed the principle of law as directly applied to the California Board of Pharmacy, which had not been the subject of a published court opinion addressing this principle for at least thirty years.

2. Sternberg would provide much needed clarification of Code sections 4036.5, subdivision (c), 4081, and 4113 to Administrative Law Judges and lower courts because there is no published decision explicitly discussing whether pharmacists-in-charge may be held strictly liable for pharmacy operations. Sternberg directly addresses this issue and clarifies the scope of these Code sections: it is appropriate to hold a pharmacist-in-charge subject to individual license discipline for misconduct of pharmacy employees, irrespective of knowledge, as long as that misconduct pertains to the practice of pharmacy.

3. While Pharmacy Law is replete with statutes that reference pharmacists-in-charge, corresponding case law discussing the pharmacist-in-charge's indispensable role as gatekeeper of a pharmacy's drug inventory is somewhat scarce. Sternberg directly addresses these responsibilities by confirming that the pharmacist-in-charge is responsible for ensuring the pharmacy's compliance with state and federal laws pertaining to the practice of pharmacy. And, Sternberg explains that these responsibilities are not abstract concepts, but are linked with other Pharmacy Law statutes, including Code section 4081.

Sternberg would thus be the first appellate court decision explaining that, as long as the conduct of pharmacy employees relates to the practice of pharmacy, the pharmacist-in-charge is ultimately responsible for that conduct. This is important because, as recognized by this Court's decision, incentivizing pharmacists-in-charge to "take necessary precautions to adequately supervise and maintain the inventory of dangerous drugs" helps protect the public.

4. Sternberg explains that pharmacists are required to take affirmative measures to maintain pharmacy security. In doing so, this Court explains that the definition of pharmacy facilities includes the pharmacy's phone ordering system. The Court's decision also explains the importance of conducting random checks or audits, and that the pharmacist-in-charge is ultimately responsible if the pharmacist-in-charge declines to do so. Finally, Sternberg explains that if a pharmacist-in-charge gives an employee authority over pharmacy equipment, the pharmacist is responsible for how the employee utilizes that equipment.

Ms. Herold noted that a future article will be developed regarding this decision for the next *Script.*

President Gutierrez stated that staff is requesting that the board ratify the decision to publish the Sternberg decision.

Motion: Ratify the decision to publish the Sternberg decision.

M/S: Veale/Law

Support: 9 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler				x
Castellblanch				x
Gutierrez	x			
Hackworth				x
Law	x			
Lippe	x			
Murphy	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

b. Making the Underlying Administrative Case Precedential (Board Case No. 3377; OAH No. 2010080067)

Mr. Room stated that there is also the potential to make the underlying decision from Board Case No. 3377 into a precedential decision.

He explained that to do this the board would need to vote to make this decision precedential under Government Code Section 11425.60.

Ms. Herold stated that she is concerned that if the board makes the entire decision precedential then they are essentially stating that the discipline was appropriate for the violation. She explained that the violation in the case occurred 10 years ago and at the time three years' probation was appropriate. However, if a similar violation occurred now, the board would take much more stringent action.

Mr. Room stated that the board could make the decision precedential, excluding the discipline section. The board agreed with Mr. Room's recommendation.

Motion: Make the Sternberg decision precedential, excluding the discipline section.

M/S: Veale/Lippe

Support: 9 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler				x
Castellblanch				x
Gutierrez	x			
Hackworth				x
Law	x			
Lippe	x			
Murphy	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

The board adjourned to closed session at 5:00 p.m.

President Gutierrez returned the meeting to open session at 5:46 p.m. and adjourned the meeting for the day at 5:48 p.m.

Friday, October 30, 2015

Call to Order **9:00 a.m.**

XVII. <u>Call to Order and Establishment of Quorum</u>

President Gutierrez called the meeting to order at 9:00 a.m. Board members present: Ricardo Sanchez, Greg Murphy, Allen Schaad, Stanley Weisser, Amy Gutierrez, Deborah Veale, Victor Law and Albert Wong.

XVIII. Petitions for Early Termination or Modification of Probation

Administrative Law Judge Ann Elizabeth Sarley presided over the petitions for early termination or modification of probation for the following licensees.

a. Eugenia Tom, TCH 18794
b. Alice Watchorn, TCH 116919
c. James Greenlee, RPH 48842

XIX. Closed Session

Pursuant to Government Code section 11126(c)(3), the board convened in closed session to deliberate on the petitions for early termination of probation at 11:40 a.m.

President Gutierrez returned the meeting to open session at 12:00 p.m. and adjourned the meeting at 12: 02 p.m.

Note: The SB 493 Committee met following the conclusion of the board meeting

CALIFORNIA STATE BOARD OF PHARMACY
STRATEGIC PLAN DEVELOPMENT ROADMAP

Average Time to Complete Each Phase

1 Week	6 Weeks	2 Weeks	3 Weeks	
Preliminary Meeting & Set-up	**Environmental Scan**	**Board Meeting Planning Session**	**Create & Finalize Plan**	**Action Planning**
• Preliminary meeting with client	• Conduct focus group with staff	• Create facilitation plan	• SOLID drafts plan	• Prioritize objectives
• Introduce facilitators	• Survey stakeholders	• Conduct planning session	• Review plan with client and make adjustments	• Establish timeframes
• Set schedule and decide dates	• Conduct Board member interviews	• Revisit vision	• Board approval or adoption	• Determine metrics
• Decide roles	• Executive Officer interview	• Revisit mission	• Post plan to website	• Assign responsibilities
• Define process	• Compile and analyze data	• Revisit values		• Draft action plan
• Create customized development plan for client	• Review findings with client	• Review environmental scan results		• Review plan with client and make adjustments
		• Establish goals and objectives		

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planning solutions

Facilitator Biographies

Dennis Zanchi

Since joining the SOLID team in 2013, Dennis has conducted focus groups for the Department of Justice as well as DCA boards and bureaus. Dennis has worked on strategic plans for Psychology, BPELSG and Optometry. Prior to DCA, Dennis worked with colleges nationwide facilitating interactive sessions on a variety of education-related topics, including sessions designed to draw out opinions, build consensus, and guide groups to discover new solutions. He helped college administrators build a better framework for understanding student loan default prevention, financial literacy, and student retention. He also develops evaluation measurement methods to quantify the success of various initiatives. Prior to working with colleges, Dennis worked with credit unions nationwide to develop consumer research and marketing plans. He is a graduate of CSU, Sacramento.

Elisa Chohan

Elisa Chohan joined the SOLID team in 2013. Since then, Elisa has partnered with the Board of Registered Nursing, the Bureau of Real Estate Appraisers, the Cemetery and Funeral Bureau, the Court Reporters Board and the Structural Pest Control Board to develop their organization's strategic plans. Elisa came directly from the Bureau of Automotive Repair (BAR) Technical Training Unit. At BAR, Elisa was responsible for the implementation of new processes as well as the creation of new curricula with a focus on adult learning theory and collaborative learning strategies. Prior to starting her career in state service, Elisa was a high school teacher in the Sacramento area, where she worked to develop accreditation plans and process improvement measures to increase institutional efficiency. She has extensive experience with classroom management and developed strategies for behavioral and learning challenges. Elisa graduated from University of California, Davis with a B.A. in History and earned her Masters of Education degree in 2012 from Sacramento State University.

Noel Cornelia

Noel brings over 10 years of experience providing innovative ideas for graphic facilitation of strategic planning sessions in the areas of project management, administration, construction, engineering, and employee recognition. Noel leads participants in the areas of team building, strategic visioning, process improvement, planning, conflict resolution, SWOT, brainstorming, reflection, mission statements, and storyboarding. Noel is the State of California's leading expert in Graphic Recording and Graphic Facilitation training and consulting. She is a Certified True Colors instructor whose sole clients were executives and managers. Noel is a consultant for a dynamic government firm, local universities, private sector businesses, and educators seeking to engage audiences visually. Recently, Noel created the first comprehensive academy for visual communication exclusively for the public sector to build teams and strengthen California's leaders. Noel graduated from CSU, Sacramento, is pursuing graduate studies in Art Therapy, and has been a small business owner for over 14 years.

Ted Evans

Ted Joined SOLID in 2014. At DCA he has developed strategic plans for the Architects Board and the Bureau of Security and Investigative Services. Ted previously worked as a Systems Engineer on the new product implementation team at Meridian Systems. While at Meridian, he created deployment plans, training coursework, knowledge base documentation, and testing metrics. Additionally, he created process maps to support and train clients in their transition to new software. Ted also brings over 15 years of operational management expertise, specializing in process improvement. He developed and implemented successful strategic plans and operations analysis for technology service providers and high-volume restaurant/entertainment facilities. Ted has degrees in Information Technology and Physical Science/Mathematics, and a Bachelor of Science from CSU, Sacramento in Business Administration with a concentration in Human Resources & Organizational Behavior.

Brianna Miller

Brianna joined the SOLID team in 2015. Brianna has worked for the Department of Consumer Affairs (DCA) since 2010, serving at the Board of Optometry, the Bureau of Automotive Repair (BAR) and, most recently, as the DCA's Policy Coordinator in the Division of Programs & Policy Review. In her role as Policy Coordinator, Brianna facilitated policy discussions in monthly Policy Review Committee meetings. Additionally, Brianna has drafted procedural guides and handbooks, and has led presentations for DCA staff and stakeholders. Brianna graduated from University of California, Davis with a B.A. in Psychology and is expecting to complete a Master's of Science degree in Industrial/Organizational Psychology in Summer 2015. Brianna brings graduate-level Organizational Development and Organizational Psychology knowledge in psychometrics, data analysis, needs assessments, job analyses and employee behavior to SOLID's clients.

Overview of Board Member Role in Disciplinary Actions

Presented to the Pharmacy Board (10/28/15)

Administrative Proceedings B&P Code, §§ _____ Gov. Code, § 11500 *et seq*	An administrative proceeding refers to any action to deny, restrict or revoke a license. The proceeding begins when the Executive Officer files a charging document – usually a **Statement of Issues** (to deny a license) or an **Accusation** (to restrict or revoke a license). Rarely, the EO issues a citation, which may be appealed through an administrative proceeding.
Most Common Types of Decisions: Default, Stipulation, Proposed Decisions	If the licensee fails to respond to a charging document, a **default** decision is prepared and submitted the Board members for vote. If the licensee and the Executive Officer agree to particular enforcement outcome, a **stipulation** is prepared and presented to the Board members for vote. If neither of the above occurs, the case is sent to a formal hearing before an administrative law judge (ALJ). After considering the evidence from the hearing (usually documents and witness testimony), the ALJ issues a **proposed decision** (a recommended resolution), which is then presented to the Board members for vote.
Review of Decisions Gov. Code § 11500, *et seq.*; B&P Code, § _____; Title 16, C.C.R. § _____	Board members, by **majority vote of a quorum**, must approve any decision (proposed decision, stipulation or default) before the decision becomes final and the formal discipline (penalty), if any, can take effect. Each Board member reviews any decision presented for vote. Each case is evaluated on a case-by-case basis, but things a member might consider: 1. Whether the Board's highest priority, protection of the public, is effected by the decision; 2. Whether the Board's Disciplinary Guidelines are satisfied or whether variation is warranted; 3. Whether the standards of practice were used as a basis for reaching the decision; and 4. Whether the decision may be reasonably and practically implemented and 5. Whether the case contains factual or legal errors.
Member Questions and Communications about Decisions Gov. Code § 11430.10, *et seq.*	Communications with staff concerning pending proceedings, including decisions, are limited by the provisions of the Administrative Procedure Act. There are two parties to any disciplinary proceeding – complainant (the Executive Officer and other staff) and respondent (the licensee). The Board members decide the case and therefore act as judges. To avoid the fact or appearance of bias or impropriety, communications between one

	party (staff or the licensee) and Board members are limited. There are two common exceptions to this restriction. First, staff may answer questions of procedure and ministerial questions (*e.g.*, when is a vote due, when will a decision become effective). Second, EO or other board staff or the Deputy Attorney General may communicate about stipulated decisions – and only stipulated decisions – only to explain why the stipulated decision should be adopted. Board members may direct questions about a decision to the Board's legal counsel, who is not involved in the investigative stage of the proceeding. Questions about permissible or impermissible communications should also be directed to legal counsel.
Mail Ballots Gov. Code, § 11526 Board policy	Proposed decisions, stipulations and default decisions are generally mailed (electronically or otherwise) to each Board member for voting. The Board member may vote to adopt, reject (non-adopt) or seek to hold the case (discussed in detail below). A ____ calendar day deadline is generally given for a mail ballot to be completed and returned to the Board's office. Board staff reviews the ballots and, if there is not a request to hold, and a quorum of votes has not been received by the Board, prepares the decision for the President's signature.
Holding Disciplinary Cases for Closed Session Board Meetings Board Policy	When voting on a mail ballot, a Board member may wish to discuss a particular aspect of the decision before voting. If two members mark their ballot to "hold for discussion," the case will be scheduled for the closed session of the Board's next meeting. At the time the ballot is prepared, the Board member should record his or her concern. Recording the concern facilitates the discussion by allowing staff, legal counsel and other members an opportunity to prepare to respond to the concern as appropriate. Since there can also be a delay before the next meeting, it can also help preserve the member's memory about his or her concerns. When a matter is held for closed session, Board legal counsel will be present to advise and assist the Board.
Closed session: Stipulations	If the board is deliberating about what to do with a stipulation, it can • Adopt • Reject and set for hearing • Make counter offer and if accepted, will dispose of the matter •

Closed session: Proposed Decision	If a board is deliberating on a Proposed Decision, it can • Adopt the proposed decision of the ALJ • Reject (Non-adopt) the proposed decision and after review of the transcripts and the record and develop its own decision • Remand (return) the decision to the ALJ for the taking of additional evidence. The proposed decision must address all points of evidence submitted. If it does not, the decision can be returned to the ALJ for additional consideration • Make technical or minor changes to the proposed decision. • Mitigate (lessen, reduce) the proposed penalty NOTE: Board cannot increase cost recovery.
Closed Session: Rejection (non-adoption) Gov. Code, § 11517	If the Board votes to reject a Proposed Decision of an ALJ, absent specific direction to the contrary from the Board, the transcript and exhibits of hearing will be ordered and it will provide an opportunity for written argument. The Executive Officer will fix the date for submission of written argument to ensure Board members have time to review any materials prior to a Board meeting. The board meets in closed session to determine the outcome of the case and board counsel writes the decision.
Petition for Reconsideration Gov. Code, § 11521	At any time before the effective date of the decision, the board on its own motion or either of the parties may request reconsideration. The board may grant a stay of up to 30 days to allow a party to file a petition for reconsideration. The EO, president or full board may grant a stay of up to 10 days to consider a petition for reconsideration. If granted for a case in which a hearing was held, the record (transcript and exhibits) is ordered. The members deliberate in closed session to determine if they would like to issue a revised decision.
Appeals of Decisions (Writs of Mandamus) Gov. Code, § 11523	In the event one of the parties believes there to be legal basis to challenge a board decision, the party may file an appeal though a writ of mandamus. In the event the court remands the matter to the board for further action, the board allows written argument. After considering argument, the board deliberates in closed session about the decision to take. Board counsel sits with the board and writes any new decision.
Petitions for Penalty Relief	If a licensee files a petition for penalty relief (for either

Gov. Code, § 11522; B&P Code, § _____ Board Policy	reinstatement or modification or termination of existing probation), as long as that petition meets statutory requirements, the matter will be heard by the Board members themselves at a Board meeting. Absent direction to the contrary, an ALJ sits with the members to preside over the hearing.
Enforcement Actions – Disclosure to the Public Gov. Code, § 6250, *et seq*. B&P Code, §125.9 Department of Consumer Affairs' *Guidelines for Access to Public Records*	Enforcement actions, including citation and disciplinary actions, are a matter of public record.

Medication Article 9.1
Prescription Drug Take-Back Programs
As Discussed at the October 2015 Board Meeting

Section 1776
Pharmacies, hospitals/clinics with onsite pharmacies, distributors and reverse distributors licensed by the board and licensed skilled nursing facilities may offer, under the requirements in this article, specified prescription drug-take back services to the public to provide options for the public to destroy unwanted, unused or outdated prescription drugs. Each of these entities must comply with regulations of the federal Drug Enforcement Administration and the Board of Pharmacy regulations contained in this article.

All board-licensed authorized collectors should be vigilant to prevent patients or their agents from disposing of prohibited items through drug take-back collection methods. Federal, state and other laws prohibit the deposit in drug take-back receptacles of the following: medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, hazardous medications (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers).

Only California-licensed pharmacies and drug distributors (licensed wholesalers and third-party logistics providers) who are licensed in good standing with the board and also registered with the Drug Enforcement Administration as collectors may participate in drug take back programs authorized under this article.

Section 1776.1 Pharmacies

(a) Pharmacies may assist patients seeking to destroy unwanted, previously dispensed prescription drugs as provided in this article. Provision of such services is voluntary.

(b) Pharmacies may provide take-back services to patients as provided in sections 1776 - 1776.4. Retail pharmacies and hospital/clinics with onsite pharmacies may establish collection receptacles in their facilities. Pharmacies may operate collection receptacles as specified in in section 1776.4 in skilled nursing facilities licensed under Health and Safety Code section 1250(c).

(c) There are multiple federal and state requirements governing the collection and destruction of dangerous drugs. Pharmacies are expected to know and adhere to these requirements when operating a prescription drug take-back program.

(d) For purposes of this article, prescription drugs means dangerous drugs as defined by California Business and Professions Code section 4022, including controlled substances. Controlled substances may be commingled in collection receptacles or mail back packages or envelopes with other dangerous drugs. Once drugs are deposited into a collection receptacle or mail back envelope or package by a patient, they are not to be separated by pharmacy staff or others.

(e) The following dangerous drugs and devices are expressly prohibited from collection in

a pharmacy's collection receptacles: medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers). Signage shall be placed on collection receptacles as referenced in section 1776.3.

(f) Prescription drugs that are eligible for collection in drug take-back programs operated by pharmacies are only those prescription drugs that have been dispensed by a pharmacy or practitioner to a patient or patient's agent. Dangerous drugs that have not been dispensed to patients (such as outdated drug stock in a pharmacy, drug samples provided to a medical practitioner or medical waste) may not be collected in pharmacy drug take-back programs.

1. Pharmacy staff shall not review, accept, count, sort, or handle prescription drugs returned from the public.
2. A pharmacy shall not accept or possess prescription drugs returned to the pharmacy by skilled nursing homes, residential care homes, other facilities, health care practitioners or other entities.
3. A pharmacy shall not dispose of quarantined, recalled or outdated prescription drugs from pharmacy stock in a drug take-back collection receptacle. Instead the pharmacy must return these items to a reverse distributor.

(g) A pharmacy must be registered with the federal Drug Enforcement Administration as a collector for purposes of operating a prescription drug take-back program. Such pharmacies cannot employ anyone convicted of a felony related to controlled substances, or anyone who has had a DEA permit denied, surrendered or revoked.

(h) Any pharmacy that operates a drug take-back collection program as authorized in this article shall notify the board on a form designated by the board within 30 days of establishing the collection program. Additionally:

1. Any pharmacy that ceases to operate a drug take-back program shall notify the board within 30 days on a form designated by the board.
2. Any pharmacy operating a mail back program or maintaining collection receptacles shall identify to the board that it provides such services annually at the time of renewal of the pharmacy license, and shall identify all locations where its collection receptacles are located.
3. Any tampering with a storage receptacle or theft of deposited drugs shall be reported to the board with 14 days.
4. Any tampering, damage or theft of a removed liner shall be reported to the board within 14 days.

(i) Before establishing a collection receptacle, the pharmacy must obtain collector status from the federal Drug Enforcement Administration. If the pharmacy later ceases to operate the collection receptacle, the pharmacy must notify the Drug Enforcement Administration within 30 days.

1776.2 Mail Back Package and Envelope Services from Pharmacies

(a) Pharmacies that provide prescription drug take-back services may do so by establishing mail back services, whereby the public may obtain from the pharmacy

preaddressed mailing envelopes or packages for returning prescription drugs to a destruction location.

(b) All envelopes and packages must be preaddressed to a location registered with the Drug Enforcement Administration as a collector that has onsite a method appropriate to destroy the prescription drugs. The pharmacy is responsible for ensuring that all preaddressed envelopes and packages it makes available to the public are preaddressed to be delivered to facilities that comply with this section.

(c) The preaddressed envelopes and packages must be water and spill proof, tamper evident, tear resistant and sealable. The exterior shall be nondescript and not include markings that indicate the envelope or package contains prescription drugs. Postage shall be prepaid on each envelope or package.

(d) The preaddressed envelope and package shall contain a unique identification number for each envelope and package, and certain instructions for users to mail back drugs.

(e) The pharmacy distributing mail back envelopes and packages shall create and maintain records required by section 1776.5.

(f) Individuals who mail back prescription drugs as provided in this section do not need to identify themselves as the senders.

(g) Once filled with unwanted prescription drugs, the mail back packages or envelopes shall be mailed and not accepted by the pharmacy for return, processing or holding.

1776.3 Collection Receptacles in Pharmacies

(a) Pharmacies that provide prescription drug take-back services to the public may do so by establishing a collection receptacle in the pharmacy whereby the public may deposit their unwanted prescription drugs for destruction. The receptacle shall be securely locked and substantially constructed, with a permanent outer container and a removal inner liner.

(b) The pharmacy operating the collection receptacle must securely install the receptacle so it cannot be removed. The receptacle shall be installed in an inside location, where the receptacle is visible to pharmacy employees, but not located in emergency areas. In hospitals/clinics with a pharmacy on the premises, the collection receptacle must be located in an area that is regularly monitored by employees and not in the proximity of emergency or urgent care.

(c) The receptacle shall include a small opening that allows deposit of drugs into the inside of the receptacle directly into the inner liner.

(d) In hours when the pharmacy is closed, the collection receptacle shall be locked so that drugs may not be deposited into the collection receptacle.

(e) The pharmacy is responsible for the management and maintenance of the receptacle. Pharmacy staff shall not accept, count, sort or handle prescription drugs returned from the public, but instead direct the public to deposit the drugs into the collection receptacle themselves.

(f) The receptacle shall be locked and have a removable inner liner to contain the deposited prescription drugs.

(g) A liner as used in this article shall be made of material used and rated to contain chemotherapy waste. The liner shall be yellow and labeled with the words "chemotherapy waste."

(1) The liner shall waterproof, tamper evident and tear resistant.

(2) The liner shall be opaque to prevent viewing or removal of any contents once the liner has been removed from a collection receptacle. The liner shall be clearly marked to display the maximum contents (for example, in gallons). The liner shall bear a permanent, unique identification number established by the pharmacy or pre-entered onto the liner by the liner's manufacturer.

(h) The liner shall be removable as specified in this section. The receptacle shall allow the public to deposit prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and liner. Once a prescription drug or any other item is placed in the collection receptacle, the prescription drug or item cannot be removed or counted.

(i) A liner may be removed from a locked receptacle by two employees of the pharmacy who shall immediately seal the liner and record in a log their participation in the removal of each liner from a collection receptacle. Removed liners shall not be opened, x-rayed, analyzed or penetrated.

(j) Immediately after a liner is removed from a collection receptacle, the liner shall be placed for storage, handling, and transport in a rigid container that may be disposable, reusable, or recyclable. Containers shall be leak resistant, have tight-fitting covers, and be kept clean and in good repair. Containers may be of any color and shall be labeled with the words "Chemo Waste" so the sides may be visible from any lateral direction.

(l) Liners that have been filled and removed from a collection receptacle, and stored in a rigid container must be stored in a secured, locked location in the pharmacy no longer than three days.

(m) The pharmacy shall maintain a log to record information about all liners that have been placed into or removed from a collection receptacle. The log shall contain:

1. The unique identification numbers of all unused liners in possession of the pharmacy
2. The unique identification number and dates a liner is placed in the collection receptacle,
3. The date the liner is removed from the collection receptacle and placed in a rigid container,
4. The names and signatures of the two pharmacy employees who removed and witnessed the removal of a liner from the collection receptacle, and
5. The date the liner was provided to a licensed DEA-registered reverse distributor for destruction, and the signature of the two pharmacy employees who witnessed the delivery to the reverse distributor.

(n) The pharmacy shall ensure the sealed inner liners and their contents are shipped to a distributor's registered location by common or contract carrier (such as UPS, FEDEX or

USPS) or by licensed distributor pick-up at the licensed pharmacy's premises.

(o) The collection receptacle shall contain signage developed by the board advising the public that it is permissible to deposit Schedule II-V drugs into the receptacle, but not Schedule I drugs. Labeling shall also identify that medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers) may not be deposited into the receptacle. The name and phone number of the collector pharmacy responsible for the receptacle shall also be affixed to the collection receptacle.

(p) The board shall develop signage to appear on the collection receptacle to provide consumer information the collection process.

1776.4 Collection in Skilled Nursing Facilities

Skilled nursing facilities licensed under Health and Safety Code section 1250(c) may participate in drug take-back programs as authorized by this article.

(a) Skilled nursing facility personnel may dispose of a current resident's unwanted or unused prescription drugs by using mail back packages or envelopes and packages based upon a request by the resident patient. Mail back envelopes and packages shall conform to the requirements specified in section 1776.1. Records shall be kept by the skilled nursing facility noting the specific quantity of each prescription drug mailed back, the unique identification number of the mail back package and the preaddressed location to which the mail back envelope is sent.

(b) Only retail pharmacies and hospitals/clinics with onsite pharmacies may establish collection receptacles in skilled nursing facilities for the collection and ultimate disposal of unwanted prescription drugs.

1. Any pharmacy and hospital/clinic with an onsite pharmacy operating collection receptacles in skilled nursing facilities shall be registered and maintain registration with the DEA as collectors.
2. Any pharmacy or hospital/clinic with an onsite pharmacy that operates a collection receptacle at a skilled nursing facility shall notify the board within 30 days of establishing a collection receptacle on a form designated by the board.
3. Any pharmacy or hospital/clinic with an onsite pharmacy that ceases to operate a collection site at a skilled nursing facility shall notify the board within 30 days on a form designated by the board.
4. Any pharmacy operating a collection site at a skilled nursing facility shall list all collection receptacles it operates annually at the time of renewal of the pharmacy license.

(c) When a pharmacy or hospital/clinic with an onsite pharmacy installs a collection receptacle in a skilled nursing facility, only the pharmacy shall remove, seal, transfer, and store or supervise the removal, sealing, transfer and storage of sealed inner liners at long-term care facilities as specified in this section.

(d) Every pharmacy and hospital/clinic pharmacy that operates a collection site at any

skilled nursing facility shall notify the board within 14 days of any loss from the collection receptacle or secured storage location for the storage of removed liners.

(e) Within three business days after the permanent discontinuation of use of a medication by a prescriber, as a result of the resident's transfer to another facility or as a result of death, the skilled nursing facility may place the patient's unneeded prescription drugs into a collection receptacle. Records of such deposit shall be made in the patient's records, with the name and signature of the employee discarding the drugs.

(f) A collection receptacle must be located in a secured area regularly monitored by skilled nursing facility employees.

(g) The collection receptacle shall be securely fastened to a permanent structure so that it cannot be removed.

(h) The receptacle shall be securely locked and substantially constructed, with a permanent outer container and a removal inner liner.

(i) The outer container shall include a small opening that allows deposit of drugs into the inside of the outer container and directly into the inner liner.

(j) The outer container shall prominently display a sign indicating that prescription drugs and controlled drugs in Schedules II – V may be deposited. The name and phone number of the collector pharmacy responsible for the receptacle shall also be affixed to the collection receptacle.

(k) Once deposited, the prescription drugs shall not be counted, inventoried or otherwise individually handled.

(l) A liner as used in this article shall be made of material used and rated to contain chemotherapy waste. The liner shall be yellow and labeled with the words "chemotherapy waste."

1. The liner shall waterproof, tamper evident and tear resistant.
2. The liner shall be opaque to prevent viewing or removal of any contents once the liner has been removed from a collection receptacle. The liner shall be clearly marked to display the maximum contents (for example, in gallons). The liner shall bear a permanent, unique identification number established by the pharmacy or pre-entered onto the liner by the manufacturer.

(m) The installation, removal, transfer and storage of inner liners shall be performed only by:

1. One employee of the authorized collector and one supervisory level employee of the long-term care facility (e.g., a charge nurse or supervisor) designated by the authorized collector, or
2. By or under the supervision of two employees of the authorized collector pharmacy.

(n) Upon removal from the collection receptacle, the liner shall be immediately sealed, and placed for storage, handling, and transport in a rigid container that may be disposable, reusable, or recyclable. Containers shall be leak resistant, have tight-fitting covers, and be kept clean and in good repair. Containers may be of any color and shall be labeled with the words "Chemo Waste" so the sides may be visible from

any lateral direction.

(o) Sealed inner liners that are placed in a container may be stored at the skilled nursing facility for up to three business days in a securely locked, substantially constructed cabinet or a securely locked room with controlled access until transfer to a reverse distributor for destruction.

(p) Liners housed in a container may be delivered to a reverse distributor for destruction by two pharmacy employees delivering the sealed inner liners and their contents directly to a reverse distributor's registered location, or by common or contract carrier or by reverse distributor pickup at the skilled nursing facility.

(q) Records of the destruction shall be maintained that provide the date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealed inner was transferred, the unique identification number and the size (e.g., 5 gallon, 10 gallon) of each liner transferred, and if applicable, the names and signatures of the two employees who transferred each liner.

1776.4 Reverse Distributors

(a) A licensed reverse distributor (either a reverse wholesaler or a reverse third-party logistics provider) may accept the sealed inner liners of collection receptacles. Once received, the reverse distributor shall establish records required by this section.

(b) A licensed reverse distributor may not count, inventory or otherwise sort or x-ray the contents of inner liners. All liners shall be incinerated by an appropriately DEA-licensed distributor.

(c) Two employees of the reverse distributor shall pick up or accept the receipt of inner liners from DEA registrants.

(d) A reverse distributor shall not employ as an agent or employee who has access to or influence over controlled substances, any person who has been convicted of any felony offense related to controlled substances or who at any time had a DEA registration revoked or suspended, or has surrendered a DEA registration for cause.

(e) Each reverse distributor with an incineration site shall maintain a record of the destruction on DEA form 41. The records shall be complete, accurate, and include the name and signature of the two employees who witness the destruction.

(f) For each sealed liner or mail back package received from collectors or law enforcement pursuant to federal CFR section 1317.55, the reverse distributor shall maintain records of the number of sealed inner liners or mail back envelopes/package, including the:

1. Date of acquisition
2. Number and the size (e.g., five 10-gallon liners, etc.)
3. Inventory number of each liner or envelope/package
4. The date and place and method of destruction
5. Number of packages and inner liners received
6. Number of packages and inner liners destroyed
7. The number and signature of the two employees of the registrant that witnessed the destruction.

1776.5 Record Keeping Requirements for Board Licensees Providing Drug Take-Back Services

Each entity authorized by this article to collect unwanted prescription drugs from patients shall maintain the following records.

(a) When obtaining unused mail-back packages and envelopes for future distribution:

1. The collector pharmacy shall maintain records that identify: the date the envelope or package was obtained by the pharmacy, the number of packages/envelopes made available to the public, and the unique identification number of each package.
2. For unused packages and envelopes provided to a skilled nursing facility or third party to make available to patients and other authorized individuals: the name of the third party and physical address of the location receiving the unused packages, date sent, and the number of unused packages sent with the corresponding unique identification number.

(b) For each mail-back package or envelope distributed by a pharmacy, the pharmacy shall record the serial number of each package or envelope distributed and the date distributed.

(c) For sealed mail-back packages received by the reverse distributor: the date of receipt and the unique identification of the individual package or envelope,

(d) For sealed mail back packages destroyed onsite by the reverse distributor collector: number of sealed mail-back packages destroyed, the date and method of destruction, the unique identification number of each mail-back package destroyed, and the names and signatures of the two employees of the registrant who witness the destruction.

(e) For pharmacies using collection receptacles, for each liner:

1. Date each unused liner is acquired, its unique identification number and size (e.g., five gallon, 10-gallon). The pharmacy shall assign the unique identification number if the liner does not already contain one.
2. Date each liner is installed in a receptacle, the address of the location where each liner is installed, the unique identification and size (e.g., five gallon, 10-gallon), the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed each installation.
3. Date each inner liner is removed and sealed, the address of the location from which each inner liner is removed, the unique identification number and size (e.g., 5 gallon, 10 gallon) of each inner liner removed, the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed each removal.
4. Date each sealed inner liner is transferred to storage, the unique identification and size (e.g., 5-gallon, 10 gallon) of each inner liner stored, and the names and signatures of the two employees that transferred each sealed inner liner to storage.
5. Date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each

sealed inner was transferred, the unique identification number and the size (e.g., 5 gallon, 10 gallon) of each liner transferred, and the names and signatures of the two employees who transferred each sealed inner liner to the reverse distributor or distributor.

(f) For each reverse distributor (wholesaler or third-party logistics provider) accepting liners, immediately upon receipt of a liner:

1. The date of receipt of each liner, the unique serial number of the liner, the pharmacy from which the liner was received, the method by which the liner was delivered to the reverse distributor (e.g., personal delivery by two pharmacy staff, shipping via common carrier).
2. For each liner destroyed by the reverse distributor collector: the method and date of destruction, listed by the unique identification number of liner and other items required by (f)(1), and the names and signatures of the two employees of the registrant who witness the destruction.