California State Board of Pharmacy
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STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
PUBLIC BOARD MEETING
MINUTES

DATE: January 27-28, 2015

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

BOARD MEMBERS PRESENT:
Stanley C. Weisser, President
Amy Gutierrez, PharmD, Vice President
Greg Lippe, Public Member
Victor Law, RPh
Allen Schaad, RPh
Ricardo Sanchez, Public Member
Lavanza Butler, RPh
Deborah Veale, RPh, Treasurer (1/27/15 only)
Ramón Castellblanch, PhD, Public Member (1/27/15 only)
Albert Wong, PharmD
Rosalyn Hackworth, Public Member (1/27/15 only)
Ryan Brooks, Public Member (1/27/15 only)

BOARD MEMBERS NOT PRESENT: Gregory Murphy, Public Member

STAFF PRESENT:
Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Michael Santiago, DCA Staff Counsel
Laura Freedman, DCA Staff Counsel
Janice Dang, Supervising Inspector
Joshua Room, Deputy Attorney General (1/28/15 only)
Liz McCaman, Researcher
Laura Hendricks, Staff Analyst

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

Tuesday, January 27, 2015

Call to Order 9:05 a.m.

I. Call to Order, Establishment of Quorum and General Announcements

President Weisser called the meeting to order at 9:05 a.m. President Weisser welcomed new board member Ricardo Sanchez. President Weisser recognized former board member Holly Strom and former competency committee member Bob Levin.

President Weisser conducted a roll call. Board members present: Gregory Lippe, Deborah Veale, Ricardo Sanchez, Amy Gutierrez, Stanley Weisser, Rosalyn Hackworth, Allen Schaad, Victor Law, Ramon Castellblanch and Lavanza Butler. Note: Albert Wong arrived at 9:08 a.m. and Ryan Brooks arrived at 9:27 a.m.

II. Approval of the Full Board Meeting Minutes of October 28-29, 2014 and December 17, 2014

Dr. Gutierrez noted that some of the vote counts need to be corrected for the October minutes. Ms. Hendricks noted that Dr. Castellblanch was incorrectly noted as being in attendance.

Motion: Approve the October 28-29, 2014 minutes including the corrections discussed.

M/S: Lippe/Butler

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

Dr. Gutierrez noted that she had chaired that December 9, 2014 Board Meeting and added that Ryan Brooks had attended via telephone conference.

Albert Wong arrived at 9:08 a.m.

Motion: Approve the December 17, 2014 minutes including the corrections discussed.

M/S: Gutierrez/Hackworth

Support: 9 Oppose: 0 Abstain: 2

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	

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

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

IV. Recognition and Celebration of Pharmacists Licensed for 50 Years in California

President Weisser recognized Bob Levin, Drew Donovan and Bob Miller

Ryan Brooks arrived at 9:27 a.m.

V. Organizational Development Committee

a. Future Board Meeting Dates for 2015

President Weisser announced the board meeting dates for 2015.

- April 21 & 22, 2015
- July 28 & 29, 2015
- October 28-29, 2015

b. Budget Update/Report

1. *Budget Report for 2014/2015*
   President Weisser reported that the new budget year began July 1, 2014. He added that the board's spending authorization for the year is $19,881,000 which is a seven percent increase from the prior year.

   President Weisser stated that as of December 1, 2014, the board has expended $7,469,100 of its current year budget. He noted that as the charts provided in the meeting materials detail, 56 percent of the expenditures are attributed to salary and wages and 17 percent is attributed to enforcement related costs.

   President Weisser reported that the board's revenue for the first five months of this year is $9,129,500 and has come primarily from application and renewal fees, 87 percent; with citation and fines accounting for approximately 8 percent.

2. *Fund Condition Report*
   President Weisser reviewed the projected fund condition report as prepared by the Department of Consumer Affairs. He noted that the fund will continue to decrease unless the board increases its fees.

3. *Fee Audit Update*
   President Weisser again stated that the board will need to pursue a fee increase to sustain operations. As a precursor to making such a determination, the board pursued a contract for completion of an independent fee audit. President Weisser noted that the board secured a contract with Macias Consulting Group to complete this independent audit for the board.

   President Weisser reported that he recently met with the auditors to gain a thorough understanding of the audit process and preliminary findings. He added that based on the preliminary findings of the auditors, it is clear that the board will need to increase fees.

   President Weisser concluded that legislation will be necessary to facilitate any fee increase as all of the board's current fees are at their statutory maximum levels.

   The board asked when the last fee increase occurred. Ms. Herold responded that the last time the board increased its fees legislatively was 2010. Ms. Herold reported on the various board activities that have resulted in the need for a fee increase.

   Dr. Gutierrez asked what percentage of revenue comes from pharmacies and what percent comes from pharmacists. Ms. Herold responded that 16 percent comes from pharmacies and 31 percent comes from pharmacists.

The board asked that the individual licensees not be expected to pay for the increase in costs for compounding site licenses. Ms. Herold responded that sterile compounding fees would be calculated in a way that the burden would not be placed on individual licensees.

Awet Kidane, director of the Department of Consumer Affairs, greeted the board and thanked them for their work in consumer protection.

4. *Update on BreEZe, DCA's New Computer System*
   For a number of years the department has worked to replace and/or enhance its legacy licensing and enforcement tracking systems used by most DCA agencies. The system selected was framed around a commercial off the shelf product (COTS) that was intended to streamline processes, provide better access for consumers and licensees and help programs within the department to gain better reporting tools.

   Ms. Sodergren explained that during the board's implementation efforts, board staff discovered critical functionality deficiencies that were not detailed in the original contractual requirements that is essential to the board's ability to deploy BreEZe.

   Ms. Sodergren reported that a work stoppage order was approved for our board, and no additional significant activities have occurred since July.

   Ms. Sodergren stated that it is unclear when work will resume for the board. Ms. Sodergren added that it is anticipated that the board will be included in Release 3.

   President Weisser thanked the board staff for the over 1,300 hours they have dedicated to the project.

   Dr. Castellblanch asked if the board would have to wait to update the website until the BreEZe project begins again. Ms. Sodergren responded that the website will now be updated independently of the BreEZe project.

5. *Board Member Reimbursement and Mail Vote Information*
   President Weisser directed the board and the public to view the meeting materials for information on board member reimbursement and mail voting.

c. Personnel Update

1. *Board Member Update*
   Ms. Herold welcomed Ricardo Sanchez to the board.

2. *Board Staff Update*
   Ms. Herold briefly reviewed the employee promotions, new hires and departures. Ms. Herold noted that Supervising Inspector Robert Ratcliff Pharm. D. had retired. She

announced that Janice Dang Pharm.D. would be taking over as lead supervising inspector.

Dr. Gutierrez asked how the duty inspector call-in line was working now that the inspector positions are fully staffed. Ms. Herold provided a brief overview of the procedures for the duty inspector call-in line and noted that a detailed report including statistics would be provided at a future Enforcement Committee meeting.

Dr. Dang provided insight into the types of calls and questions received. She noted that many calls come from other health care providers.

Dr. Wong stated that if there is significant demand, the board should consider expanding the program. Mr. Law noted that the board could consider charging callers once they reached a certain time threshold.

Ms. Herold stated that the board would be using data from the calls to create a question and answer document for the website.

Dr. Castellblanch asked what the inspectors hired for the drug diversion team are responsible for. Ms. Herold responded that the team uses CURES data proactively to investigate possible diversion.

3. *Mandatory Board Member Training*

Ms. Herold reported that as part of the requirements of being a board member there are several training courses that need to be completed. She noted that some of these training courses need to be done annually while others are a requirement of appointment or reappointment. Below is a list of the required trainings.

- Board Member Orientation Training –required upon appointment or reappointment
- Ethics Training – every two years
- Sexual Harassment Prevention Training – every two years
- Drivers Training – every four years

Ms. Hendricks indicated that she would contact each board member individually with their training plan.

The board asked if they could take the orientation and the training online. Ms. Herold responded that at this time there are no webinars or video conferencing available for the orientation.

Ms. Herold reminded the board members that the Form 700's are due April 1, 2015.

VI. <u>Communication and Public Education Committee</u>

Chairperson Hackworth provided a report of the meetings held December 10, 2014 and January 13, 2015

a. Summary of Presentation on the 43rd Annual Report of the Research Advisory Panel of California

Chairperson Hackworth reported that Laurence R. Upjohn, Pharm.D., Chief with the Science and Education section of the California State Department of Public Health/Food and Drug Branch, spoke to the committee about the 43rd Annual Report of the Research Advisory Panel of California.

Chairperson Hackworth explained that California law, Health & Safety Code sections 11480 and 11481, requires proposed research projects using certain opioid, stimulant and hallucinogenic drugs classified as schedule I and schedule II controlled substances as their main study drug(s), to be reviewed and authorized by the Research Advisory Panel of California. She added that the Board of Pharmacy has an appointee on the panel.

Chairperson Hackworth stated that the Research Advisory Panel primarily seeks to ensure the safety and protection of participating human research subjects and the adequate security of the controlled substances used in the study.

Chairperson Hackworth reported that the committee asked if the group pays special attention to opioid dependency studies that may be sponsored by pharmaceutical companies. Dr. Upjohn explained to the committee that every study now requires financial disclosures and it needs to be in the informed consent documents so the subject knows if a physician is being influenced by a pharmaceutical company.

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

b. Preparation for a Future Board Meeting Forum on Elements of Quality Patient Consultation

Chairperson Hackworth stated that the importance of patient consultation by a pharmacist has been discussed by the board and committee and all agree that consultations are still not being conducted as they should be.

Chairperson Hackworth reported that the committee noted that pharmacists are not always encouraged by their employers to conduct proper consultations because of time constraints, even though two chain pharmacies received large fines for their pharmacists failing to consult. Chairperson Hackworth stated that during the meeting committee members reiterated that pharmacists are legally obligated to consult.

Chairperson Hackworth reported that the committee discussed how pharmacies are evolving to become greater health care entities and the board is going to have to work on this evolution.

The board asked the deans of the schools of pharmacies to report to the committee on how students are educated on consultation. Ms. Herold noted that at the CPhA meeting the board was given the opportunity to have a forum on patient consultation.

c. Discussion and Possible Action to Pursue Legislation Designed to Facilitate Implementation of Standardized Translations on Labels

Chairperson Hackworth reported that at its last two committee meetings, the committee discussed whether including the purpose or condition on a prescription label should be a general requirement. Comments reflected that patients can get confused over their medications and there may be better adherence to medication therapy if the patient understood the purpose or condition for which they are taking the medication. The committee noted that many physicians do not include purpose on the prescription document.

Chairperson Hackworth reported that at its December 10, 2014, meeting the committee members discussed a draft legislative proposal to require translated "directions for use" utilizing the vetted translations that are available on the board's website. The standardized directions for use on the board's website are available in Chinese, Korean, Russian, Spanish, and Vietnamese.

Chairperson Hackworth stated that previous meetings, the committee and board members discussed the benefits of providing patients with medication instructions printed in the patient's native language, as well as the issue of a pharmacist's liability if there is an error on the label and the pharmacist cannot read or write the translated language on the label or in ancillary information. Chairperson Hackworth added that the committee discussed the mode of implementing such a proposal, be it via regulation or legislation. There was consensus that a starting point could be to require the use of the translated "directions for use" that are provided on the board's website.

Chairperson Hackworth reported that at the January 13, 2015 meeting, the committee continued its discussion of draft language to add section 4076.55 to the Business and Professions Code. The committee reached consensus on draft language and voted on a recommendation for the board's consideration. This language is listed below.

4076.55 Standardized Directions for Use and Translations of Directions for Use on Labels

> (a) For all dangerous drugs dispensed to patients in California, whenever possible, a dispenser shall use a standardized direction for use on the label

of the prescription container from the list that appears in California Code of Regulations, Title 16, section 1707.5(a).
(b) The board shall make available translations of the standardized directions for use that are listed in California Code of Regulations, Title 16, section 1707.5(a) in at least the five most frequently spoken non-English languages in California. These translations shall be approved by state-certified translators.

These translated standardized directions for use shall be posted on the board's website.

(c) Upon the request of a patient, a dispenser may select the appropriate translated standardized direction for use from those established in subdivision (b) and append it to the label on the patient's prescription container. Whenever a translated direction for use appears on a prescription container label, the English version of this direction must also appear on the label. The translated direction for use shall appear in the patient-centered area of the label pursuant to California Code of Regulations, Title 16, section 1707.5(a). The English version must appear in other areas of the label outside this patient-centered area.

(d) A dispenser shall not be liable for any error that results from a dispenser's inability to understand the non-English language translation made available under subdivision (b), unless gross negligence has been committed by the dispenser.

(e) A dispenser may provide his or her own translated directions as an alternative to the process identified in this section. The translated directions for use shall appear in the patient-centered area of the label pursuant to California Code of Regulations, Title 16, section 1707.5(a). The English version must appear in other areas of the label outside this patient-centered area.

Ms. Veale asked if the committee had come to a consensus on including purpose on the label. Ms. Herold answered that purpose on the label is still an ongoing discussion and would require working with other healthcare professionals.

Mr. Lippe expressed his concern with the term "gross negligence" and the possibility that it might encourage litigation. Mr. Santiago responded that this would be true for any language that limits liability; someone could always choose to file a lawsuit. Mr. Lippe recommended removing the phrase "unless gross negligence has been committed by the dispenser." Mr. Santiago stated that there may be some opposition to just providing blanket immunity.

Ms. Veale asked why the board was including limited liability language if it required a legislative change, which would take longer than a regulatory change. Chairperson Hackworth responded that the legislation was necessary because it would not only apply to pharmacists but all dispensers.

Mr. Santiago stated that subdivision (d) would have to be placed in the civil code.

Ms. Veale expressed her concern with fitting all the information on the label.

Ms. Veale asked how a pharmacist would handle the translation of a prescription that has unique directions for use. Dr. Wong stated that they would not be required to translate them; the language only requires translation for the standard directions for use provided on the board's web site.

Ms. Veale clarified that if it was not one of the standard directions for use on the board's web site they would not have to provide the translation. President Weisser responded that they would still have to provide an oral translation, as currently required by law.

Mr. Brooks encouraged the committee to consider patient privacy when they discuss including purpose on the prescription label. Ms. Butler stated that if the patient asks to put the purpose on the label the pharmacist should be able to provide it.

Mr. Brooks expressed his desire to see analytics on how many medication errors occur due to lack of translation. Chairperson Hackworth responded that the committee has heard multiple reports on the problem.

The board discussed the fact that because of the immunity language this would be required to go back to the legislature.

The board discussed the process by which the translated directions for use on the board's website were vetted.

Some members of the board expressed their concern with mandating pharmacists to use the translated directions.

Ms. Veale asked why the board is not allowing the translations to be provided on a separate document, similar to New York's requirements. Ms. Hackworth responded that the committee was concerned with the document becoming separated from the bottle and lost.

Dr. Wong noted that his pharmacy and other chain pharmacies are already providing translations, even without the board mandating it.

Dr. Castellblanch reminded the board that the legislative process would allow for stakeholder input and further refining of the language.

President Weisser expressed the importance of patients receiving their medication with a label in a language they can read.

Mr. Brooks again expressed his desire for data on medication errors that occur due to the lack of translations available.

The board discussed the timeline to sponsor legislation this year. Ms. Herold explained that it would be in the board's best interest to take a leadership role in translating labels.

The board asked if the immunity language would apply to a pharmacy that chooses to use its own translations. Mr. Santiago responded that as drafted, the limited liability would not apply to a pharmacist who used his or her own translations.

President Weisser asked if the board would have to pursue legislation even if it decided to remove the limited liability language. Mr. Santiago responded that because the board is mandating translations to be provided upon the request of the patient, the board must pursue legislation.

Dr. Gutierrez asked if the committee determined if current software was capable of providing the translations in the five languages on the board's website. Dr. Castellblanch responded that previously the board heard a presentation from a software provider on the availability of translation software. Ms. Veale explained that the challenge may not be with the availability of translation software, rather with the label printers' capability to print various languages on the label.

The board recessed for a break at 11:19 a.m. and resumed at 12:00 p.m.

Sara DeGuia from California Pan Ethnic Health Network stressed the importance of patients receiving labels in a language that they understand. She added that there is data available that shows limited English speakers have difficulty reading their medication labels.

Ms. DeGuia stated that the five languages provided on the board's website would cover 85 percent of the limited English speakers in California.

President Weisser stated that including the liability language will give the pharmacist the confidence to use the translations. Ms. DeGuia agreed.

Ms. DeGuia stated that while patients will find ways to get their labels translated, having to do so creates an undue burden on them and violates their privacy. She added that

doctor offices are now providing translation services and insurance companies provide translated paperwork. Mr. Law asked if the insurance providers and doctors are mandated to provide translations. Ms. DeGuia explained that federal law requires insurance providers to provide translations and the insurance providers in turn require doctors to use translation services.

The board expressed the need to make the translated directions for use easier to find on the board's website.

Brian Warren from the California Pharmacists Association stated that the association would encourage the board to use the strongest limited liability language possible. Mr. Warren reminded the board that pharmacies already provide verbal translation services.

The board again discussed the difficulties that may arise from printing the translations on the label rather than an auxiliary document.

Angie Manettie stated that the California Retailers Association would oppose the legislation as drafted and asked the board to consider the software challenges for pharmacies printing the translations on the label.

Rebecca Cupp reported that Ralph's is currently only able to print labels in Spanish and noted that it took a lot of work to accomplish this.

Don Gilbert representing Rite Aid stated that in order to practice pharmacy responsibly and to be profitable, pharmacies need to provide translations for the community they serve. He added that the board was rushing to draft the legislation. President Weisser responded that the board and the committee have worked for many months to draft this language. Mr. Gilbert encouraged the board to consider if the language provided addressed the challenges raised during the discussion at the meeting.

The board asked how Rite Aid provides translations. Mr. Gilbert explained that Rite Aid provided verbal translations and written translations on auxiliary documents.

Jennifer Snyder with the National Association of Chain Drug Stores encouraged the board not to mandate written translations, but instead encourage and promote written translations as best practices.

Dr. Gray, as an individual, recommended changing the language from "whenever possible" to "when applicable." He also stated that the language would not apply to physicians or dentists.

Martin Cable, retired pharmacist, stated that it is the pharmacist's professional responsibility to communicate as much information to the patient as possible, regardless

of the language.

Dr. Wong showed the board labels printed by his pharmacy in Chinese and Vietnamese and stated that his pharmacy has been providing this service for over 20 years.

Mr. Brooks, Mr. Law and Dr. Wong expressed concern with mandating written translations when many pharmacies are already providing the service.

Dr. Castellblanch stated that the Institute of Medicine has reported that limited English speakers have difficulty obtaining translated labels and this leads to medication errors.

Chairperson Hackworth read the committee recommendation as follows:

Committee Recommendation (Motion): Pursue legislation to add Business and Professions Code section 4076.55 as provided below.

> **4076.55 Standardized Directions for Use and Translations of Directions for Use on Labels**
>
> (a) For all dangerous drugs dispensed to patients in California, whenever possible, a dispenser shall use a standardized direction for use on the label of the prescription container from the list that appears in California Code of Regulations, Title 16, section 1707.5(a).
>
> (b) The board shall make available translations of the standardized directions for use that are listed in California Code of Regulations, Title 16, section 1707.5(a) in at least the five most frequently spoken non-English languages in California. These translations shall be approved by state-certified translators.
>
> These translated standardized directions for use shall be posted on the board's website.
>
> (c) Upon the request of a patient, a dispenser may select the appropriate translated standardized direction for use from those established in subdivision (b) and append it to the label on the patient's prescription container. Whenever a translated direction for use appears on a prescription container label, the English version of this direction must also appear on the label. The translated direction for use shall appear in the patient-centered area of the label pursuant to California Code of Regulations, Title 16, section 1707.5(a). The English version must appear in other areas of the label outside this patient- centered area.
>
> (d) A dispenser shall not be liable for any error that results from a dispenser's inability to understand the non-English language translation made available under subdivision

(b), unless gross negligence has been committed by the dispenser.

(e) A dispenser may provide his or her own translated directions as an alternative to the process identified in this section. The translated directions for use shall appear in the patient-centered area of the label pursuant to California Code of Regulations, Title 16, section 1707.5(a). The English version must appear in other areas of the label outside this patient-centered area.

Support: 2 Oppose: 10 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 considered removing the liability language to avoid the legislative process. Dr. Castallblanch explained that the committee heard testimony from the industry expressing their concerns with pharmacists being held liable for providing translations in languages not spoken by the pharmacist.

Mr. Lippe recommended making the following amendments: change the term "whenever possible" to "when applicable" in subdivision (a); allow the translation to be provided either on the label or on a separate document; remove subdivision (d) and move subdivision (e) to the civil code.

Mr. Law stated that the board has heard testimony that many pharmacies are already providing these services and stated he would vote against the legislation.

Board staff clarified that if a patient requests a translation, the pharmacist must provide the translation, if it is one of the standard directions for use translated on the board's website. Consequently the board amended subdivision (c) to read: "Upon the request of a patient, a dispenser ~~may~~ shall, if available, select the appropriate translated standardized direction for use…"

The board recessed for lunch at 1:40 p.m. and resumed at 2:00 p.m.

For clarity the board projected the proposed language via PowerPoint so that the public and the board could reviewed it line-by-line and make appropriate amendments. Below is the language as amended by the board during this line-by-line review.

Business and Professions Code Section 4076.55 - Standardized Directions for Use and Translations of Directions for Use on Labels

(a) For all dangerous drugs dispensed to patients in California, ~~whenever possible~~ when applicable, a dispenser shall use a standardized direction for use on the label of the prescription container from the list that appears in California Code of Regulations, Title 16, section 1707.5(a).

(b) The board shall make available translations of the standardized directions for use that are listed in California Code of Regulations, Title 16, section 1707.5(a) in at least ~~the~~ five languages other than English. ~~most frequently spoken non-English languages in California.~~ These translations shall be approved by state-certified translators. These translated standardized directions for use shall be posted on the board's website.

(c) Upon the request of a patient, a dispenser ~~may~~ shall, if available, select the appropriate translated standardized direction for use from those established in subdivision (b) and append it to the label on the patient's prescription container or provide a supplemental document. Whenever a translated direction for use appears on a prescription container label, the English version of this direction must also appear on the label. The translated direction for use shall appear in the patient-centered area of the label pursuant to California Code of Regulations, Title 16, section 1707.5(a). The English version ~~must~~ may appear in other areas of the label outside this patient-centered area.

~~(d) A dispenser shall not be liable for any error that results from a dispenser's inability to understand the non-English language translation made available under subdivision (b), unless gross negligence has been committed by the dispenser.~~
Move section (d) to the Civil Code.

~~(e)~~ (d) A dispenser may provide his or her own translated directions as an alternative to the process identified in this section. The translated directions for use shall appear in the patient- centered area of the label pursuant to California Code of Regulations, Title 16, section 1707.5(a) or a supplemental document. The English version ~~must~~ may

appear in other areas of the label outside this patient-centered area.

Civil Code Section 1714.20

(d) A dispenser who complies with Business and Professions Code Section 4076.55 shall not be liable for any error that results from a dispenser's inability to understand the non-English language translation ~~made available under subdivision (b), unless gross negligence has been committed by the dispenser~~

Sara DeGuia expressed concern that the language applied the limited liability too broadly.

Jennifer Snyder with the National Association of Chain Drug Stores again stated that the association feels that the legislation is not necessary as pharmacies are already providing translation services.

Dr. Wong and Mr. Law again expressed their opposition to mandating translations.

Motion: Amend Business and Professions Code Section 4076.55 as provided above.

M/S: Lippe/Castellblanch

Support: 7 Oppose: 5 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. Discussion of Additional Recommendations Designed to Facilitate Implementation of Standardized Translations on Labels

Chairperson Hackworth reported that the committee discussed a regulation change to ask pharmacies to provide in their written policies to provide interpretive services and translation services. The language recommended by the committee is below.

Title 16 CCR section 1707.5(d)

1707.5 (d) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive and translation services in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language, if interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.

Sara DeGuia from CPHEN expressed her support of the language.

Dr. Gray stated that the board should change the language to say "and all board required translation."

Committee Recommendation (Motion): Amend board regulation at Title 16 CCR section 1707.5(d) to insert the words "and translation."

Support: 11 Oppose: 0 Abstain: 1

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

e. Update on The Script

Chairperson Hackworth reported that the Board of Pharmacy newsletter The Script is in the review process and the issue highlights new laws, board enforcement actions, hospital drug diversion, the Medical Board's release of their revised pain management guidelines and the board's policy statement encouraging the elimination of tobacco products in pharmacies.

f. Update on the Future Redesign of the Board's Website

Chairperson Hackworth reported that the board will be redirecting its IT person to redesign the website so it will be simpler to use with less information on each page. The redesign will take 4-6 months of the IT person's time spread out over a year. She added that during the revision, old information on the site will be removed.

g. Summary of Discussion of National Association of Boards of Pharmacy's .Pharmacy Suffix for Online Pharmacies

Chairperson Hackworth reported that the National Association of Boards of Pharmacy (NAPB) launched the .pharmacy Top-Level Domain (TLD) to provide consumers around the world with a means for identifying safe, legal and ethical online pharmacies and related resources. She added that eligible trademark holders may apply to NABP for approval to register .pharmacy domain names and, once approved, will be able to register the domain.

Chairperson Hackworth noted that general availability will begin in June 2015, at which time all entities providing pharmacy-related products, services or information that meets .pharmacy eligibility standards will be able to apply to register for the domain.

Chairperson Hackworth reported that the committee discussed that the new .pharmacy domain will apply to all pharmacies in the U.S. and internationally. For the first time, consumers will be able to tell if an online pharmacy is legitimate. Chairperson Hackworth noted that boards of pharmacy will also be able to have .pharmacy websites and the California Board already has a name reserved. She added that in the future, the board will be able to post information there.

Chairperson Hackworth stated that Ms. Herold serves on the NABP advisory committee. Ms. Herold briefly reported on the committee's work.

The board stated that the .Pharmacy program should be advertised by the board.

The board discussed the possibility of creating a seal that can be placed on a pharmacy website indicating that the board has verified is legitimately licensed by the board.

A member of the public strongly encouraged the board attend the upcoming NABP spring conference because important matters are discussed and voted on and last year California was the only pharmacy board not in attendance.

h. Update on Media Activity

Chairperson Hackworth briefly reviewed the board's media activity. The complete list of media activity can be viewed in the meeting materials.

i. Public Outreach Activities Conducted by the Board

Chairperson Hackworth briefly reviewed the board's outreach activities and thanked Ms. Herold for her outreach work. The complete list of media activity can be viewed in the meeting materials.

Ms. Hackworth left the meeting at the conclusion of her report.

VIII. Licensing Committee Report

Chairperson Veale reported that there has been no Licensing Committee Meeting since June 26, 2014.

a. Status of Implementation of Recently Enacted Legislation Impacting Licensing Programs of the Board

1. *Implementation of Assembly Bill 2605 (Bonilla, Chapter 507, Statutes of 2014) Regarding Licensing of Third-Party Logistics Providers*
   Chairperson Veale explained that AB 2605 was board sponsored to ensure the appropriate and continued regulation over third-party logistics providers. Specifically, the measure creates three new licensing classifications for the board, as well as establishes the requirements for application, licensure and renewal. The specific new licensing classifications include:
   - Third-Party Logistics Providers
   - Nonresident Third-Party Logistics Providers
   - Designated Representative-3PL

   Chairperson Veale reported that during the October 2014 board meeting, members were advised that implementation of these provisions will require changes to the existing licensing and application computer system used by the board, which is a bit more complicated because of the department's current efforts to convert to the new BreEZe computer system.

   Chairperson Veale stated that the freeze exemption was approved and board staff is working with the department to identify the necessary programming requirements. In addition, draft applications and instructions were submitted for legal review in December.

   Chairperson Veale concluded that board staff is responding to inquiries and advising individuals of the status of implementation.

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

2. *Update of Application Forms Pursuant to Other 2014 Enacted Legislation*
   SB 1159 (Lara) Professions and Vocations: License Applicants: Individual Tax Identification Number

Chairperson Veale explained that this measure requires an applicant to provide the board with either a social security number or an individual taxpayer identification number. (Prior to enactment, the board could only accept a social security number.) Implementation of this provision will require updating application and instruction forms as well as slight modification to the licensing and application computer systems.

Chairperson Veale reported that board staff was advised that the department is currently assessing the necessary changes that will be required to implement this. The department expects to release information by the end of January.

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

SB 1226 Veterans: Professional Licensing
Chairperson Veale explained that this measure requires the board, on or after July 1, 2016, to expedite the initial licensure process for an applicant who supplies satisfactory evidence to the board that the applicant has served as an active duty member of the Armed Forces and was honorably discharged. Implementation of this provision will require updating application and instruction forms.

Chairperson Veale reported that this legislation takes effect on July 1, 2016, therefore implementation efforts are not yet underway.

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

SB 1466 (Omnibus) Business and Professions
Chairperson Veale stated that SB 1466 contained two provisions that impact board licensing programs. The first amends the definition of a correctional facility. Chairperson Veale explained that implementation of this provision will require updating application and instruction forms, as well as securing changes to the existing licensing and application system.

Chairperson Veale reported that SB 1466 also changed requirements for designated representatives to require that the individual be at least 18 years of age at the time of application for licensure. This provision only requires a procedural update.

Chairperson Veale stated that board staff has initiated implementation efforts, including creations of new application forms for the licensed correctional facility license category, as well as revision of the designated representative application forms.

The board discussed the different operational needs of correctional facilities and noted that the board should review the current regulations to identify possible gaps.

b. Competency Committee Report

Chairperson Veale reported that effective December 1, 2014, the board instituted a quality assurance review of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE). This means that there is currently a delay in the release of all CPJE examination scores. This process is done periodically to ensure the reliability of the examination.

Chairperson Veale asked if the board was currently releasing scores. Ms. Herold responded that the scores are not currently being released.

Dan Robinson noted that schools of pharmacy are required by the ACPE to report exam results on the school's website in January of each year.

c. Licensing Statistics

Chairperson Veale reported that as of December 31, 2014, the board had 142,057 total licensees, including 45,289 pharmacists and 74,236 pharmacy technicians.

Chairperson Veale explained that during the first half of the fiscal year, the board received more than 10,500 applications and issued almost 8400 licenses. She added that the number of applications received increased about 15 percent and the number of licenses issued increased about 10 percent, when compared to the same time periods last fiscal year.

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

IX. SB 493 Implementation Committee

President Weisser provided a report of the meetings held on November 5, 2014 and December 16, 2014.

a. Proposed Schedule for Action on Provisions Established by SB 493 (Hernandez, Chapter 469, Statutes of 2013)

President Weisser briefly reviewed the schedule provided in the board meeting materials. He noted that the board would be voting on draft protocols, created by the committee. The protocols, if approved, will then be reviewed and hopefully approved by the Medical Board during their meeting on January 30, 2015.

b. Summary of Materials Where Board Guidance Is Envisioned, Discussion of the Requirements:

President Weisser reported that at the November and December committee meetings, the committee discussed whether written guidance to licensees should be developed in the three areas below.

1. For pharmacists who initiate and administer immunizations pursuant to recommended immunization schedules by the federal Advisory Committee of Immunization Practices
2. For Prescription Medications not Requiring a Diagnosis that Are Recommended by the CDC for Travel Outside the US
3. For Ordering and Interpreting Tests to Monitor and Manage Drug Therapies

He directed the board and the public to review the minutes from the committee meetings for details on the discussion.

c. Discussion on Requirements of the Advanced Practice Pharmacist License and Summary of Presentation by National Commission for Certifying Agencies and Board of Pharmacy Specialties Certification Programs

President Weisser reported that the advanced practice pharmacist category of pharmacist licensure will allow such licensed pharmacists to perform physical assessments; order and interpret medication-related tests; refer patients to other providers; initiate, adjust, and discontinue medications under physician protocol or as part of an integrated system such as an ACO; and participate in the evaluation and management of health conditions in collaboration with other providers.

President Weisser explained that the law (in Business and Professions Code section 4210) establishes requirements that a pharmacist must possess to become licensed as an APP. Specifically, a pharmacist must satisfy any two of the following criteria:

(A) Earn certification in a relevant area of practice, including, but not limited to, ambulatory care, critical care, geriatric pharmacy, nuclear pharmacy, nutrition support pharmacy, oncology pharmacy, pediatric pharmacy, pharmacotherapy, or psychiatric pharmacy, from an organization recognized by the Accreditation Council for Pharmacy Education or another entity recognized by the board.
(B) Complete a postgraduate residency through an accredited postgraduate institution where at least 50 percent of the experience includes the provision of direct patient care services with interdisciplinary teams.
(C) Have provided clinical services to patients for at least one year under a collaborative practice agreement or protocol with a physician, advanced practice pharmacist, pharmacist practicing collaborative drug therapy management, or health system.

President Weisser explained that the committee discussed whether to require certification programs to apply to the board, or if the board would simply list the specific entities they will recognize. Also, would a pharmacist be allowed to count the hours they spent completing their postgraduate residency as required in item (B) to complete the one year of clinical services under a collaborative practice agreement as required in item

(C); or if they would be required to complete the year of clinical services *after* they complete their residency.

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

d. Discussion and Possible Action To Add Title 16 Section 1730 To Provide Acceptance of Programs Certified by the National Commission for Certifying Agencies

President Weisser reported that at the December committee meeting, the committee heard a presentation on the National Commission for Certifying Agencies (NCCA) by chair Chad Buckendahl. President Weisser noted that the committee meeting minutes provided details about the presentation and NCCA certification process, below is a brief summary of the NCCA standards.

Overview of NCCA Standards

- NCCA accredits certification programs, not organizations, agencies, or testing services as an organization may have multiple programs all with different testing and methodology
- Programs may be sponsored by non-profit or for-profit organizations
- Accreditation is generally awarded for five years. Every program is evaluated at *least* every five years.
- NCCA Standards are intended to be consistent with the Standards for Educational and Psychological Testing (AERA, APA, & NCME, 2014), and others
- The purpose is to evaluate process and products, not content. NCCA reviewers are not content experts (for example they are not pharmacists). Therefore, they look to see if the program has subject matter experts involved at key points in the program to ensure the appropriate knowledge is there.

Ms. Herold noted that if the board chose to accept programs certified by the NCCA the language in California Code of Regulations 1730 should read "The board recognizes the pharmacy patient care certification accredited programs certified by the National Commission for Certify Agencies (NCCA)…"

Brian Lawson, from the Board of Pharmacy Specialties, commented that they support the board recognizing NCCA accredited programs.

Motion: Add Title 16 to the California Code of Regulations as Section 1730 to provide acceptance of programs certified by the National Commission for Certifying Agencies.

Article 3.5
Advanced Practice Pharmacist

1730 Acceptable Certification Programs

The board recognizes the pharmacy patient care certification accredited programs certified by the National Commission for Certify Agencies (NCCA) for purposes of satisfying the requirements in Business and Professions Code Section 4210(a)(2)(A).

M/S: Law/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 explained that the board would need to establish the documentation requirements for APPs so that the board can issue licenses. Below is the language that was provided during the board meeting.

1730.1 Documentation Requirements for Advanced Practice Pharmacist Licensure

(a) Documentation of possession of a certification as specified in California Business and Professions Code section 4210(a)(2)(A) shall be via:
(1) A notarized copy of the certification award that includes the name of the applicant pharmacist, the area of specialty and date of completion, or
(2) A letter from the certification program attesting the award of the certification that includes the name of the applicant pharmacist, the area of specialty and the date of completion.
(b) Documentation of completion of a postgraduate residency earned through an accredited postgraduate institution as specified in California Business and Professions Code section 4210(a)(2)(B) shall be via either:
1. A notarized copy of the residency certificate awarded by the postgraduate institution that includes the name of the applicant pharmacist, the area of specialty, and dates of participation and completion, or
2. A letter of completion of a postgraduate residency signed by the dean or residency program director of the postgraduate institution and sent directly to the board from the

postgraduate institution that lists the name of the applicant pharmacist, the dates of participation and completion, and areas of specialty.

(c) Documentation of experience earned under a collaborative practice agreement or protocol for at least one year as specified in California Business and Professions Code section 4210(a)(2)(C) shall be via:

(1) A copy of an agreement or protocol under which the applicant pharmacist has provided clinical services to patients, and

(2) A letter from the supervising practitioner attesting under penalty of perjury that the applicant pharmacist has completed at least one year of the experience providing clinical services to patients.

Ms. Herold asked the board to review this language and approve it so that it can move forward in the regulation process.

Ms. Veale commented that she would change (c) to say "at least 1,500 hours" instead of one year. Ms. Herold recommended keeping in the term "one year" in order to be compliant with statue. Ms. Veale proposed amending the language to "at least one year with no less than 1,500 hours…" The board agreed with this amendment.

Steve Gray, from Kaiser, asked if the board intended the term "institution" to be very broad, not just limited to a hospital. Ms. Herold explained that it was not intended for the term institution to mean only a hospital.

Motion: Approve the language as provided at the meeting with the amendment to section (c).

> (c) Documentation of experience earned under a collaborative practice agreement or protocol for at least one year with no less than 1,500 hours as specified in California Business and Professions Code section 4210(a)(2)(C) shall be via:

M/S: Lippe/Law

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			

e. Discussion and Possible Action to Amend Title 16 California Code of Regulations Section 1749 Fee Schedule

Ms. Herold explained that the board needs to approve the fees for the APP license. The proposed fee schedule is below.

Article 6. Fees
1749. Fee Schedule.
The fees for the issuance and renewal of licenses, certificates, and permits, and the penalties to be assessed for failure to renew in accordance with sections 163.5, 4110, 4127.5, 4196, and 4400 of the Business and Professions Code are hereby fixed as follows:
(a) The fee for the issuance of a pharmacy license is four hundred dollars ($400). The fee for the annual renewal of pharmacy license is two hundred fifty dollars ($250). The penalty for failure to renew is one hundred and twenty five dollars ($125).
(b) The fee for the issuance of a temporary license is two hundred fifty dollars ($250).
(c) The fee for the issuance of a pharmacy technician license shall be one hundred five dollars ($105). The fee for the biennial renewal of a pharmacy technician license shall be one hundred thirty dollars ($130). The penalty for failure to renew a pharmacy technician license is sixty-five dollars ($65).
(d) The fee for application and examination as a pharmacist is one hundred eighty-five dollars ($185).
(e) The fee for regrading an examination is eighty-five dollars ($85).
(f)**(1)** The fee for the issuance of an original pharmacist license is one hundred fifty dollars ($150).
(2) The fee for application and issuance of an advanced practice pharmacist license is three hundred dollars ($300).
(g)**(1)** The fee for the biennial renewal of a pharmacist's license is one hundred fifty dollars ($150). The penalty fee for failure to renew is seventy-five dollars ($75).
(2) The fee for the biennial renewal of an advanced practice pharmacist license is three hundred dollars ($300). The penalty fee for failure to renew is one hundred fifty dollars ($150).
(h) The fee for the issuance or renewal of a wholesaler's license is six hundred dollars ($600). The penalty for failure to renew is one hundred fifty dollars ($150).
(i) The fee for the issuance or renewal of a hypodermic license is one hundred twenty five dollars ($125). The penalty for failure to renew is sixty-two dollars and fifty cents ($62.50).
(j) The fee for the issuance of a license as a designated representative pursuant to Section 4053 of the Business and Professions Code shall be two hundred fifty dollars ($250). If the applicant is not issued a license as a designated representative, the board shall refund one hundred ten dollars ($110) of the fee. The fee for the annual renewal of a license as a

designated representative shall be one hundred fifty dollars ($150). The penalty for failure to renew is seventy-five dollars ($75).
(k) The fee for the issuance or renewal of a license as a nonresident wholesaler is six hundred dollars ($600). The penalty for failure to renew is one hundred fifty dollars ($150).
(l) The fee for an intern pharmacist license is seventy-five dollars ($75). The fee for transfer of intern hours or verification of licensure to another state is twenty dollars ($20).
(m) The fee for the reissuance of any permit, license, or certificate, or renewal thereof, which must be reissued because of change in the information, other than name change, is one hundred dollars ($100).
(n) The fee for evaluation of continuing education courses for accreditation is forty dollars ($40) for each hour of accreditation requested.
(o) The fee for the issuance of a clinic license is four hundred dollars ($400). The fee for the annual renewal of a clinic license is two hundred fifty dollars ($250). The penalty for failure to renew is one hundred and twenty five dollars ($125).
(p) The fee for the issuance of a nongovernmental license, or renewal of a license, to compound sterile drug products is six hundred dollars ($600). The penalty for failure to renew is one hundred fifty dollars ($150).
(q) The fee for the issuance of a license as a designated representative for a veterinary food-animal drug retailer shall be two hundred fifty dollars ($250). If the applicant is not issued a license as a designated representative, the board shall refund one hundred fifty dollars ($150) of the fee. The fee for the annual renewal of a license as a designated representative shall be one hundred ten dollars ($110). The penalty for failure to renew is fifty-five dollars ($55).
(r) The fee for a veterinary food-animal drug retailer license is four hundred dollars ($400). The annual renewal fee for a veterinary food-animal drug retailer is two hundred and fifty dollars ($250). The fee for the issuance of a temporary license is two hundred and fifty dollars ($250)
(s) The fee for the issuance of a retired pharmacist license shall be thirty dollars ($30).

Authority cited: Sections 163.5 and 4005, Business and Professions Code. Reference: Sections 163.5, 4005, 4110, 4112(h), 4120, 4127.5, 4196, 4200,**4210** 4400, 4401 and 4403, Business and Professions Code.

Motion: Amend Title 16 of the California Code of Regulations Section 1749 (f) and (g).

M/S: Gutierrez/Law

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. Discussion and Possible Action to Add Title 16 California Code of Regulations Section 1746.1 on the Protocol Requirements for Pharmacists Who Furnish Self-Administered Hormonal Contraceptives

President Weisser explained that at this meeting, the board will review and comment on the developed protocol for pharmacists to provide self-administered hormonal contraception. The version approved by the board at this meeting will be provided to the Medical Board at its meeting on January 30th. If both boards approve the same text, this board may initiate a rulemaking to adopt the protocol as a regulation.

President Weisser reported that the requirements for the development of a protocol for self-administered hormonal contraception state the protocol must be approved by the Medical Board and the Board of Pharmacy. These requirements include:

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

President Weisser noted that the SB 493 Implementation Committee reviewed and discussed a draft version of this protocol at the November and December committee meetings. At the December SB 493 Implementation Committee, the committee approved the protocol and moved it to the board for review and approval.

Note: Word-smithing changes were being reviewed as the board meeting packet was being finalized. Immediately following these minutes is the protocol as presented at the meeting, as well as the version that was edited per the board's discussion and presented to the Medical Board.

Ms. Herold noted that as the committee motioned to approve a prior version the board should vote down the committee's original motion and vote on the revised protocol being presented at this meeting.

Motion: Vote down the committee's recommendation to approve the protocol for self-administered hormonal contraception.

M/S: Brooks/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			

Ms. Liz McCaman reviewed the changes that were made to the protocol after the last committee meeting.

The board discussed if the protocol should reference a "health care facility" or "pharmacy." It was determined it would be best to use the phrase "pharmacy or health care facility."

The board changed section 10 to read "The pharmacist, in consultation with the patient..."

The board changed all of the words "furnished" to "dispensed."

Mr. Brooks asked if patients can fill out the self-screening tool online before coming to the pharmacy. President Weisser commented that the self-screening tool should be part of the consultation and should be face-to-face. Mr. Brooks responded that having the

screening tool online would be helpful for patients. Dr. Gutierrez commented that the form could be filled out online ahead of time and then reviewed in person with the pharmacist when they come in. Ms. McCaman commented that nothing would prohibit the form from being online; however, consultation would be required when the patient comes in person to the pharmacy.

Motion: Approve the amended language and if it is approved by the Medical Board, initiate the rulemaking process.

M/S: Veale/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			

g. Discussion and Possible Action to Add Title 16 California Code of Regulations Section 1746.2 Protocol Requirements for Pharmacists Who Furnish Nicotine Replacement Products

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

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

- The pharmacist completes one hour of CE on smoking cessation therapy biennially.

President Weisser reported that the SB 493 Implementation Committee discussed a draft version of this protocol at the November and December committee meetings.

Note: Word-smithing changes were being reviewed as the board meeting packet was being finalized. Immediately following these minutes is the protocol as presented at the meeting, as well as the version that was edited per the board's discussion and presented to the Medical Board.

Ms. Herold again noted that as the committee motioned to approve a prior version the board should vote down the committee's original motion and vote on the revised protocol being presented at this meeting.

Motion: Vote down the committee's recommendation to approve the protocol for nicotine replacement therapy.

M/S: Lippe/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			

Ms. Liz McCaman reviewed the changes that were made to the protocol after the last committee meeting.

Ms. Herold commented that the schools of pharmacy compiled information on when their core curriculum included smoking cessation therapy. Based on the information provided by the schools, the language was updated to read: "…or an equivalent curriculum-based training program completed <u>within the last two years</u> on or after the year 2000 in an accredited California School of Pharmacy."

Ms. McCaman noted that the chart had been updated slightly since the committee meeting.

Dr. Gray recommended amending the language to read "prescription nicotine replacement products." Ms. McCaman asked if this would confuse pharmacists as some OTC medications can still be prescribed. Dr. Gutierrez recommended adding the sentence "Pharmacists may continue to provide over-the-counter smoking cessation products without use of this protocol" to section b(3) in order to address this issue.

The board asked if the term "furnished" or "dispensed" should be used. Ms. Herold noted that 4052.9 specifically uses the termed furnished.

The board discussed the need to alert pharmacist that they need to check with their patient's health plans to see if the plans will cover the OTC products.

Motion: Approve the amended language and if it is approved by the Medical Board, initiate the rulemaking process.

M/S: Lippe/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			

h. Discussion and Possible Action to Add Title 16 California Code of Regulations Section 1746.3 Protocol for Pharmacists Who Furnish Naloxone Pursuant to AB 1535 (Bloom, Chapter 326, Statutes of 2014)

Dr. Gutierrez noted that as the committee motioned to approve a prior version the board should vote down the committee's original motion and vote on the revised protocol being presented at this meeting.

Motion: Vote down the committee's recommendation to approve the protocol for pharmacist who furnish naloxone.

M/S: Gutierrez/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			

Ms. Liz McCaman reviewed the changes that were made to the protocol after the last committee meeting.

The board discussed the possible adverse reactions of naloxone and the need to counsel the patient regarding the reactions.

Mr. Brookes asked if law enforcement would be using the protocol to obtain naloxone. Ms. McCaman explained that law enforcement has other means of obtaining naloxone.

The board discussed the recent increase in the cost of naloxone.

Dr. Gutierrez noted that the intranasal spray is currently on fast-track to be approved by the FDA. Ms. McCaman recommended approving the protocol with the intranasal spray because it will be approved by the FDA and is currently used in numerous states.

James Gaspar, from the Department of Health Care Services, commented that there are currently training programs where upon completion the participants receive naloxone.

Dr. Gaspar recommended removing the phrase “especially long acting or extended release opioids” as it may lead patients to believe that one type is more hazardous than the other.

Dr. Gaspar added that the term “chemical dependency treatment” is an outdated term. The board elected to change the term to “addiction treatment.”

Motion: Approve the amended language with the removal of the phrase “especially long acting or extended release opioids” and change the term “chemical dependency” to

"addiction treatment." If it is approved by the Medical Board, initiate the rulemaking process.

M/S: Gutierrez/Law

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			

Dr. Gutierrez asked if the use of this protocol would be mandatory for all pharmacies. Ms. Herold responded that it would not be mandatory.

Motion: As authorized by section 4052.01 of the Business and Professions Code and upon approval of the language at this meeting and by the Medical Board of California, add section 1746.3 to title 16 of the California Code of Regulations. Authorize the executive officer to adopt the language as approved by both boards and file an emergency regulation with the Office of Administrative Law to establish a protocol for pharmacists to furnish naloxone.

M/S: Butler/Brooks

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 explained that the board would need to go back and change the education requirement in the hormonal contraception protocol, as not all schools have been providing the training for the same number of years. Ms. McCaman explained that the year listed in the protocol was tied to the USMEC, which came out in 2010 and she wanted to ensure that no training prior to this date was accepted. The board discussed ways to ensure that all of the students would have received the training based on the USMEC and determined that the language would need to be changed to: "an equivalent curriculum based training program completed on or after the year 2014 in an accredited California school of pharmacy…"

Motion: Change the language in item twelve of the hormonal contraception protocol to read "an equivalent curriculum based training program completed on or after the year 2014 in an accredited California school of pharmacy is also sufficient training to participate in this protocol."

M/S: Law/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			

X. Closed Session

Pursuant to Government Code Section 11126(c)(3), President Weisser convened the meeting to closed session to deliberate on disciplinary matters.

a. Petition for Reconsideration – Jeffrey Simone, RPH 62894
b. Petition for Reconsideration – Jonathan Alvarez, TCH 111189

Adjournment for the Day

Wednesday, January 28, 2014

President Weisser called the meeting to order at 9:15 a.m.

President Weisser conducted a roll call. Board members present: Gregory Lippe, Albert Wong, Amy Gutierrez, Stanley Weisser, Victor Law, Allen Schaad, Ricardo Sanchez and Lavanza Butler.

XII. Prescription Medication Abuse Subcommittee

In the absence of chairperson Castellblanch, Ms. Butler provided a report of the meeting held November 12, 2014.

a. Summary of Report on National Coalition Against Prescription Drug Abuse

Ms. Butler reported that the committee heard a presentation from Ms. April Rovero, Founder and CEO of the National Coalition Against Prescription Drug Abuse and the chair of both the Contra Costa County Prescription Drug Abuse Prevention Coalition and the California Prescription Drug Abuse Workgroup.

Ms. Butler explained that Ms. Rovero began her work with the coalition following her son's accidental death in 2009. Her son, Joey, was a student at Arizona State University and died from a lethal mixture of alcohol and prescription drugs.

Ms. Butler provided a brief overview of Ms. Roveros' presentation, which can be viewed in the board meeting materials.

Ms. Butler reported that during the meeting a committee member commented on options that may be available to provide training on controlled substances for peace officers.

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

b. Summary of Presentation on the Connection Between The Abuses of Prescription Pain Medications and Heroin

Ms. Butler reported that Jason Smith, a writer, business owner and a pain medication addict, who is in recovery and has been sober for two years, spoke about the Journal of the American Medical Association article and New England Journal of Medicine articles that demonstrate the relationship between prescription opioids and heroin use.

Ms. Butler provided an overview of Mr. Smith's presentation, which can be viewed in the board meeting materials.

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

c. **Summary of Report on Marin County's Efforts to Fight the Opioid Epidemic, Presented by Matt Willis, M.D., MPH, Marin County Public Health Officer**
Ms. Butler reported that Marin County Public Health Officer Dr. Matt Willis spoke on Marin County's efforts to battle the opioid epidemic and Marin County's New Community-Wide Standards for Prescribing Opioid Pain Medications. Ms. Butler explained that the county now has a common set of community standards for prescribing narcotics from hospital emergency departments that are voluntary and non- binding, but that offer a basic understanding for what to expect in pain medication prescribing in the emergency room.

Ms. Butler reported that during his presentation, Dr. Willis stated that the county collected data that showed the growing problem of high opioid prescriptions equating to high abuse and overdose death. He said the data identified key opportunities to create collaboration among a wide range of partners and to build an infrastructure to appropriately address pain management, addiction, treatment and recovery, and results in well-aligned, comprehensive efforts.

Ms. Butler reported that Dr. Willis explained to the committee that one of the things they discovered was that in the emergency department the default for narcotics prescriptions was 30 tablets. They reduced it to 15. Another small, but important discovery was that there were often pill bottles at crime scenes. He stated that the District Attorney has a process in place that when a medication is found at a crime scene, the doctor whose name is on the bottle is informed.

Ms. Butler stated that during his presentation, Dr. Willis said by utilizing CURES data they found that 40% of older patients in Marin County are taking both sedatives (benzos) and narcotics (opiates) together, which is unsafe for older patients.

The board found it surprising that so many older patients would be taking both sedatives and narcotics.

Dr. Gray recommended having pain management experts come before the committee to discuss the current treatments for pain.

d. **Summary of Report on Orange County and Santa Clara County Lawsuits Against Five Pharmaceutical Companies for False Advertising and Unfair Competition**
Ms. Butler reported that Greta Hansen, with the Santa Clara County Counsel's Office, spoke on the lawsuit filed by the District Attorney Offices from Orange County and Santa Clara County against Purdue Pharma and a number of other pharmaceutical companies claiming they used deceptive marketing tactics in their promotion of the use of opioids for long-term use to treat chronic non-cancer pain and misrepresented the risks associated with opioid use.

Ms. Butler explained that the civil law enforcement action was filed in May of 2014 after an explosion of opioid prescription use and abuse not related to an increase in sickness or pain or because of any breakthrough in research or clinical experience about the utility of opioids.

Ms. Butler reported that the two counties allege the increase is due to an expansive, decades-long deceptive marketing campaign by key members of the opioid industry and that products were marketed to vulnerable populations for the increased treatment of chronic, non-cancer conditions such as back and joint pain, arthritis and headaches.

Ms. Butler reported that the suit alleges that the defendants engaged in deceptive promotional activities while trying to convince doctors that opioids were effective in treating long-term, chronic pain, despite there being no evidence to that effect; that they misrepresented the serious risk of addiction, side effects and adverse consequences; and that they falsely claimed that opioids were better than standard, low-cost, over-the-counter treatments for these types of conditions.

Ms. Butler explained that they allege the pharmacy companies distributed the materials through front groups and used key opinion leaders and members of the medical community. Ms. Butler added that the suit alleges that they often used unbranded materials that touted opioids in general to vulnerable populations including the elderly, veterans and those experiencing chronic, debilitating pain.

Ms. Butler reported that committee members voiced the observation that pharmacy sales reps are the ones who train doctors on the medications. It was also pointed out that doctors are required to take pain management classes and then those classes are funded by the opioid manufacturers and that many of the educational class curriculums are provided by the pharmaceutical companies and may be highly influenced towards over-prescribing.

Ms. Butler also reported that the committee was concerned that cancer patients are being denied pain medications because of how difficult it is becoming to get prescription opioids.

Holly Strom, former board member, provided an example of how difficult it was for her elderly father to obtain medication for his legitimate pain.

There were no comments from the board.

e. Update On Report on Medical Board's Updated Pain Management Guidelines and California Prescription Drug Abuse Work Group Headed by the Director of the State Department of Public Health

Ms. Butler reported that in October 2014, the Medical Board approved their revised Pain Management Guidelines, the first update since the 1990's.

Ms. Butler stated that during the committee meeting, Ms. Herold provided a brief overview and said the guidelines deal more with the long-term use of opioids and don't include much information on short-term use. Ms. Herold also explained to the committee that the guidelines state there is a need to address pain and that treating pain is complicated.

Ms. Butler explained that they also make it clear that they are only guidelines and they are not intended to mandate care. Ms. Butler noted that the document mentions a pharmacist's corresponding responsibility and provides a link to the Board of Pharmacy's website.

Ms. Butler reported that during the committee meeting, an attendee stated that Marin County intends to implement a requirement that prescribers provide pharmacists with a way to reach them for brief conversations to verify a prescription or to answer questions.

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

f. Review of Additions to the Board of Pharmacy Prescription Drug Abuse Prevention Website Page

Ms. Butler reported that the committee discussed the update of the board's website.

Ms. Butler reported that the committee directed staff to begin updates and suggested adding dates to website items so that viewers can identify recent updates.

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

g. Public Outreach to Address Prescription Drug Abuse

Ms. Butler reported that due to time constraints this item was not discussed at the committee meeting.

Mr. Schaad noted that during the committee meeting the comment was made by a member of the public that the board should consider filing a lawsuit against the Attorney General's Office regarding the implementation of CURES. He asked for clarification on this item. Ms. Herold explained that some groups are upset with the time it is taking to create and implement the new CURES system which is scheduled to be released in July of 2015. The board discussed the process of the development of the new CURES system.

There were no comments from the public.

XIII. Enforcement and Compounding Committee

Chairperson Dr. Amy Gutierrez provided a report of the Enforcement and Compounding Committee Meeting held on December 17, 2014.

President Weisser thanked the board and staff for their work on the Compounding Regulation that will be discussed later in the Enforcement Committee chair report. Dr. Gutierrez commented that the tragedy in New England has changed the practice of pharmacy.

I. Enforcement Matters

a. SUMMARY OF PRESENTATION: San Mateo County Supervisor Adrienne Tissier on the San Mateo County Safe Medicine Drop-off Program

Chairperson Gutierrez reported that in 2006, San Mateo County's Pharmaceutical Disposal Program provided a convenient, environmentally sound way for citizens to dispose of both human and veterinary pharmaceutical drugs by providing disposal sites at law enforcement agencies throughout the county.

Chairperson Gutierrez stated that at the committee meeting, San Mateo County Supervisor Adrienne Tissier provided information about her county's drug take back program. Chairperson Gutierrez added that Heather Forshey, San Mateo Environmental Director, discussed the possibility of following Alameda County's lead on creating their own ordinance, which would require pharmaceutical companies to be logistically and financially responsible for taking back their unused medications.

b. SUMMARY OF DISCUSSION: The Drug Enforcement Administration's Regulations for the Take Back of Prescription Medication

Chairperson Gutierrez reported that on Tuesday, September 9, 2014, the DEA released its regulations on the take back of drugs from the public – specifically the take back of controlled substances.

Chairperson Gutierrez explained that the final rule authorizes certain DEA registrants (manufacturers, distributors, reverse distributors, narcotic treatment programs, retail pharmacies, and hospitals/clinics with an on-site pharmacy) to modify their registration with the DEA to become authorized collectors. All collectors may operate a collection receptacle at their registered location, and collectors with an on-site means of destruction may operate a mail-back program. Chairperson Gutierrez noted that retail pharmacies and hospitals/clinics with an on-site pharmacy may operate collection receptacles at long-term care facilities.

Chairperson Gutierrez stated that at the committee meeting, Ms. Herold provided an overview of the DEA's new drug take-back regulations. The committee discussion

included how an average person would know which drugs are acceptable for disposal.

Chairperson Gutierrez stated that the committee heard comments from the public in which the board was asked not to place the collection burden on pharmacists.

Ms. Herold encouraged consumers to use mail-back programs until the board enacts regulations.

Ms. Herold briefly explained the DEA's requirements (Ms. Herold's entire presentation on the DEA requirements can be found in the board meeting materials).

Dr. Gray, from Kaiser, noted that many counties and cities already have take-back programs that the committee should look at when drafting the regulation.

Ms. Herold noted that she has already been contacted by two legislator offices who are considering legislation in this area.

Bill McGuire, from Omnicell, cautioned the board to consider the OASHA requirements when they draft the regulations.

Luigina Mendez-Harper, from the New Mexico Board of Pharmacy, commented that there has been a bill introduced to mandate drug take back. She reported that the board voted to oppose the bill.

Chair Gutierrez stated the law enforcement agencies have expressed frustration with accepting used medications.

Chair Gutierrez concluded that at future meetings Enforcement Committee would be working on the draft regulations for drug take back.

c. SUMMARY OF PRESENTATION: New York's E-Prescribing Requirements for Controlled Substances

Chairperson Gutierrez explained that E-prescribing will be required for all New York State prescriptions effective March 27, 2015, pursuant to regulations adopted by New York State.

At the meeting, the committee heard a presentation via phone from the New York's Board of Pharmacy Executive Officer Larry Mokhiber. Mr. Mokhiber described the factors which led to the new requirements and reported that New York expects most pharmacies to be compliant by the March start date.

Chairperson Gutierrez asked Mr. Law and Dr. Wong if their pharmacies receive many prescriptions electronically. Mr. Law responded that he receives some, but many

doctors still prefer to handwrite prescriptions. Dr. Wong stated that he receives about 80 percent of his prescriptions electronically.

Dr. Gray commented that the New York regulation allows for numerous exceptions to electronic prescribing.

d. SUMMARY OF DISCUSSION: Evaluation of 16 CCR section 1744 Regarding Required Warning Labels on Prescription Container Labels

Chairperson Gutierrez explained that Assembly Bill 1136 (Levine), signed by the Governor on September 9, 2013, amended existing law to require a pharmacist on or after July 1, 2014, to include a written label on a prescription drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel, if in the pharmacist's professional judgment, the drug may impair a person's ability to operate a vehicle or vessel.

Chairperson Gutierrez reported that section 1744 of the board's regulations provides the specific classes of drugs which trigger a pharmacist's verbal or written notice to patients where a patient's ability to operate a vehicle (and now a vessel) may be impaired. She noted that as this section has not been revised in a number of years, recently the schools of pharmacy were asked to provide comments on the medications listed in this regulation. A number of California's schools of pharmacy provided comments. These comments are integrated into the draft language.

At the October 2014 Board Meeting, staff was directed to again modify the language based on legal counsel's opinion that the board must list every drug or drug class for which a warning label is required.

Ms. Herold and Michael Santiago stated that they would have the language drafted for the next Enforcement Committee meeting.

e. SUMMARY OF DISCUSSION: Proposed Regulation for Pharmacies Aimed at Reducing Losses of Controlled Substances

The board's staff compiled statistics regarding drug losses reported to the board over the last few years. These numbers were discussed at the Enforcement Committee meeting (and were provided in the board meeting materials). Chairperson Gutierrez explained that in 2013, 3.06 million dosage units of controlled substances were reported to the board as lost. This includes 1.7 million units that were from a major manufacturer who had a truck stolen. Chairperson Gutierrez noted that these numbers are only estimates provided by the entity when they first realize there has been a loss. As such, the reported numbers are most likely significantly less than actual losses.

Chairperson Gutierrez reported that the committee expressed concern about the

significant losses and the need for more stringent inventory controls in pharmacies to identify losses resulting from employee pilferage. In response the committee created draft language which was brought to the board in October 2014. The board asked the committee to revise the language based on discussion at the board meeting. The language below was revised by Virginia Herold and Chairperson Gutierrez after the October board meeting.

1715.65 Monthly Inventory Counts of Fastest Moving Controlled Substances

(a) Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall maintain a perpetual inventory for all controlled substances acquired by the licensee.

(b) As an alternative to the maintenance of a perpetual inventory, a pharmacy or clinic must have a policy that identifies a monthly reconciliation process for the ten highest volume controlled substances purchased by the licensee. This policy shall address reconciliation of all purchases and acquisitions, dispenses, pharmacy inventory, including inventory in quarantine for the reverse distributor for the previous 30-day period.

(c) Losses of controlled substances identified from the monthly audit shall be reported to the board as required by section 1716.5 and Business and Professions Code section 4104.

(d) The pharmacist-in-charge or consultant pharmacist for the clinic shall sign and date each monthly reconciliation within 14-days of completion.

(e) The pharmacist-in-charge or consultant pharmacist shall perform a quality assurance review of all inventories and reconciliations to establish and maintain secure methods to prevent losses of all dangerous drugs.

Ms. Herold and Chairperson Gutierrez noted that this language is a work in progress and will be refined by the committee.

Rebecca Cupp, representing Ralph's Pharmacy, offered to provide insight into their inventory system to help with the draft language.

Steve Gray, representing Kaiser, advised the board to get input from wholesalers.

f. REVIEW OF BOARD COMMENTS: Board Comments Regarding the FDA's Guidance on the Effect of Section 585 on the Food, Drug, and Cosmetics Act on Drug Product Tracing, and Wholesale Drug Distributor and Third-Party Logistics Provider Licensing Standards and Requirements

Chairperson Gutierrez reported that on November 14, 2014, the board provided comments to the Food and Drug Administration regarding the aforementioned draft guidance on the effect of section 585 on the Federal Food, Drug, and Cosmetic Act. These comments and a copy of the guidance document itself are provided in the

meeting materials.

There was no public or board comment.

g. SUMMARY: NABP Report Highlighting the Proliferation of Rogue Online Drug Sellers and the Drug Abuse Epidemic

Chairperson Gutierrez stated that on October 31, 2014, the NABP issued a report highlighting a connection between the proliferation of rogue online drug sellers and the prescription drug abuse epidemic. This report is provided in the board meeting materials

There was no public or board comment.

h. SUMMARY OF DISCUSSION: Medication Error Reduction Continuing Education Online Course Developed by Oregon State University

Chairperson Gutierrez reported that on November 17, 2014, Oregon State University released a new online continuing education course titled Patient Safety and Medication Error Reduction for Pharmacists. A copy of this document is provided in the board meeting materials.

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

i. SUMMARY OF PRESENTATION: Omnicell's Presentation and Proposal For Restocking Automated Dispensing Cabinets in Post-Acute Care Settings

Chairperson Gutierrez explained that Omnicell requested an opportunity to provide a presentation of their software for restocking of automated dispensing by pharmacy technicians in a post-acute care setting. Copies of their background information and PowerPoint presentation are included in the board meeting materials.

Chairperson Gutierrez noted that Health and Safety Code section 1261.6 is a relevant code section regarding the use of automated devices in skilled nursing facilities. A copy of this section was provided in the board meeting materials.

Chairperson Gutierrez reported that at the committee meeting, representatives from Omnicell appeared before the committee to discuss the restocking of automated dispensing cabinets (ADCs) in the post-acute care environment and who can restock based on current regulations. Omnicell stated that California is only one of three states that require pharmacists to restock automated delivery cabinets. All other states allow pharmacy technicians or nurses to restock.

Chairperson Gutierrez reported that following lengthy discussion, the committee's interpretation of current law allows a pharmacy technician to fill a cart, but does not allow a pharmacy technician to make delivery to a LTC facility and restock even with a

pharmacist's supervision via video.

Ms. Herold stated that often technology offers better control and accountability; however, current law does not allow for a waiver to accommodate new technology.

Bill McGuire, from Omnicell, asked if they would need to work with the California Department of Public Health. Ms. Herold agreed that Omnicell would need to work with CDPH as they regulate skilled nursing facilities and she also directed him to work with Supervising Inspector Janice Dang to get input from the board's perspective.

j. SUMMARY OF DISCUSSION: Use of Automated Technology in Hospitals and Skilled Nursing Facilities and the Tools for identification of Medication Diversion from These Units

Chairperson Gutierrez reported that at the September 16, 2014 Enforcement Committee meeting, the committee discussed the need to schedule a future agenda item to learn about drug storage security features of automated devices already in use in California health care facilities and how many of these features can be used to deter diversion.

Chairperson Gutierrez noted that several board members attended the American Society of Health-System Pharmacists meeting in Anaheim on December 8, 2014, and received demonstrations of the new technology by two vendors.

Mr. Law commented that hospitals that use these systems have reduced drug losses.

Ms. Butler expressed that she was impressed by how much technology has changed and improved over the years.

Dr. Gutierrez stated that even with the use of technology, having robust policies and procedures is crucial to limiting diversion.

k. SUMMARY OF DISCUSSION: Proposed Regulations for Third-Party Logistics Providers; Proposed Amendments to 16 California Code of Regulations Sections 1780 -1786

Chairperson Gutierrez reported that in 2014, the board sponsored legislation to enact provisions to license third-party logistic providers as a separate class and not as the board had previously done under the category of wholesaler. This legislation was enacted by AB 2605 (Bonilla, Chapter 507, Statutes of 2014). This legislation was needed because federal law enacted in 2013 prohibited licensure of third-party logistics providers as wholesalers.

Chairperson Gutierrez explained that the board needs to amend its regulations to ensure that third-party logistics providers must also adhere to board regulations for all

drug distributors, whether they are a wholesaler or third party-logistics provider.

A proposed mock-up of existing requirements for drug wholesalers that has been amended to include third-party logistics providers is included in the board meeting materials. Chairperson Gutierrez noted that this document is not yet completed as a self-assessment process is proposed much like the process required of drug wholesalers. Additionally, the third-party logistic provider community also needs to be advised of the developing regulations so they may participate in the process.

Chairperson Gutierrez concluded that this item will be placed on the next enforcement committee agenda.

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

l. Enforcement Statistics, 2nd Quarter 2014-15

Chairperson Gutierrez stated that the board meeting materials includes the first quarterly report of the committee's goals, enforcement workload statistics, and SB 1441 Program Statistics for the fiscal year.

Ms. Herold reported that for the last year, staff was redirected to implement the sterile compounding program. She noted that the board is now catching up on enforcement cases.

m. Meeting dates for 2015

Dr. Gutierrez stated that the committee has established the following enforcement committee dates:

- March 26, 2015
- June 24, 2015
- September 2, 2015
- December 2015 - to be determined

II. Compounding Matters

a. SUMMARY OF PRESENTATION: Dynalabs on Their DVx Testing Device

Chairperson Gutierrez reported that at the last committee meeting, Dynalabs provided information about the benefits of their testing programs and devices. A copy of their PowerPoint presentation is provided in the board meeting materials.

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

b. SUMMARY: Report of Sterile Compounding Pharmacy Inspections Conducted

Chairperson Gutierrez stated that Supervising Inspector Robert Ratcliff provided

information about sterile compounding inspections and violations identified since the last committee meeting. SI Ratcliff's PowerPoint presentation, as well as a list of FDA sterile compounding recalls, can be found in the board meeting materials.

Chairperson Gutierrez noted that Dr. Ratcliff has since retired after 20 years with the board. Joshua Room stated that it was a pleasure to work with Dr. Ratcliff. President Weisser agreed and thanked Dr. Ratcliff for all of his work.

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

The board recessed for a break at 10:43 a.m. and resumed at 11:00 a.m.

XIV. Legislation and Regulation Committee

Chairperson Lippe noted that there has been no meeting of the Legislation and Regulation Committee since April 2014.

Part 1: Legislation Report

a. Board-Sponsored Legislation

1. *Proposal to Amend Section 4209 of the Business and Professions Code*

   Chairperson Lippe explained that existing law at Business and Professions Code section 4209 establishes parameters for pharmacy practice experience and how an applicant for a pharmacist license must comply with those requirements. Board regulation provides further specificity on pharmacy practice experience and in what settings the experience is to be obtained.

   Chairperson Lippe reported that in October 2014, the Licensing Committee brought to the board a proposal to amend Business and Professions Code section 4209 to implement the board's desire to accept the PharmD degree from an ACPE accredited school as documentation that an individual has completed the required pharmacy practice experience requirements. He added that board staff is working to identify possible authors to carry this legislation.

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

2. *Proposal to Repeal Section 11164.5 of the Health and Safety Code*

   Chairperson Lippe reported that existing law at section 11164.5(a) of the Health and Safety Code requires the approval of the Board of Pharmacy and the California Department of Justice before a hospital or pharmacy may receive electronic data transmission prescriptions or computer entry prescriptions or orders.

Chairperson Lippe stated that at the October 2014 Board Meeting, the board discussed the necessity of retaining the Health and Safety Code provision and thereafter voted to recommend that subdivision (a) of Section 11164.5 of the Health and Safety Code be repealed.

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

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

Chairperson Lippe reported that the Legislature reconvened in regular session on January 5. The last day that bills may be submitted to the Office of Legislative Counsel is January 30, and the last day that bills can be introduced is February 27.

Chairperson Lippe concluded that staff is daily monitoring bills to identify proposals that may impact the practice of pharmacy or the board's jurisdiction.

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

c. Other Legislation Being Tracked by Board Staff

1. *AB 45 (Mullin) Household Hazardous Waste*

   Chairperson Lippe explained that as introduced, Assembly Bill 45 contains intent language to enact convenient household hazardous waste programs, to include curbside pickup, door-to-door collection and residential pick up services as a principal means of collecting household hazardous waste and diverting it from California's landfills and waterways. He noted that the measure is intended to include pharmaceutical waste.

   Chairperson Lippe stated that board staff will maintain contact with Assembly Member Mullin's office and monitor the measure.

2. *SB 26 (Hernandez) California Health Care Cost and Quality Database*

   Chairperson Lippe stated that as introduced, Senate Bill 26 declares legislative intent to establish a system to provide valid, timely and comprehensive health care performance information that is publicly available and can be used to improve the safety, appropriateness, and medical effectiveness of health care, and to provide care that is safe, medically effective, patient-centered, timely, affordable and equitable.

   Chairperson Lippe reported that the bill would require the Secretary of California Health and Human Services Agency to, no later than January 1, 2017, enter into a contract with one or more independent, nonprofit organizations to administer the

California Health Care Cost and Quality Database.

Chairperson Lippe explained that according to the author's office, the measure is designed to allow a consumer to access information in the database that will assist the consumer in making decisions about his or her health care.

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

d. Discussion of Possible Legislative Proposals

Ms. Herold reported that in January 2013, after the tragedy at the New England Compounding Center, the board created the sterile compounding licensure program to enable the board to inspect any facility that was shipping compounded drugs into California. The inspections included facilities that conducted large-scale, non-patient specific compounding, which the board licensed as sterile compounding pharmacies. She noted that at that time there was no federal legislation, and the FDA would periodically inspect pharmacies that were doing large-scale, non-patient specific compounding and declare them a manufacturer and issue them a warning letter.

Ms. Herold explained that recently larger states are choosing to license facilities that conduct large-scale non-patient specific compounding as outsourcing facilities rather than as pharmacies. Ms. Herold recommended that the board sponsor a spot bill that will create an outsourcing facility license. She added that she will be working with the FDA and larger states to draft the language so that it harmonizes with their existing requirements.

Dr. Gray, representing Kaiser, expressed his support for the board sponsoring the spot bill.

Rich Kruzynski, with Pharmedium, thanked the board for considering this legislation. The board asked Pharmedium to participate in the meetings where this legislation would be discussed.

Motion: Initiate legislation on 503b outsourcing facilities.

M/S: Gutierrez/Lippe

Support: 8 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			

Part 2: Regulation Report

a. Recently Approved by the Office of Administrative Law - Update on Rulemaking to Amend Title 16 California Code of Regulations Section 1707.5 Regarding Patient-Centered Labeling Requirements

Chairperson Lippe reported that in 2013, the board voted to modify its patient-centered prescription label requirements at 16 CCR Section 1707.5 (a) (1) to require that only the four items listed in section 1707.5 (a) (1) be clustered into one area of the label that comprises at least 50 percent of the label and to require these items to be printed in 12-point san serif typeface.

Chairperson Lippe stated that the Office of Administrative Law approved the rulemaking on January 8, 2015, and the regulation will become effective on April 1, 2015.

Chairperson Lippe concluded that following approval by OAL, the board issued a Subscriber Alert announcing the approval of the regulation, and encouraged pharmacies to conform their prescription container labels to the new minimum font size requirement.

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

b. Board Approved – Awaiting Notice

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

   Chairperson Lippe reported that at the July 2013 Board Meeting, the board approved proposed text to amend Sections 1702 and 1702.5 and to add Sections 1702.1 and 1702.2 to Title 16 of the California Code of Regulations. He noted that staff is preparing the required notice documents and will be noticing these proposals as one combined rulemaking.

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

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

Chairperson Lippe reported that in 2013, the board approved a proposal to initiate a formal rulemaking to amend the text of 16 California Code of Regulations Sections 1732.05. 1732.2, and 1732.5 relative to continuing education.

Chairperson Lippe then stated that at the October 2014 board meeting, the board discussed and voted to add "compounding education" as a sixth area of subject-specific continuing education in Section 1732.5. He concluded that staff is preparing the required notice documents and will be noticing these proposals as a combined rulemaking with other board-approved proposals.

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

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

   Chairperson Lippe explained that at the October 2013 Board Meeting, the board approved a proposal to amend Title 16 California Code of Regulations Section 1703 to delegate to the executive officer the authority to initiate a rulemaking to adopt "changes without regulatory effect." He added that staff is preparing the required notice documents.

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

4. *Proposal to Amend Title 16 California Code of Regulations 1793.5 Pharmacy Technician Application*

   Chairperson Lippe reported that at the July 2014 Board Meeting, the board approved a proposal to amend Title 16 California Code of Regulations Section 1793.5 to change the wording of the criminal conviction question on the pharmacy technician application, which is incorporated by reference in the regulation. He added that staff is preparing the required notice documents.

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

5. *Proposal to Amend Title 16 California Code of Regulations Sections 1784 and 1751 to Update Self-Assessment Forms 17M-13, 17M-14, 17M-26 and 17M-35*

   Chairperson Lippe stated that at the October 2014 Board Meeting, the board directed staff to initiate the formal rulemaking process to amend the text of 16 California Code of Regulations Sections 1715, 1735.2 and 1784 and to amend the Self-Assessment Forms incorporated by reference in those sections.

Chairperson Lippe noted that existing regulation requires a pharmacy, wholesaler and hospital to complete a self-assessment by July 1 of each odd-numbered year, and at other times, as specified in the regulation(s).

Ms. Herold noted that the board recently hired a regulation coordinator.

XVII. Executive Officer's Report

a. General Board Update

Ms. Herold reported that the board will need to schedule a one-day board meeting prior to the April board meeting and noted that board staff will be contacting the members for possible meeting dates.
Ms. Herold asked for a motion to sponsor a spot bill to increase the board's fees.

Motion: Sponsor a spot bill to restructure the boards' fees.

M/S: Lippe/Gutierrez

Support: 8 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 noted that the SB 493 would be holding another meeting to discuss the other provisions of the SB 493.

Ms. Herold noted that Inspector Jeff Smith has retired and thanked him for his work for the board.

Ms. Herold reported that the board would be holding a two-day inspector training and would also be contracting for additional sterile compounding training for all inspectors.

Ms. Herold stated that the inspectors and enforcement staff are focusing their efforts on closing cases prior to the end of the fiscal year.

Ms. Herold explained that a new content outline for the CPJE is being developed by the competency committee.

b. Duty Inspector Update

Ms. Herold explained the process for consumers and licensees who call into the board with questions for the inspectors.

c. Request for the Board to Award Continuing Education for Staff Presented Education to Licensees in 2015

Ms. Herold reported that board member Hackworth is coordinating a training course on drug diversion in the San Diego area. Ms. Herold stated that at the meeting she would present on corresponding responsibility, the DEA would present on drug diversion and Dr. Steve Gray would present on pharmacy law. Ms. Herold asked the board to approve two hours of continuing education for attendees.

Dr. Gray noted that his portion of the presentation would be awarded continuing education through ACPE. Ms. Herold clarified that the board would need to approve the two hours for her presentation and the DEA's presentation.

Motion: Award two hours of continuing education for the presentations by Ms. Herold and the DEA.

M/S: Lippe/Gutierrez

Support: 8 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. Medical Board Update

Ms. Herold provided an overview of the written update provided by executive director Kim Kirchmeyer. The entire update has been provided immediately following these minutes.

Mr. Law asked if the Medical Board has discussed adding purpose on the label. Ms. Herold responded that some of the board members have expressed their support; however, she is unsure if the entire board has expressed an opinion.

The board recessed for a lunch break at 12:05 p.m. and resumed at 1:00 p.m.

Time Certain **1:00 p.m.**

XVI. Discussion and Possible Action to Make Changes in Response to Comments or to Adopt or Amend Proposed Text at Title 16 California Code of Regulations Section 1735 et seq., and 1751 et seq., Relating to Pharmacy Compounding

The regulation language discussed was provided to the board and the public during the meeting and can be found on the board's website at:
http://www.pharmacy.ca.gov/meetings/agendas/2015/15_jan_bd_comp_lang.pdf

Dr. Gutierrez, Ms. Herold and Mr. Room provided a PowerPoint presentation on the updates made to the language based on comments. The presentation can be found following these minutes.

Dr. Gutierrez explained that she would go through the regulation and explain the board's responses to the comments received on each section.

Section 1735

Mr. Room explained that subdivision (c) was removed for clarity.

Motion: Approve 1735.

M/S: Sanchez/Law

Support: 8 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			

Section 1735.1
Dr. Gutierrez and Mr. Room reviewed the changes made to section 1735.1.

Mr. Room recommended simplifying the definition of integrity to "means retention of potency." Dr. Gutierrez agreed.

The board clarified that subdivision (v) should read "Non-sterile-to-sterile batch means any compounded drug preparation containing 1 (one) or more dosage units…"

Dr. Tony Park asked if the language allowed for any emergency situations. Mr. Room responded that it did not, he asked the public to provide examples of emergencies during the 15-day comment period.

Lynn Paulson, from CSHP, and Rich Kruzynski, from Pharmedium, discussed the challenges of maintaining a potency of +/- 10% in hospital compounding and reconstituted products. Mr. Room asked them to submit additional comments including possible language.

Ms. Herold recommended that the board not modify the language in response to the verbal comments being made, rather, to instead ask the public to submit the comments in writing so that the board could formally respond.

Motion: Approve 1735.1.

Note: subdivision (v) should read "Non-sterile-to-sterile batch means any compounded drug preparation containing **1 (one)** or more dosage units…"

M/S: Schaad/Lippe

Support: 8 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			

Section 1735.2
Dr. Gutierrez and Mr. Room reviewed the changes made to section 1735.2.

Mr. Room explained that the goal of this section is to ensure that anytime a prescriber places an order, they provide the pharmacist with a specific quantity and the specific need for the products. He added that pharmacists must use their professional judgment to assess the information prior to compounding.

Ms. Herold noted that the section regarding self-assessments should be removed. The board agreed.

The board discussed the compounding requirements for prescriber office use. Mr. Room clarified that it has never been the board's intention to allow for unlimited compounding for prescriber office use.

Dr. Park and Dr. Gray asked the board to consider amending the section on the requirement for fair market pricing of each drug preparation. Mr. Room responded that the board is attempting to address the issue of collusion between prescribers and compounding pharmacies for purposes of insurance reimbursement.

Grant Miller, of the California Veterinary Medical Association, explained that many of the requirements in the proposed regulation do not apply to the practice of compounding in the veterinary setting. Two representatives from Roadrunner Pharmacy (a veterinary exclusive compounding pharmacy) echoed the comments made by the California Veterinary Medical Association. The board asked that the association submit comments during the 15-day comment period.

The board again discussed the requirements for compounding for prescriber office use and clarified that the intention is to permit prescribers to order their own patient supply and be responsible for the quantity of, receipt of and payment for the drugs.

Mr. Schaad left the room at 2:50 p.m. and returned at 3:00 p.m.

Motion: Strike section (k) and move section (l) to become the new section (k). Approve 1735.2.

Note: Mr. Schadd was not present for the vote.

M/S: Lippe/Sanchez

Support: 7 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			

Section 1735.3
Dr. Gutierrez reviewed the changes made to section 1735.3.

Mr. Room noted that subdivision (a)(6) must be changed to read: "…and the limitations of section 1735.2 subdivision (k)."

Motion: Amend subdivision (a)(6) to reference 1735.2 subdivision (k). Approve 1735.3.

M/S: Sanchez/Law

Support: 8 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			

Section 1735.4
Dr. Gutierrez and Mr. Room reviewed the changes made to section 1735.4.

Motion: Approve 1735.4.

M/S: Law/Weisser

Support: 8 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			

Section 1735.5
Mr. Room reviewed the changed made to section 1735.5 and explained that the changes made to this section were mostly typographical.

Motion: Approve 1735.5

M/S: Sanchez/Lippe

Support: 8 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			

Section 1735.6

Mr. Room noted that the only substantive changes to this section were the addition of requirements to keep records of cleaning and specific record requirements for decontamination for hazardous drug compounding.

Motion: Approve 1735.6
M/S: Lippe/Sanchez

Support: 8 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			

Section 1735.7
Mr. Room reported that change to this section was replacing "product" with "preparation."

Motion: Approve 1735.7

M/S: Law/Sanchez

Support: 8 Oppose: 0 Abstain: 0

Section 1735.8
Mr. Room reviewed the changes to section 1735.8. He added that subdivision (e) should be amended to read "within patient care areas of a hospital ~~pharmacy~~…"

Motion: Strike "pharmacy" from subdivision (e). Approve 1735.8.

M/S: Lippe/Sanchez

Support: 8 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			

Section 1751
Mr. Room and Dr. Gutierrez briefly reviewed the changes made to 1751.

Motion: Approve 1751.

M/S: Weisser/Law

Support: 8 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			

Section 1751.1
Mr. Room noted that the section was amended to make allowances for the use of air pressure differentials and air velocity measurements. He added that it also requires the pharmacy to keep records of the dates, names and license numbers of the prescriber to which the drugs compounded for future use were provided.

Motion: Approve 1751.1.

M/S: Sanchez/Butler

Support: 8 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			

Section 1751.2
Mr. Room noted that there was a typographical error in 1752.2 (a). He explained that it should read: "The telephone number of the pharmacy. The telephone number is not required on the label for sterile drug preparations dispensed to inpatients by a hospital pharmacy."

Motion: Amend 1752.2 (a) as discussed. Approve 1752.2.

M/S: Weisser/Butler

Support: 8 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			

Section 1751.3
Mr. Room noted that 1751.3 (d) should be removed and the language in 1751.3 (d)(1) should be made the new subdivision (d).

Mr. Room stated that 1751.3 (a)(18) should be amended to read: "Facility management including certification and ~~prevention~~ maintenance of controlled…"

Mr. Room stated that 1751.3 (c)(2) should be amended to read; "End-product evaluation and testing ~~where appropriate~~."

Motion: Approve 1751.3 with the three amendments discussed.

M/S: Lippe/Butler

Support: 8 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			

Lavanza Butler left the meeting at 3:10 p.m.

Section 1751.4

Dr. Gutierrez reviewed the changes made to 1751.4. She noted that "e.g. sterile isopropyl alcohol" should be stricken in subdivision (e) for both daily and monthly cleaning.

Lynn Paulson explained the process by which hospitals *disinfect* their compounding surfaces and *wash* the walls and floors; she noted that the two processes are very different. Dr. Gutierrez requested that she submit her comments during the comment period.

Lynn Paulson expressed her concern with the temperature requirements for the compounding areas.

Motion: Strike both occurrences of "e.g. sterile isopropyl alcohol" in subdivision (e). Approve 1751.4.

M/S: Schaad/Sanchez

Support: 7 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			

Section 1751.5
Dr. Gutierrez briefly reviewed the changes made to 1751.5.

Dr. Gray asked the board to clarify if references to rashes and sunburns only applied to exposed areas. The board asked Dr. Gray to submit his comments in writing. Ms. Sodergren noted that Dr. Gray would be unable to submit his comment in writing because it is not subject to the fifteen day comment period, as it is not underlined in red.

Michael Santiago explained that the only comments that could be accepted as within scope during the fifteen day comment period were those sections that were in red font. If comments were submitted to sections that were in black font (meaning they had been unchanged), the comments would be rejected as outside of the scope of the 15-day comment period.

The board discussed the concern that even when covered rashes, sunburns and conjunctivitis could increase the probability of contamination. The board elected to leave the section unchanged.

Motion: Approve 1751.5.

M/S: Schaad/Weisser

Support: 7 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			

Section 1751.6
Mr. Room noted that there were no significant changes to this section.

Motion: Approve 1751.6.

M/S: Schaad/Weisser

Support: 7 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			

Section 1751.7
Dr. Gutierrez briefly reviewed the changes to section 1751.7.

Motion: Approve 1751.7.

M/S: Lippe/Sanchez

Support: 7 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			

Section 1751.8
Dr. Gutierrez and Mr. Room reviewed the changes to section 1751.8.

Mr. Room noted that subdivision (f) (1) should be amended to add the sentence: "A PEC used solely to compound 'immediate use' preparations need not be placed within an ISO 7 buffer area or cleanroom."

Mr. Room stated that subdivision (e)(3) should be deleted.

Doug O'Brien, from Kaiser, stated that subdivision (e) unnecessarily limits the beyond-use date to 12 hours from the time it was compounded. The board asked for the comment to be submitted in writing.

Mr. Room noted that subdivision (d)(4) should be deleted.

Motion: Amend the three sections of 1751.8 as discussed. Approve 1751.8.

M/S: Weisser/Lippe

Support: 7 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			

Section 1753
Mr. Lippe noted that the only changes to this section was the addition of the words "policies and procedures" and motioned to approve the language.
M/S: Lippe/Sanchez

Support: 7 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: Adopt the revised language to the modified text that was noticed for a 15-day comment period February 6 - 20, 2015, and to notice this revised language for an additional 15-day comment period. Delegate authority to the Executive Officer to adopt this modified text and to make any non-substantive or technical changes at the conclusion of the second 15-day comment period if no adverse public comments are received during this comment period, and proceed with the rulemaking.

M/S: Gutierrez/Schaad

Support: 7 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			

Dr. Wong asked if anyone was doing anything about the increase in the cost of prescription drugs. Mr. Law asked if anything was being done to address drug shortages. Mr. Santiago stated that these two items could not be discussed at this time and must be placed on future agendas.

Present Weisser adjourned the meeting at 3:45 p.m.

Protocol for Pharmacists Who Furnish Self-Administered Hormonal Contraceptives

As Provided to the Board of Pharmacy on January 27, 2015

Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraception

(a) A pharmacist furnishing self-administered hormonal contraception pursuant to Section 4052.3 of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraception

(1) Authority: Section 4052.3(a)(1) of the California Business and Professions C~~c~~ode authorizes a pharmacist to furnish self-administered hormonal contraceptives in accordance with a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol in this section satisfies that requirement.

(2) Purpose: To provide timely access to self-administered hormonal contraception medication and to ensure that the patient receives adequate information to successfully comply with therapy.

(3) Definition of Self-Administered Hormonal Contraception: Hormonal contraception products with the following routes of administration are considered self-administered:

- Oral;
- Transdermal;
- Vaginal;
- Depot Injection.

(4) Procedure: When a patient requests self-administered hormonal contraception, the pharmacist shall complete the following steps:

- Ask the patient to use and complete the self-screening tool;
- Review the self-screening answers and clarify responses if needed;
- Measure and record the patient's seated blood pressure if combined hormonal contraceptives are requested or recommended.
- Before furnishing self-administered hormonal contraception, the pharmacist shall ensure that the patient is ~~properly and~~ appropriately trained in administration of the requested or recommended contraceptive medication.
- When a self-administered hormonal contraceptive is furnished, the patient shall be provided with appropriate counseling and information on the product furnished, including:
    - Dosage;
    - Effectiveness;
    - Potential side effects;
    - Safety;
    - The importance of receiving recommended preventative health screenings;
    - That self-administered hormonal contraception does not protect against sexually transmitted infections (STIs).

(5) Self-Screening Tool: The pharmacist shall provide the patient with a self-screening tool containing the list of questions specified in this protocol. The patient shall complete the self-screening tool, and the pharmacist shall use the answers to screen for all Category 3 and 4 conditions and characteristics for self-administered hormonal contraception from the current United States Medical Eligibility Criteria for Contraceptive Use (USMEC) developed by the federal Centers for Disease Control and Prevention (CDC). The patient shall complete the self-screening tool annually, or whenever the patient indicates a major health change.

A copy of the most recently completed self-screening tool shall be securely stored within the originating ~~pharmacy~~ health care facility for a period of at least three years from the date ~~when the last self-administered hormonal contraception product was furnished~~of dispense.

This self-screening tool should be made available in alternate languages for patients whose primary language is not English.

(6) Fact Sheet: The pharmacist shall provide the patient with the FDA-required patient product information leaflet included in all self-administered hormonal contraception products, as required by the Business and Professions C~~c~~ode Section 4052.3(c). The pharmacist shall ~~review~~ answer any questions the patient may have regarding self-administered hormonal contraception.

Pharmacists ~~are encouraged to~~should provide the patient with a copy of a~~the~~ current consumer-friendly comprehensive birth control guide such as that created by the FDA, and a copy of an administration~~method~~-specific factsheet; examples of appropriate guides and factsheets are ~~from the Association of Reproductive Health Professionals, all~~ available on the Board of Pharmacy's website.

(7) Follow-Up Care: Upon furnishing a self-administered hormonal contraceptive, or if is determined that use of a self-administered hormonal contraceptive is not recommended, the pharmacist shall refer the patient for appropriate follow-up care to the patient's primary care provider or, if the patient does not have a primary care provider, to nearby clinics. A patient who is determined not to be an appropriate candidate for self-administered hormonal contraception~~ve~~ shall be advised of the potential risk and referred to an appropriate health care provider for further evaluation.

(8) Notifications: The pharmacist shall notify the patient's primary care provider of any drug(s) or device(s) furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. 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 provide the patient with a written record of the

drug(s) or device(s) furnished and advise the patient to consult a ~~physician~~n appropriate health care professional of the patient's choice.

(9) Referrals and Supplies: If self-administered hormonal contraception services are not immediately available ~~at the pharmacy~~ or the pharmacist declines to furnish pursuant to a conscience clause, the pharmacist shall refer the patient to another ~~self-administered hormonal contraception~~appropriate health care provider.

The pharmacist also shall comply with all state mandatory reporting laws, including sexual abuse laws.

(10) Product Selection: The patient, in consultation with the pharmacist, may select any hormonal contraceptive listed in the current version of the USMEC as Category 1 or 2, based on the information reported in the self-screening tool and the blood pressure (if recorded by the pharmacist). The USMEC shall be kept current and maintained in the ~~pharmacy~~health care facility, and shall be available on the Board of Pharmacy's website.

~~Furthermore, g~~Generic equivalent products may be furnished.

(11) Documentation: Each self-administered hormonal contraceptive furnished by a pharmacist pursuant to this protocol shall be documented in a patient medication record and securely stored within the originating ~~pharmacy~~ health care facility for a period of at least three years from the date ~~when the last self-administered hormonal contraceptive was furnished~~of dispense. A patient medication record shall be maintained in an automated data processing or manual record mode such that the required information under title 16, sections 1717 and 1707.1 of the California Code of Regulations is readily retrievable during the ~~pharmacy's~~ facility's normal operating hours.

(12) Training: Prior to furnishing self-administered hormonal contraception, pharmacists who participate in this protocol must have completed a minimum of one hour of a b~~B~~oard-approved continuing education program specific to self-administered hormonal contraception, application of the USMEC, and other CDC guidance on contraception. An equivalent curriculum-based training program completed on or after the year 2010 in an accredited California s~~S~~chool of p~~P~~harmacy is also sufficient training to participate in this protocol.

(13) Patient Privacy: All pharmacists furnishing self-administered hormonal contraception in a ~~pharmacy~~ health care facility shall operate under the ~~pharmacy's~~ facility's policies and procedures to ensure that patient confidentiality and privacy are maintained.

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(14) Self-Screening Tool Questions

HORMONAL CONTRACEPTION SELF-SCREENING TOOL QUESTIONS

1	What was the first date of your last menstrual period?	/ /	
2	Have you ever taken birth control pills, or used a birth control patch, ring, or shot/injection? (If no, go to question 3)	Yes ☐	No ☐
	Did you ever experience a bad reaction to using hormonal birth control?	Yes ☐	No ☐
	Are you currently using birth control pills, or a birth control patch, ring, or shot/injection?	Yes ☐	No ☐
3	Have you ever been told by a medical professional not to take hormones?	Yes ☐	No ☐
4	Do you smoke cigarettes?	Yes ☐	No ☐
5	Do you think you might be pregnant now?	Yes ☐	No ☐
6	Have you given birth within the past 6 weeks?	Yes ☐	No ☐
7	Are you currently breastfeeding an infant who is less than 1 month of age?	Yes ☐	No ☐
8	Do you have diabetes?	Yes ☐	No ☐
9	Do you get migraine headaches, or headaches so bad that you feel sick to your stomach, you lose the ability to see, it makes it hard to be in light, or it involves numbness?	Yes ☐	No ☐
10	Do you have high blood pressure, hypertension, or high cholesterol?	Yes ☐	No ☐
11	Have you ever had a heart attack or stroke, or been told you had any heart disease?	Yes ☐	No ☐
12	Have you ever had a blood clot in your leg or in your lung?	Yes ☐	No ☐
13	Have you ever been told by a medical professional that you are at a high risk of developing a blood clot in your leg or in your lung?	Yes ☐	No ☐
14	Have you had bariatric surgery or stomach reduction surgery?	Yes ☐	No ☐
15	Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?	Yes ☐	No ☐
16	Do you have or have you ever had breast cancer?	Yes ☐	No ☐
17	Do you have or have you ever had hepatitis, liver disease, liver cancer, or gall bladder disease, or do you have jaundice (yellow skin or eyes)?	Yes ☐	No ☐
18	Do you have lupus, rheumatoid arthritis, or any blood disorders?	Yes ☐	No ☐
19	Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)?	Yes ☐	No ☐

	If yes, list them here:		
20	Do you have any other medical problems or take regular medication?	Yes ☐	No ☐
	If yes, list them here:		

Note: Authority cited: Section 4052.3, Business and Professions Code. Reference: Section 4052(a)(10), Business and Professions Code.

Protocol Sources

Centers for Disease Control and Prevention, "United States Medical Eligibility Criteria for Contraceptive Use," (2010) *available at* http://www.cdc.gov/reproductivehealth/unintendedpregnancy/USMEC.htm.

This resources serves as the basis for which self-administered hormonal contraception medications from which a pharmacist may select.

Centers for Disease Control and Prevention, "U.S. Selected Practice Recommendations for Contraceptive Use, 2013," *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6205a1.htm.

This document from the CDC offers guidance on how to use contraceptive methods most effectively. It is adapted from a World Health Organization (WHO) publication, and endorsed by the American College of Obstetricians and Gynecologists (ACOG).

S. Shotorbani, et al., "Agreement Between Women's and Providers' Assessment of Hormonal Contraceptive Risk Factors," 73 CONTRACEPTION 501, 501-506 (2006).

This article provided a Medical History Questionnaire that was used in the development of the protocol's self-assessment tool. The article's research found 96% agreement between women's self-administered risk factor questionnaire and their providers' evaluation of their medical eligibility for hormonal contraceptive use.

CPhA/CSHP, "Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraceptives."

This draft protocol was consulted in development of the Board's recommended protocol.

Food and Drug Administration Office of Women's Health, "HPV, HIV, Birth Control" (last updated June 24, 2014), *available at* http://www.fda.gov/ForConsumers/ByAudience/ForWomen/WomensHealthTopics/ucm117971.htm

This site contains a consumer-friendly birth control guide recommended for patient education.

Office on Women's Health, U.S. Department of Health and Human Services, "Birth Control Methods" (last updated Nov. 21, 2011), *available at* http://www.womenshealth.gov/publications/our-publications/fact-sheet/birth-control-methods.pdf.

This fact sheet was consulted in development of the Board's recommended fact sheet.

Division of Reproductive Health, Centers for Disease Control and Prevention, "Contraception" (last updated Oct. 14, 2014), http://www.cdc.gov/reproductivehealth/unintendedpregnancy/contraception.htm.

This website, especially the chart, is recommended as a resource for pharmacists choosing to provide additional user-friendly information on various birth control methods.

The American College of Obstetricians and Gynecologists, "Birth Control - Especially for Teens," FAQ112 (Dec. 2013), *available at* http://www.acog.org/Patients/FAQs/Birth-Control-Especially-for-Teens.

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This opinion paper discusses pharmacist training on page 432. Both pharmacists and pharmacy students generally expressed interest in more education specifically on appropriate product selection.

Fatim Lakha, et al., "The Acceptability of Self-Administration of Subcutaneous Depo-Provera," 72 CONTRACEPTION 14-18 (2005).

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This research finds that pharmacy reinjection of contraception is a viable option for many women, and is most successful when combined with primary care provider support and integration.

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This research concludes that reading the leaflet did not greatly affect adherence but aroused anxiety and decreased adherence in some patients.

21 C.F.R §§ 201 "Labeling," *available at* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=201.
These FDA regulations require manufacturers to include comprehensive patient leaflets in both prescription-only and OTC products.

21 C.F.R. § 310.501 "Patient Package Inserts for Oral Contraceptives," (Apr. 1, 2014), *available at* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=310.501.
These FDA regulations are specific to leaflet requirements for oral contraceptives.

Protocol for Pharmacists Who Furnish Self-Administered Hormonal Contraceptives

As Provided to the Medical Board of California on January 30, 2015

Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraception

(a) A pharmacist furnishing self-administered hormonal contraception pursuant to Section 4052.3 of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraception

(1) Authority: Section 4052.3(a)(1) of the California Business and Professions C~~c~~ode authorizes a pharmacist to furnish self-administered hormonal contraceptives in accordance with a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol in this section satisfies that requirement.

(2) Purpose: To provide timely access to self-administered hormonal contraception medication and to ensure that the patient receives adequate information to successfully comply with therapy.

(3) Definition of Self-Administered Hormonal Contraception: Hormonal contraception products with the following routes of administration are considered self-administered:

- Oral;
- Transdermal;
- Vaginal;
- Depot Injection.

(4) Procedure: When a patient requests self-administered hormonal contraception, the pharmacist shall complete the following steps:

- Ask the patient to use and complete the self-screening tool;
- Review the self-screening answers and clarify responses if needed;
- Measure and record the patient's seated blood pressure if combined hormonal contraceptives are requested or recommended.
- Before furnishing self-administered hormonal contraception, the pharmacist shall ensure that the patient is ~~properly and~~ appropriately trained in administration of the requested or recommended contraceptive medication.
- When a self-administered hormonal contraceptive is furnished, the patient shall be provided with appropriate counseling and information on the product furnished, including:
    - Dosage;
    - Effectiveness;
    - Potential side effects;
    - Safety;
    - The importance of receiving recommended preventative health screenings;
    - That self-administered hormonal contraception does not protect against sexually transmitted infections (STIs).

(5) Self-Screening Tool: The pharmacist shall provide the patient with a self-screening tool containing the list of questions specified in this protocol. The patient shall complete the self-screening tool, and the pharmacist shall use the answers to screen for all Category 3 and 4 conditions and characteristics for self-administered hormonal contraception from the current United States Medical Eligibility Criteria for Contraceptive Use (USMEC) developed by the federal Centers for Disease Control and Prevention (CDC). The patient shall complete the self-screening tool annually, or whenever the patient indicates a major health change.

A copy of the most recently completed self-screening tool shall be securely stored within the originating pharmacy or health care facility for a period of at least three years from the date ~~when the last self-administered hormonal contraception product was furnished~~of dispense.

This self-screening tool should be made available in alternate languages for patients whose primary language is not English.

(6) Fact Sheet: The pharmacist shall provide the patient with the FDA-required patient product information leaflet included in all self-administered hormonal contraception products, as required by the Business and Professions C~~c~~ode Section 4052.3(c). The pharmacist shall ~~review~~ answer any questions the patient may have regarding self-administered hormonal contraception.

Pharmacists ~~are encouraged to~~should provide the patient with a copy of a~~the~~ current consumer-friendly comprehensive birth control guide such as that created by the FDA, and a copy of an administration~~method~~-specific factsheet; examples of appropriate guides and factsheets are ~~from the Association of Reproductive Health Professionals, all~~ available on the Board of Pharmacy's website.

(7) Follow-Up Care: Upon furnishing a self-administered hormonal contraceptive, or if is determined that use of a self-administered hormonal contraceptive is not recommended, the pharmacist shall refer the patient for appropriate follow-up care to the patient's primary care provider or, if the patient does not have a primary care provider, to nearby clinics. A patient who is determined not to be an appropriate candidate for self-administered hormonal contraception~~ve~~ shall be advised of the potential risk and referred to an appropriate health care provider for further evaluation.

(8) Notifications: The pharmacist shall notify the patient's primary care provider of any drug(s) or device(s) furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. 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 provide the patient with a written record of the

drug(s) or device(s) furnished and advise the patient to consult a ~~physician~~n appropriate health care professional of the patient's choice.

(9) Referrals and Supplies: If self-administered hormonal contraception services are not immediately available ~~at the pharmacy~~ or the pharmacist declines to furnish pursuant to a conscience clause, the pharmacist shall refer the patient to another ~~self-administered hormonal contraception~~appropriate health care provider.

The pharmacist also shall comply with all state mandatory reporting laws, including sexual abuse laws.

(10) Product Selection: The ~~pharmacist~~~~patient~~pharmacist, in consultation with the patient, may select any hormonal contraceptive listed in the current version of the USMEC as Category 1 or 2, based on the information reported in the self-screening tool and the blood pressure (if recorded by the pharmacist). The USMEC shall be kept current and maintained in the pharmacy or ~~pharmacy~~health care facility, and shall be available on the Board of Pharmacy's website.

~~Furthermore, g~~Generic equivalent products may be furnished.

(11) Documentation: Each self-administered hormonal contraceptive furnished by a pharmacist pursuant to this protocol shall be documented in a patient medication record and securely stored within the originating pharmacy or ~~pharmacy~~ health care facility for a period of at least three years from the date ~~when the last self-administered hormonal contraceptive was furnished~~of dispense. A patient medication record shall be maintained in an automated data processing or manual record mode such that the required information under title 16, sections 1717 and 1707.1 of the California Code of Regulations is readily retrievable during the pharmacy or ~~pharmacy's~~ facility's normal operating hours.

(12) Training: Prior to furnishing self-administered hormonal contraception, pharmacists who participate in this protocol must have completed a minimum of one hour of a b~~B~~oard-approved continuing education program specific to self-administered hormonal contraception, application of the USMEC, and other CDC guidance on contraception. An equivalent curriculum-based training program completed on or after the year 2014~~0~~ in an accredited California s~~S~~chool of p~~P~~harmacy is also sufficient training to participate in this protocol.

(13) Patient Privacy: All pharmacists furnishing self-administered hormonal contraception in a pharmacy or ~~pharmacy~~ health care facility shall operate under the pharmacy or ~~pharmacy's~~ facility's policies and procedures to ensure that patient confidentiality and privacy are maintained.

(14) Self-Screening Tool Questions

HORMONAL CONTRACEPTION SELF-SCREENING TOOL QUESTIONS

1	What was the first date of your last menstrual period?	/ /	
2	Have you ever taken birth control pills, or used a birth control patch, ring, or shot/injection? (If no, go to question 3)	Yes ☐	No ☐
	Did you ever experience a bad reaction to using hormonal birth control?	Yes ☐	No ☐
	Are you currently using birth control pills, or a birth control patch, ring, or shot/injection?	Yes ☐	No ☐
3	Have you ever been told by a medical professional not to take hormones?	Yes ☐	No ☐
4	Do you smoke cigarettes?	Yes ☐	No ☐
5	Do you think you might be pregnant now?	Yes ☐	No ☐
6	Have you given birth within the past 6 weeks?	Yes ☐	No ☐
7	Are you currently breastfeeding an infant who is less than 1 month of age?	Yes ☐	No ☐
8	Do you have diabetes?	Yes ☐	No ☐
9	Do you get migraine headaches, or headaches so bad that you feel sick to your stomach, you lose the ability to see, it makes it hard to be in light, or it involves numbness?	Yes ☐	No ☐
10	Do you have high blood pressure, hypertension, or high cholesterol?	Yes ☐	No ☐
11	Have you ever had a heart attack or stroke, or been told you had any heart disease?	Yes ☐	No ☐
12	Have you ever had a blood clot in your leg or in your lung?	Yes ☐	No ☐
13	Have you ever been told by a medical professional that you are at a high risk of developing a blood clot in your leg or in your lung?	Yes ☐	No ☐
14	Have you had bariatric surgery or stomach reduction surgery?	Yes ☐	No ☐
15	Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?	Yes ☐	No ☐
16	Do you have or have you ever had breast cancer?	Yes ☐	No ☐
17	Do you have or have you ever had hepatitis, liver disease, liver cancer, or gall bladder disease, or do you have jaundice (yellow skin or eyes)?	Yes ☐	No ☐
18	Do you have lupus, rheumatoid arthritis, or any blood disorders?	Yes ☐	No ☐
19	Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)?	Yes ☐	No ☐
	If yes, list them here:		
20	Do you have any other medical problems or take regular medication?	Yes ☐	No ☐
	If yes, list them here:		

Note: Authority cited: Section 4052.3, Business and Professions Code. Reference: Section 4052(a)(10), Business and Professions Code.

Protocol Sources

Centers for Disease Control and Prevention, "United States Medical Eligibility Criteria for Contraceptive Use," (2010) *available at* http://www.cdc.gov/reproductivehealth/unintendedpregnancy/USMEC.htm.

This resources serves as the basis for which self-administered hormonal contraception medications from which a pharmacist may select.

Centers for Disease Control and Prevention, "U.S. Selected Practice Recommendations for Contraceptive Use, 2013," *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6205a1.htm.

This document from the CDC offers guidance on how to use contraceptive methods most effectively. It is adapted from a World Health Organization (WHO) publication, and endorsed by the American College of Obstetricians and Gynecologists (ACOG).

S. Shotorbani, et al., "Agreement Between Women's and Providers' Assessment of Hormonal Contraceptive Risk Factors," 73 CONTRACEPTION 501, 501-506 (2006).

This article provided a Medical History Questionnaire that was used in the development of the protocol's self-assessment tool. The article's research found 96% agreement between women's self-administered risk factor questionnaire and their providers' evaluation of their medical eligibility for hormonal contraceptive use.

CPhA/CSHP, "Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraceptives."

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Medical Board Update

MEDICAL BOARD OF CALIFORNIA
Executive Office

Prescribing Task Force:

At its October 24, 2014 Meeting, the Medical Board of California (MBC) approved the revised *Guidelines for Prescribing Controlled Substances for Pain*. This document was put together through extensive collaboration with multiple interested parties. Once the document was approved, the MBC began disseminating the document to its licensees and all stakeholders.

In addition, the Prescription Opioid Misuse and Overdose Prevention led by the California Department of Public Health used these Guidelines to issue a press release on December 30, 2014 notifying the public of this state workgroup on this issue. The MBC continues to remain involved in this workgroup and is working with its state partners to reduce the issues around misuse and abuse of prescription opioids.

The Prescribing Task Force will hold a meeting in late February to early March to look at best practices. Several presentations will take place at this meeting from entities that have found ways to identify physicians who may be overprescribing. The Task Force will use this information to write Newsletter articles, update its website, provide outreach presentations, and identify other education tools for physicians and the public.

Interstate Compact:
The MBC, at its meeting on January 30 will be reviewing and discussing an Interstate Compact that has been developed by other state medical boards. This Interstate Compact has been finalized and it is being asked that state medical boards support this compact and also seek legislation to approve the compact within each state. Twenty-five states have supported this compact to date, and seven are seeking legislation to implement it within their state. Such a compact would allow individuals to be licensed in multiple states in an expedited manner, while still maintaining the autonomy of the individual states.

Joint Protocols:
The MBC will be reviewing the Board of Pharmacy protocols required for self-administered hormonal contraception, nicotine replacement products, and naloxone hydrochloride at its January 30, 2015 meeting. The MBC thanks the Board of Pharmacy for the work they have put into completing these protocols.

March is Prescription Drug Awareness Month
Lastly, the MBC will be planning outreach events for the month of March to educate all consumers and licensees on the issues surrounding prescription drug misuse and abuse. The MBC looks forward to working with the Board of Pharmacy on this issue. The MBC is also putting together a Healing Arts Board Outreach event in March. This would allow an individual from each Healing Arts Board to provide a short presentation on the functions of their board and be available for questions. The MBC will be working with legislative offices to find a venue to provide such an event. More information will be provided in the future.

Thank you for this opportunity to provide an update on the MBC. I apologize for not being able to provide this in-person.

Protocol for Pharmacists Who Furnish Naloxone

As Provided to the Board of Pharmacy on January 27, 2015

Pharmacists Protocol for Dispensing Naloxone Hydrochloride

Assembly Bill 1535 (Chapter 326, Statutes of 2014) permits pharmacists to furnish naloxone hydrochloride based on a statewide protocol adopted by the California State Board of Pharmacy and the Medical Board of California.

On the following page is the approved protocol. Pharmacists may use this protocol after they have completed one hour of continuing education credit specific to naloxone hydrochloride, or an equivalent curriculum-based training program completed in a board-recognized~~n ACPE-accredited~~ s~~S~~chool of p~~P~~harmacy (a requirement of the new law).

Prior legislation (Assembly Bill 635, Chapter 707, Statutes of 2013) permits a licensed health care provider who is authorized by law to prescribe an opioid antagonist to prescribe and dispense to a person at risk of an opioid-related overdose or to a family member or friend. This protocol does not affect any prescriptions furnished under California Civil Code S~~s~~ection 1714.22.

This protocol was prepared with the intent to keep it simple and to comply with the statutory requirements established by Assembly Bill 1535. The statutory provisions for pharmacists furnishing naloxone hydrochloride are found in California Business and Professions Code S~~s~~ection 4052.01.

When considering a specific clinical situation, pharmacists are encouraged to consult the Substance Abuse Mental Health Services Administration's "Opioid Prevention Toolkit" (2014), available at http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit-Updated-2014/SMA14-4742; prescribers will find guidance for identifying patients at risk for overdose, engaging them in prevention and risk-reduction efforts, and accessing opioid-dependence treatment, including naloxone.

Other resources include Prescribe to Prevent, http://prescribetoprevent.org/pharmacists; and Harm Reduction Coalition, http://harmreduction.org/issues/overdose-prevention/tools-best-practices/od-kit-materials.

Protocol for Pharmacists Furnishing Naloxone Hydrochloride

(a) A pharmacist furnishing naloxone hydrochloride pursuant to Section 4052.01 of the Business and Professions C~~c~~ode shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Naloxone Hydrochloride

(1) Authority: Section 4052.01(a) of the California Business and Professions C~~c~~ode authorizes a pharmacist to furnish naloxone hydrochloride in accordance with a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol in this section satisfies that requirement.

(2) Purpose: To provide ~~timely~~ access to naloxone hydrochloride ~~and to provide~~via standardized procedures so that~~for~~ pharmacists may~~to~~ educate about~~on~~ and furnish naloxone hydrochloride ~~in order~~ to decrease ~~and prevent~~ harm from opioid[1] overdose.

~~(3) Screening: The pharmacist may provide naloxone hydrochloride to anyone who uses or has a history of using prescription opioids—especially long acting or extended release opioids—or illicit opioids, or anyone who has contact with someone who uses or has a history of using prescription or illicit opioids.~~

(3~~4~~) Procedure: When someone requests naloxone hydrochloride, or when a pharmacist in his or her professional judgment decides to advise of the availability and appropriateness of naloxone hydrochloride, the pharmacist shall complete the following steps:

- Screen for the following conditions:[2]
  - i. Whether the potential recipient[3] currently uses or has a history of using illicit or prescription opioids—especially long acting or extended release opioids (If yes, skip question ii and continue with Procedure);
  - ii. Whether the potential recipient is in contact with anyone who uses or has a history of using illicit or prescription opioids—especially long acting or extended release opioids (If yes, continue with Procedure);
  - iii. Whether the person to whom the naloxone hydrochloride would be administered has a known hypersensitivity to naloxone? (If yes, do not furnish).
- Provide training in opioid overdose prevention, recognition, response, and administration of the antidote naloxone.
- When naloxone hydrochloride is furnished:

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[1] For purposes of this protocol, "opioid" is used generally to cover both naturally derived opiates and synthetic and semi-synthetic opioids.

[2] These screening questions shall be made available in alternate languages for patients whose primary language is not English.

[3] For purposes of this protocol, "recipient" means the person to whom naloxone hydrochloride is furnished.

- The pharmacist shall provide the recipient with appropriate counseling and information on the product furnished, including dosing, effectiveness, adverse effects, storage conditions, shelf-life, and safety. The recipient is not permitted to waive the required consultation.
- The pharmacist shall provide the recipient with any informational resources on hand and/or referrals to appropriate resources if the recipient indicates interest in chemical dependency treatment, recovery services, or medication disposal resources at this time.

- The pharmacist shall answer any questions the recipient may have regarding naloxone hydrochloride.

~~the following steps:~~
~~Ask whether the person to whom the naloxone hydrochloride would be administered has a known hypersensitivity to naloxone (If yes, do not furnish).~~
~~Before furnishing naloxone hydrochloride, the pharmacist shall provide training in opioid overdose prevention, recognition, response, and administration of the antidote naloxone.~~
~~Before furnishing naloxone hydrochloride, the pharmacist shall provide training in opioid overdose prevention, recognition, response, and administration of the antidote naloxone.~~
~~When naloxone hydrochloride is furnished:~~
~~The recipient shall be provided with appropriate counseling and information on the product furnished, including dosing, effectiveness, potential side effects, storage conditions, shelf-life, and safety. The recipient is not permitted to waive the required consultation.~~
~~The pharmacist shall ask the recipient if he or she wants chemical dependency treatment, recovery services, or medication disposal resources at this time. If yes, the pharmacist shall provide the recipient with any informational resources on hand and/or referrals to appropriate resources.~~
~~The pharmacist shall review any questions the recipient may have regarding naloxone hydrochloride.~~

~~(5) Refills: The pharmacist shall review indications for use and administration of naloxone hydrochloride upon refill.~~

(4~~6~~) Product Selection: Naloxone hydrochloride ~~for take-home use can currently~~may be supplied as an intramuscular injection, intranasal spray, and auto-injector~~, or other formulations~~. Other FDA approved products may be used. Those administering naloxone should choose the route of administration based on the formulation available, how well they can administer it, the setting, and local context.

(5~~7~~) Suggested ~~Rx~~Kit Labeling:

Intramuscular	Intranasal	Auto-Injector

Naloxone 0.4mg/1ml single dose vial, # 2 vials SIG: Inject 1 ml intramuscularly upon signs of opioid overdose. Call 911. May repeat x 1. Syringe 3ml 25G X 1" # 2 SIG: Use as directed for naloxone administration. Kit should contain 2 vials and 2 syringes. ~~Naloxone 0.4mg/ml single dose vial,~~ ~~# 2 vials~~ ~~SIG: Inject 1 ml intramuscularly upon signs of opioid overdose. Call 911. May repeat x 1.~~ ~~Syringe 3ml 25G X 1" # 2~~ ~~SIG: Use as directed for naloxone administration.~~ ~~Kit should contain 2 vials and 2 syringes.~~	2ml needleless syringe prefilled with naloxone (1mg/1ml concentration), # 2 syringes SIG: Spray one-half (1ml) of the naloxone into each nostril upon signs of opioid overdose. Call 911. May repeat x 1. Mucosal Atomization Device (MAD) # 2 SIG: Use as directed for naloxone administration. Kit should contain 2 prefilled needleless syringes and 2 atomizers.~~Naloxone 2mg/2ml prefilled syringe, # 2 syringes~~ ~~SIG: Spray one-half of the syringe into each nostril upon signs of opioid overdose. Call 911. May repeat x 1.~~ ~~Mucosal Atomization Device (MAD) # 2~~ ~~SIG: Use as directed for naloxone administration.~~ ~~Kit should contain 2 prefilled syringes and 2 atomizers.~~	Naloxone 0.4 mg/0.4 ml #1 twin pack SIG: Use one auto-injector upon signs of opioid overdose. Call 911. May repeat x 1. Kit is commercially available as a twin pack with directions for administration included.~~Naloxone 0.4 mg/0.4 ml~~ ~~#1 twin pack~~ ~~SIG: Use one auto-injector upon signs of opioid overdose. Call 911. May repeat x 1.~~ ~~Kit is commercially available as a twin pack with directions for administration included.~~

Optional items for the kits include alcohol pads, rescue breathing masks, and rubber gloves.

Kit labels shall include an expiration date for the naloxone hydrochloride furnished. An example of appropriate labeling is available on the Board of Pharmacy website. ~~Prescriptions shall include an expiration date for the naloxone hydrochloride furnished.~~

(6~~8~~) Fact Sheet: The pharmacist shall provide the recipient a copy of the current naloxone fact sheet approved by the Board of Pharmacy. This fact sheet shall be made available in alternate languages for patients whose primary language is not English.

(7~~9~~) Notifications: If the recipient of the naloxone hydrochloride is also the person to whom the naloxone hydrochloride would be administered, then the naloxone recipient is considered a patient for purposes of this protocol and notification may be required under this section.

If the patient gives verbal or written consent, then the pharmacist shall notify the patient's primary care provider of any drug(s) and/or device(s) furnished, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the patient and that primary care provider.

If the patient does not have a primary care provider, or chooses not to give notification consent, then the pharmacist shall provide a written record of the drug(s) and/or device(s) furnished and advise the patient to consult an appropriate health care provider of the patient's choice.

(8~~10~~) Documentation: Each naloxone hydrochloride product furnished by a pharmacist pursuant to this protocol shall be documented in a medication record for the ~~person to whom~~ naloxone ~~is being furnished~~recipient, and securely stored within the originating health care facility for a period of at least three years from the date ~~when the last naloxone hydrochloride product was furnished~~of dispense. The medication record shall be maintained in an automated data processing or manual record mode such that the required information under title 16, sections 1717 and 1707.1 of the California Code of Regulations is readily retrievable during the facility's normal operating hours.

(9~~11~~) Training: Prior to furnishing naloxone hydrochloride, pharmacists who participate in this protocol must have successfully completed a minimum of one hour of an ~~Board-~~approved continuing education program specific to the use of naloxone hydrochloride, or an equivalent curriculum-based training program completed in a~~n ACPE-accredited~~board recognized s~~S~~chool of p~~P~~harmacy.

(10~~2~~) Privacy: All pharmacists furnishing naloxone hydrochloride in a ~~pharmacy~~ health care facility shall operate under the ~~pharmacy's~~ facility's policies and procedures to ensure that recipient confidentiality and privacy are maintained.

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Note: Authority cited: Section 4052.01, Business and Professions Code.

Protocol Sources

Scott Burris, et al., "Stopping an Invisible Epidemic: Legal Issues in the Provision of Naloxone To Prevent Opioid Overdose," DREXEL L. REV. 1(2):273-339, 326 (2009).

This law review article recommends fostering naloxone distribution through pharmacies, and using EC statutes as a model.

Substance Abuse and Mental Health Services Administration, "Opioid Overdose Toolkit," *available at* http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit-Updated-2014/SMA14-4742.

This resource provides materials to develop policies to prevent opioid overdose.

The Network for Public Health Law, "Legal Interventions To Reduce Overdose Mortality: Naloxone Access and Overdose Good Samaritan Laws" (Aug. 2014), *available at* https://www.networkforphl.org/_asset/qz5pvn/naloxone-_FINAL.pdf.

This article describes naloxone access nationwide.

Harm Reduction Coalition, "Guide to Developing and Managing Overdose Prevention and Take-Home Naloxone Projects" (2012), *available at* http://harmreduction.org/issues/overdose-prevention/tools-best-practices/manuals-best-practice/od-manual/.

This manual outlines the process of developing an overdose prevention program, including with a take-home naloxone component.

Northeast Behavioral Health, "Opioid Overdose Prevention and Reversal via Peer-Administered Narcan" (2012), *available at* http://harmreduction.org/wp-content/uploads/2012/02/od-train-the-trainer-parents.pdf.

This PowerPoint presentation provides information to educate peers on opioid prevention and reversal.

CA Department of Health Care Services, "Pharmacist Protocol for Furnishing Naloxone for the Prevention of Opioid Overdose" (last updated Oct. 29, 2014).
This draft protocol was consulted in development of the Board's recommended protocol.

World Health Organization, "Community Management of Opioid Overdose" (2014).
This resource provides materials to develop policies to prevent opioid overdose.

Drug Policy Alliance, "What Is Naloxone?" (Aug. 2014), *available at* http://www.drugpolicy.org/resource/what-naloxone.
This fact sheet provides comprehensives information on naloxone.

Massachusetts Department of Health and Human Services, "Dispensing of Naloxone by Standing Order" (2014), *available at* http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/dhpl/pharmacy/dispensing-of-naloxone-by-standing-order-.html.
This site contacts a pamphlet recommended as the base for the Board's factsheet.

N. Zaller, et al., "The Feasibility of Pharmacy-Based Naloxone Distribution Interventions: A Qualitative Study with Injection Drug Users and Pharmacy Staff in Rhode Island," 48 SUBST. USE MISUSE 8 (2013).
This research supports pharmacy-based naloxone intervention, but notes barriers including misinformation and costs.

Traci C. Green, et al., "Responding to Opioid Overdose in Rhode Island: Where the Medical Community Has Gone and Where We Need To Go," R.I. MED. J. 29-33 (Oct. 2014), *available at* http://www.rimed.org/rimedicaljournal/2014/10/2014-10-29-dadt-green.pdf.
This article gives an overview of opioid overdose, provides guidance resources, and emphasizes the importance of Good Samaritan Laws.

Protocol for Pharmacists Who Furnish Naloxone

As Provided to the Medical Board of California on January 30, 2015

Protocol for Pharmacists Furnishing Naloxone Hydrochloride

(a) A pharmacist furnishing naloxone hydrochloride pursuant to Section 4052.01 of the Business and Professions C~~c~~ode shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Naloxone Hydrochloride

(1) Authority: Section 4052.01(a) of the California Business and Professions C~~c~~ode authorizes a pharmacist to furnish naloxone hydrochloride in accordance with a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol in this section satisfies that requirement.

(2) Purpose: To provide ~~timely~~ access to naloxone hydrochloride ~~and to provide~~via standardized procedures so that~~for~~ pharmacists may~~to~~ educate about~~on~~ and furnish naloxone hydrochloride ~~in order~~ to decrease ~~and prevent~~ harm from opioid[1] overdose.

~~(3) Screening: The pharmacist may provide naloxone hydrochloride to anyone who uses or has a history of using prescription opioids—especially long acting or extended release opioids—or illicit opioids, or anyone who has contact with someone who uses or has a history of using prescription or illicit opioids.~~

(3~~4~~) Procedure: When someone requests naloxone hydrochloride, or when a pharmacist in his or her professional judgment decides to advise of the availability and appropriateness of naloxone hydrochloride, the pharmacist shall complete the following steps:

- Screen for the following conditions:[2]

i. Whether the potential recipient[3] currently uses or has a history of using illicit or prescription opioids~~—especially long acting or extended release opioids~~ (If yes, skip question ii and continue with Procedure);

ii. Whether the potential recipient is in contact with anyone who uses or has a history of using illicit or prescription opioids~~—especially long acting or extended release opioids~~ (If yes, continue with Procedure);

iii. Whether the person to whom the naloxone hydrochloride would be administered has a known hypersensitivity to naloxone? (If yes, do not furnish).

- Provide training in opioid overdose prevention, recognition, response, and administration of the antidote naloxone.
- When naloxone hydrochloride is furnished:

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[1] For purposes of this protocol, "opioid" is used generally to cover both naturally derived opiates and synthetic and semi-synthetic opioids.

[2] These screening questions shall be made available in alternate languages for patients whose primary language is not English.

[3] For purposes of this protocol, "recipient" means the person to whom naloxone hydrochloride is furnished.

- The pharmacist shall provide the recipient with appropriate counseling and information on the product furnished, including dosing, effectiveness, adverse effects, storage conditions, shelf-life, and safety. The recipient is not permitted to waive the required consultation.
- The pharmacist shall provide the recipient with any informational resources on hand and/or referrals to appropriate resources if the recipient indicates interest in ~~chemical dependency~~addiction treatment, recovery services, or medication disposal resources at this time.

- The pharmacist shall answer any questions the recipient may have regarding naloxone hydrochloride.

~~the following steps:~~
~~Ask whether the person to whom the naloxone hydrochloride would be administered has a known hypersensitivity to naloxone (If yes, do not furnish).~~
~~Before furnishing naloxone hydrochloride, the pharmacist shall provide training in opioid overdose prevention, recognition, response, and administration of the antidote naloxone.~~
~~Before furnishing naloxone hydrochloride, the pharmacist shall provide training in opioid overdose prevention, recognition, response, and administration of the antidote naloxone.~~
~~When naloxone hydrochloride is furnished:~~
~~The recipient shall be provided with appropriate counseling and information on the product furnished, including dosing, effectiveness, potential side effects, storage conditions, shelf-life, and safety. The recipient is not permitted to waive the required consultation.~~
~~The pharmacist shall ask the recipient if he or she wants chemical dependency treatment, recovery services, or medication disposal resources at this time. If yes, the pharmacist shall provide the recipient with any informational resources on hand and/or referrals to appropriate resources.~~
~~The pharmacist shall review any questions the recipient may have regarding naloxone hydrochloride.~~

~~(5) Refills: The pharmacist shall review indications for use and administration of naloxone hydrochloride upon refill.~~

(4~~6~~) Product Selection: Naloxone hydrochloride ~~for take-home use can currently~~may be supplied as an intramuscular injection, intranasal spray, and auto-injector~~, or other formulations~~. Other FDA approved products may be used. Those administering naloxone should choose the route of administration based on the formulation available, how well they can administer it, the setting, and local context.

(5~~7~~) Suggested ~~Rx~~Kit Labeling:

Intramuscular	Intranasal	Auto-Injector
Naloxone 0.4mg/1ml single dose vial, # 2 vials SIG: Inject 1 ml intramuscularly upon signs of opioid overdose. Call 911. May repeat x 1. Syringe 3ml 25G X 1" # 2 SIG: Use as directed for naloxone administration. Kit should contain 2 vials and 2 syringes. ~~Naloxone 0.4mg/ml single dose vial,~~ ~~# 2 vials~~ ~~SIG: Inject 1 ml intramuscularly upon signs of opioid overdose. Call 911. May repeat x 1.~~ ~~Syringe 3ml 25G X 1" # 2~~ ~~SIG: Use as directed for naloxone administration.~~ ~~Kit should contain 2 vials and 2 syringes.~~	2ml needleless syringe prefilled with naloxone (1mg/1ml concentration), # 2 syringes SIG: Spray one-half (1ml) of the naloxone into each nostril upon signs of opioid overdose. Call 911. May repeat x 1. Mucosal Atomization Device (MAD) # 2 SIG: Use as directed for naloxone administration. Kit should contain 2 prefilled needleless syringes and 2 atomizers.~~Naloxone 2mg/2ml prefilled syringe, # 2 syringes~~ ~~SIG: Spray one-half of the syringe into each nostril upon signs of opioid overdose. Call 911. May repeat x 1.~~ ~~Mucosal Atomization Device (MAD) # 2~~ ~~SIG: Use as directed for naloxone administration.~~ ~~Kit should contain 2 prefilled syringes and 2 atomizers.~~	Naloxone 0.4 mg/0.4 ml #1 twin pack SIG: Use one auto-injector upon signs of opioid overdose. Call 911. May repeat x 1. Kit is commercially available as a twin pack with directions for administration included.~~Naloxone 0.4 mg/0.4 ml~~ ~~#1 twin pack~~ ~~SIG: Use one auto-injector upon signs of opioid overdose. Call 911. May repeat x 1.~~ ~~Kit is commercially available as a twin pack with directions for administration included.~~

Optional items for the kits include alcohol pads, rescue breathing masks, and rubber gloves.

Kit labels shall include an expiration date for the naloxone hydrochloride furnished. An example of appropriate labeling is available on the Board of Pharmacy website. ~~Prescriptions shall include an expiration date for the naloxone hydrochloride furnished.~~

(6~~8~~) Fact Sheet: The pharmacist shall provide the recipient a copy of the current naloxone fact sheet approved by the Board of Pharmacy. This fact sheet shall be made available in alternate languages for patients whose primary language is not English.

(7~~9~~) Notifications: If the recipient of the naloxone hydrochloride is also the person to whom the naloxone hydrochloride would be administered, then the naloxone recipient is considered a patient for purposes of this protocol and notification may be required under this section.

If the patient gives verbal or written consent, then the pharmacist shall notify the patient's primary care provider of any drug(s) and/or device(s) furnished, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the patient and that primary care provider.

If the patient does not have a primary care provider, or chooses not to give notification consent, then the pharmacist shall provide a written record of the drug(s) and/or device(s) furnished and advise the patient to consult an appropriate health care provider of the patient's choice.

(8~~10~~) Documentation: Each naloxone hydrochloride product furnished by a pharmacist pursuant to this protocol shall be documented in a medication record for the ~~person to whom~~ naloxone ~~is being furnished~~recipient, and securely stored within the originating pharmacy or health care facility for a period of at least three years from the date ~~when the last naloxone hydrochloride product was furnished~~of dispense. The medication record shall be maintained in an automated data processing or manual record mode such that the required information under title 16, sections 1717 and 1707.1 of the California Code of Regulations is readily retrievable during the pharmacy or facility's normal operating hours.

(9~~11~~) Training: Prior to furnishing naloxone hydrochloride, pharmacists who participate in this protocol must have successfully completed a minimum of one hour of an ~~Board-~~approved continuing education program specific to the use of naloxone hydrochloride, or an equivalent curriculum-based training program completed in a~~n ACPE-accredited~~board recognized s~~S~~chool of p~~P~~harmacy.

(10~~2~~) Privacy: All pharmacists furnishing naloxone hydrochloride in a pharmacy or ~~pharmacy~~ health care facility shall operate under the pharmacy or ~~pharmacy's~~

facility's policies and procedures to ensure that recipient confidentiality and privacy are maintained.

Note: Authority cited: Section 4052.01, Business and Professions Code.

Protocol Sources

Scott Burris, et al., "Stopping an Invisible Epidemic: Legal Issues in the Provision of Naloxone To Prevent Opioid Overdose," DREXEL L. REV. 1(2):273-339, 326 (2009).

This law review article recommends fostering naloxone distribution through pharmacies, and using EC statutes as a model.

Substance Abuse and Mental Health Services Administration, "Opioid Overdose Toolkit," *available at* http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit-Updated-2014/SMA14-4742.

This resource provides materials to develop policies to prevent opioid overdose.

The Network for Public Health Law, "Legal Interventions To Reduce Overdose Mortality: Naloxone Access and Overdose Good Samaritan Laws" (Aug. 2014), *available at* https://www.networkforphl.org/_asset/qz5pvn/naloxone-_FINAL.pdf.

This article describes naloxone access nationwide.

Harm Reduction Coalition, "Guide to Developing and Managing Overdose Prevention and Take-Home Naloxone Projects" (2012), *available at* http://harmreduction.org/issues/overdose-prevention/tools-best-practices/manuals-best-practice/od-manual/.

This manual outlines the process of developing an overdose prevention program, including with a take-home naloxone component.

Northeast Behavioral Health, "Opioid Overdose Prevention and Reversal via Peer-Administered Narcan" (2012), *available at* http://harmreduction.org/wp-content/uploads/2012/02/od-train-the-trainer-parents.pdf.

This PowerPoint presentation provides information to educate peers on opioid prevention and reversal.

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This draft protocol was consulted in development of the Board's recommended protocol.

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This resource provides materials to develop policies to prevent opioid overdose.

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This fact sheet provides comprehensives information on naloxone.

Massachusetts Department of Health and Human Services, "Dispensing of Naloxone by Standing Order" (2014), *available at* http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/dhpl/pharmacy/dispensing-of-naloxone-by-standing-order-.html.
This site contacts a pamphlet recommended as the base for the Board's factsheet.

N. Zaller, et al., "The Feasibility of Pharmacy-Based Naloxone Distribution Interventions: A Qualitative Study with Injection Drug Users and Pharmacy Staff in Rhode Island," 48 SUBST. USE MISUSE 8 (2013).
This research supports pharmacy-based naloxone intervention, but notes barriers including misinformation and costs.

Traci C. Green, et al., "Responding to Opioid Overdose in Rhode Island: Where the Medical Community Has Gone and Where We Need To Go," R.I. MED. J. 29-33 (Oct. 2014), *available at* http://www.rimed.org/rimedicaljournal/2014/10/2014-10-29-dadt-green.pdf.
This article gives an overview of opioid overdose, provides guidance resources, and emphasizes the importance of Good Samaritan Laws.

Protocol for Pharmacists Who Furnish Nicotine Replacement Products

As Provided to the Board of Pharmacy on January 27, 2015

Protocol for Pharmacists Furnishing Nicotine Replacement Products

(a) A pharmacist furnishing nicotine replacement products pursuant to Section 4052.9 of the Business and Professions C~~c~~ode shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Nicotine Replacement Products

(1) Authority: Section 4052.9(a) of the California Business and Professions C~~c~~ode authorizes a pharmacist to furnish nicotine replacement products approved by the federal Food and Drug Administration for use by prescription-only in accordance with a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol in this section satisfies that requirement.

(2) Purpose: To provide timely access to nicotine replacement products and to ensure that the patient receives information to appropriately initiate smoking cessation medication therapy.

(3) Explanation of Products Covered: Nicotine replacement products approved by the federal Food and Drug Administration and ~~prescribed~~ provided by a pharmacist for smoking cessation are covered under this protocol.

(4) Procedure: When a patient requests nicotine replacement therapy or other smoking cessation medication, or when a pharmacist in his or her professional judgment decides to initiate smoking cessation treatment and counseling, the pharmacist shall complete the following steps:

- Review the patient's current tobacco use and past quit attempts.
- Ask the patient the following screening questions:
    - Are you pregnant or plan to become pregnant? (If yes, do not furnish and refer to an appropriate health care provider)
    - Have you had a ~~recent~~ heart attack within the last 2 weeks? (If yes, furnish with caution and refer to an appropriate health care provider)
    - Do you have any history of heart palpitations, irregular heartbeats, or have you been diagnosed with a serious arrhythmia? (If yes, furnish with caution and refer to an appropriate health care provider)
    - Do you currently experience frequent chest pain or have you been diagnosed with unstable angina? (If yes, furnish with caution and refer to an appropriate health care provider)
    - Do you have any history of allergic rhinitis (e.g., nasal allergies)? (If yes, avoid nasal spray)
    - Have you been diagnosed with temporal mandibular joint (TMJ) dysfunction? (If yes, avoid nicotine gum)

These screening questions shall be made available in alternate languages for patients whose primary language is not English.

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- When a nicotine replacement product is furnished:
  - The pharmacist shall review the instructions for use with every patient using a nicotine replacement product.
  - Pharmacists should recommend the patient seek additional assistance for behavior change, including but not limited to the California Smokers' Helpline (1-800-NO-BUTTS), web-based programs (e.g., http://smokefree.gov), apps, and local cessation programs.
- The pharmacist shall ~~review~~ answer any questions the patient may have regarding smoking cessation therapy and/or nicotine replacement products.

(5) Product Selection: The patient, in consultation with ~~Based on the information gathered from the patient during the Procedure outlined above,~~ the pharmacist, may ~~select~~ select any nicotine replacement product (alone or in combination) from the list of therapies specified in this protocol in the Table "Nicotine Replacement Therapy Medications for Smoking Cessation." This list shall be kept current and maintained in the ~~pharmacy~~health care facility, and shall be available on the Board of Pharmacy's website.

~~Furthermore, g~~Generic equivalent products may be furnished.

(6) Notifications: The pharmacist shall notify the patient's primary care provider of any ~~prescription~~ drug(s) and/or device(s) furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. 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 provide the patient with a written record of the ~~prescription~~ drug(s) and/or device(s) furnished and advise the patient to consult an appropriate health care provider of the patient's choice.

(7) Documentation: Each nicotine replacement product ~~prescribed~~ provided for smoking cessation and furnished by a pharmacist pursuant to this protocol shall be documented in a patient medication record and securely stored within the originating ~~pharmacy~~ health care facility for a period of at least three years from the date ~~when the last nicotine replacement product was furnished~~of dispense. A patient medication record shall be maintained in an automated data processing or manual record mode such that the required information under title 16, sections 1717 and 1707.1 of the California Code of Regulations is readily retrievable during the ~~pharmacy's~~ facility's normal operating hours.

(8) Training: Prior to furnishing ~~prescription~~ nicotine replacement products, pharmacists who participate in this protocol must have completed a minimum of

two hours of an ~~Board~~ approved continuing education program specific to smoking cessation therapy and nicotine replacement therapy, or an equivalent curriculum-based training program completed on or after the year 2000 in an accredited California s~~S~~chool of p~~P~~harmacy.

Additionally, pharmacists who participate in this protocol must complete ongoing continuing education focused on smoking cessation therapy from an ~~Board~~ approved provider once every two years.

(9) Patient Privacy: All pharmacists furnishing nicotine replacement products in a ~~pharmacy~~ health care facility shall operate under the ~~pharmacy's~~ facility's policies and procedures to ensure that patient confidentiality and privacy are maintained.

10) Nicotine Replacement Therapy Medications for Smoking Cessation
Insert chart

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Note: Authority cited: Section 4052.9, Business and Professions Code. Reference: Section 4052(a)(10), Business and Professions Code.

Protocol Sources

Centers for Disease Control and Prevention, "Quitting Smoking," *available at* http://www.cdc.gov/tobacco/data_statistics/fact_sheets/cessation/quitting/index.htm.
This resource describes the methods of quitting smoking and their effectiveness.

CPhA/CSHP, "Pharmacists Protocol for Dispensing Nicotine Replacement Products."
This draft protocol was consulted in development of the Board's recommended protocol.

Frank Vitale, "Brief Intervention Protocol for Assisting Patients with Tobacco Cessation," 64 AM. J. HEALTH-SYST PHARM. 2583 (2007).
This commentary provides important resources and specific dialogue for a pharmacists' procedure for assisting patients with tobacco cessation.

Nicole Van Hoey, "Opportunities for Smoking Cessation Services in Emerging Models of Care," America's Pharmacist (Oct. 2014).
This Continuing Education provided helpful referral resources, especially smartphone resources.

University of California, San Francisco, "Smoking Cessation Leadership Center," http://smokingcessationleadership.ucsf.edu/.
This site offers evidence-based resources for providers as well as continuing education opportunities in smoking cessation for CME and CEU credit.

University of California, San Francisco, "Rx for Change," http://rxforchange.ucsf.edu/.
This site offers evidence-based resources for providers and non-providers.

Accreditation Council for Pharmacy Education, "Basic Tobacco Intervention Workshop," P.L.A.N. Search Detail, *available at* https://www.acpe-accredit.org/pwtool/plan/DetailResultsPLAN.aspx?progtype=1&id=267501&cosp=289079&fromdate=10/27/2014.

This website shows ACPE-approved education involving smoking cessation.

Agency for Healthcare Research and Quality, "Treating Tobacco Use and Dependence: 2008—Clinical Practice Guideline," *available at* http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/tobacco/clinicians/index.html.

This site provides tobacco reference materials and guides for health care providers.

Nicotine Replacement Therapy Medications for Smoking Cessation

	Nicotine Replacement Therapy (NRT) Formulations Used as Monotherapy					Combination NRT
	Gum	Lozenge	Patch	Nasal Spray	Inhaler	
Product	Nicorette[1], Generic OTC 2 mg, 4 mg original, cinnamon, fruit, mint	Nicorette Lozenge,[1] Nicorette Mini Lozenge,[1] Generic OTC 2 mg, 4 mg cherry, mint	NicoDerm CQ[1], Generic OTC (NicoDerm CQ, generic) Rx (generic) 7 mg, 14 mg, 21 mg (24-hour release)	Nicotrol NS[2] Rx Metered spray 0.5 mg nicotine in 50 mcL aqueous nicotine solution	Nicotrol Inhaler[2] Rx 10 mg cartridge delivers 4 mg inhaled nicotine vapor	Combinations with demonstrated efficacy Nicotine patch + nicotine gum Nicotine patch + nicotine lozenge Nicotine patch + nicotine nasal spray Nicotine patch + nicotine oral inhaler
Precautions	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Temporomandibular joint disease ▪ Pregnancy[3] and breastfeeding ▪ Adolescents (<18 years)	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Pregnancy[3] and breastfeeding ▪ Adolescents (<18 years)	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Pregnancy[3] (Rx formulations, category D) and breastfeeding ▪ Adolescents (<18 years)	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Underlying chronic nasal disorders (rhinitis, nasal polyps, sinusitis) ▪ Severe reactive airway disease ▪ Pregnancy[3] (category D) and breastfeeding ▪ Adolescents (<18 years)	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Bronchospastic disease ▪ Pregnancy[3] (category D) and breastfeeding ▪ Adolescents (<18 years)	▪ See precautions for individual agents
Dosing	*1st cigarette ≤30 minutes after waking:* 4 mg *1st cigarette >30 minutes after waking:* 2 mg Weeks 1–6: 1 piece q 1–2 hours Weeks 7–9: 1 piece q 2–4 hours Weeks 10–12: 1 piece q 4–8 hours ▪ Maximum, 24 pieces/day ▪ Chew each piece slowly ▪ Park between cheek and gum when peppery or tingling sensation appears (~15–30 chews) ▪ Resume chewing when tingle fades ▪ Repeat chew/park steps until most of the nicotine is gone (tingle does not return; generally 30 min) ▪ Park in different areas of mouth ▪ No food or beverages 15 minutes before or during use ▪ Duration: up to 12 weeks	*1st cigarette ≤30 minutes after waking:* 4 mg *1st cigarette >30 minutes after waking:* 2 mg Weeks 1–6: 1 lozenge q 1–2 hours Weeks 7–9: 1 lozenge q 2–4 hours Weeks 10–12: 1 lozenge q 4–8 hours ▪ Maximum, 20 lozenges/day ▪ Allow to dissolve slowly (20–30 minutes for standard; 10 minutes for mini) ▪ Nicotine release may cause a warm, tingling sensation ▪ Do not chew or swallow ▪ Occasionally rotate to different areas of the mouth ▪ No food or beverages 15 minutes before or during use ▪ Duration: up to 12 weeks	*>10 cigarettes/day:* 21 mg/day x 4–6 weeks 14 mg/day x 2 weeks 7 mg/day x 2 weeks *≤10 cigarettes/day:* 14 mg/day x 6 weeks 7 mg/day x 2 weeks ▪ May wear patch for 16 hours if patient experiences sleep disturbances (remove at bedtime) ▪ Duration: 8–10 weeks	1–2 doses/hour (8–40 doses/day) One dose = 2 sprays (one in each nostril); each spray delivers 0.5 mg of nicotine to the nasal mucosa ▪ Maximum – 5 doses/hour or – 40 doses/day ▪ For best results, initially use at least 8 doses/day ▪ Do not sniff, swallow, or inhale through the nose as the spray is being administered ▪ Duration: 3–6 months	6–16 cartridges/day Individualize dosing; initially use 1 cartridge q 1–2 hours ▪ Best effects with continuous puffing for 20 minutes ▪ Initially use at least 6 cartridges/day ▪ Nicotine in cartridge is depleted after 20 minutes of active puffing ▪ Inhale into back of throat or puff in short breaths ▪ Do NOT inhale into the lungs (like a cigarette) but "puff" as if lighting a pipe ▪ Open cartridge retains potency for 24 hours ▪ No food or beverages 15 minutes before or during use ▪ Duration: 3–6 months	*Reserve for patients smoking ≥10 cigarettes/day:* Long-acting NRT: to prevent onset of severe withdrawal symptoms ▪ Nicotine patch 21 mg/day x 4-6 weeks 14 mg/day x 2 weeks 7 mg/day x 2 weeks PLUS Short-acting NRT: used as needed to control breakthrough withdrawal symptoms and situational urges for tobacco ▪ Nicotine gum (2 mg) 1 piece q 1–2 hours as needed *OR* ▪ Nicotine lozenge (2 mg) 1 lozenge q 1–2 hours as needed *OR* ▪ Nicotine nasal spray 1 spray in each nostril q 1–2 hours as needed *OR* ▪ Nicotine inhaler 1 cartridge q 1–2 hours as needed

	Nicotine Replacement Therapy (NRT) Formulations Used as Monotherapy					Combination NRT
	Gum	Lozenge	Patch	Nasal Spray	Inhaler	
Adverse Effects	▪ Mouth/jaw soreness ▪ Hiccups ▪ Dyspepsia ▪ Hypersalivation ▪ Effects associated with incorrect chewing technique: – Lightheadedness – Nausea/vomiting – Throat and mouth irritation	▪ Nausea ▪ Hiccups ▪ Cough ▪ Heartburn ▪ Headache ▪ Flatulence ▪ Insomnia	▪ Local skin reactions (erythema, pruritus, burning) ▪ Headache ▪ Sleep disturbances (insomnia, abnormal/vivid dreams); associated with nocturnal nicotine absorption	▪ Nasal and/or throat irritation (hot, peppery, or burning sensation) ▪ Rhinitis ▪ Tearing ▪ Sneezing ▪ Cough ▪ Headache	▪ Mouth and/or throat irritation ▪ Cough ▪ Headache ▪ Rhinitis ▪ Dyspepsia ▪ Hiccups	▪ See adverse effects listed for individual agents
Advantages	▪ Might satisfy oral cravings ▪ Might delay weight gain ▪ Patients can titrate therapy to manage withdrawal symptoms ▪ Variety of flavors are available	▪ Might satisfy oral cravings ▪ Might delay weight gain ▪ Easy to use and conceal ▪ Patients can titrate therapy to manage withdrawal symptoms ▪ Variety of flavors are available	▪ Provides consistent nicotine levels over 24 hours ▪ Easy to use and conceal ▪ Once daily dosing associated with fewer compliance problems ▪ FDA-approved for use in combination with bupropion SR	▪ Patients can titrate therapy to rapidly manage withdrawal symptoms	▪ Patients can titrate therapy to manage withdrawal symptoms ▪ Mimics hand-to-mouth ritual of smoking (could also be perceived as a disadvantage)	▪ Provides consistent nicotine levels over 24 hours and patients can titrate therapy to manage withdrawal symptoms and situational urges for tobacco ▪ Research studies suggest combination therapy provides a small, but meaningful increase in success rates compared to NRT monotherapy ▪ Attractive option for patients who have previously failed treatment with NRT monotherapy ▪ See advantages listed for individual agents
	▪ Need for frequent dosing can compromise compliance ▪ Might be problematic for patients with significant dental work ▪ Proper chewing technique is necessary for effectiveness and to minimize adverse effects ▪ Gum chewing may not be acceptable or desirable for some patients	▪ Need for frequent dosing can compromise compliance ▪ Gastrointestinal side effects (nausea, hiccups, heartburn) might be bothersome	▪ When used as monotherapy, cannot be titrated to acutely manage withdrawal symptoms ▪ Not recommended for use by patients with dermatologic conditions (e.g., psoriasis, eczema, atopic dermatitis)	▪ Need for frequent dosing can compromise compliance ▪ Nasal administration might not be acceptable or desirable for some patients; nasal irritation often problematic ▪ Not recommended for use by patients with chronic nasal disorders or severe reactive airway disease	▪ Need for frequent dosing can compromise compliance ▪ Cartridges might be less effective in cold environments (≤60°F)	▪ Increased cost of therapy ▪ See disadvantages listed for individual agents

[1] Marketed by GlaxoSmithKline.
[2] Marketed by Pfizer.
[3] The U.S. Clinical Practice Guideline states that pregnant smokers should be encouraged to quit without medication based on insufficient evidence of effectiveness and theoretical concerns with safety. Pregnant smokers should be offered behavioral counseling interventions that exceed minimal advice to quit.

Abbreviations: NRT, nicotine replacement therapy; OTC, over-the-counter (non-prescription product); Rx, prescription product.

For complete prescribing information, please refer to the manufacturers' package inserts.

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Protocol for Pharmacists Who Furnish Nicotine Replacement Products

As Provided to the Medical Board of California on January 30, 2015

Protocol for Pharmacists Furnishing Nicotine Replacement Products

(a) A pharmacist furnishing nicotine replacement products pursuant to Section 4052.9 of the Business and Professions C~~c~~ode shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Nicotine Replacement Products

(1) Authority: Section 4052.9(a) of the California Business and Professions C~~c~~ode authorizes a pharmacist to furnish nicotine replacement products approved by the federal Food and Drug Administration for use by prescription-only in accordance with a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol in this section satisfies that requirement.

(2) Purpose: To provide timely access to nicotine replacement products and to ensure that the patient receives information to appropriately initiate smoking cessation medication therapy.

(3) Explanation of Products Covered: Prescription n~~N~~icotine replacement products approved by the federal Food and Drug Administration and ~~prescribed~~ provided by a pharmacist for smoking cessation are covered under this protocol. Pharmacists may continue to provide over-the-counter smoking cessation products without use of this protocol.

(4) Procedure: When a patient requests nicotine replacement therapy or other smoking cessation medication, or when a pharmacist in his or her professional judgment decides to initiate smoking cessation treatment and counseling, the pharmacist shall complete the following steps:

- Review the patient's current tobacco use and past quit attempts.
- Ask the patient the following screening questions:
    - Are you pregnant or plan to become pregnant? (If yes, do not furnish and refer to an appropriate health care provider)
    - Have you had a ~~recent~~ heart attack within the last 2 weeks? (If yes, furnish with caution and refer to an appropriate health care provider)
    - Do you have any history of heart palpitations, irregular heartbeats, or have you been diagnosed with a serious arrhythmia? (If yes, furnish with caution and refer to an appropriate health care provider)
    - Do you currently experience frequent chest pain or have you been diagnosed with unstable angina? (If yes, furnish with caution and refer to an appropriate health care provider)
    - Do you have any history of allergic rhinitis (e.g., nasal allergies)? (If yes, avoid nasal spray)

- Have you been diagnosed with temporal mandibular joint (TMJ) dysfunction? (If yes, avoid nicotine gum)

These screening questions shall be made available in alternate languages for patients whose primary language is not English.

- When a nicotine replacement product is furnished:
  - The pharmacist shall review the instructions for use with every patient using a nicotine replacement product.
  - Pharmacists should recommend the patient seek additional assistance for behavior change, including but not limited to the California Smokers' Helpline (1-800-NO-BUTTS), web-based programs (e.g., http://smokefree.gov), apps, and local cessation programs.
- The pharmacist shall ~~review~~ answer any questions the patient may have regarding smoking cessation therapy and/or nicotine replacement products.

(5) Product Selection: The ~~patient~~pharmacist, in consultation with ~~Based on the information gathered from the patient during the Procedure outlined above,~~ the ~~pharmacist~~patient, may ~~select~~ select any nicotine replacement product (alone or in combination) from the list of therapies specified in this protocol in the Table "Nicotine Replacement Therapy Medications for Smoking Cessation." This list shall be kept current and maintained in the pharmacy or ~~pharmacy~~health care facility, and shall be available on the Board of Pharmacy's website.

~~Furthermore, g~~Generic equivalent products may be furnished.

(6) Notifications: The pharmacist shall notify the patient's primary care provider of any prescription ~~prescription~~ drug(s) and/or device(s) furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. 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 provide the patient with a written record of the prescription ~~prescription~~ drug(s) and/or device(s) furnished and advise the patient to consult an appropriate health care provider of the patient's choice.

(7) Documentation: Each nicotine replacement product ~~prescribed~~ provided for smoking cessation and furnished by a pharmacist pursuant to this protocol shall be documented in a patient medication record and securely stored within the originating pharmacy or ~~pharmacy~~ health care facility for a period of at least three years from the date ~~when the last nicotine replacement product was furnished~~of dispense. A patient medication record shall be maintained in an automated data processing or manual record mode such that the required information under title 16, sections 1717 and 1707.1 of the California Code of Regulations is readily retrievable during the pharmacy or ~~pharmacy's~~ facility's normal operating hours.

(8) Training: Prior to furnishing prescription nicotine replacement products, pharmacists who participate in this protocol must have completed a minimum of two hours of an ~~Board-~~approved continuing education program specific to smoking cessation therapy and nicotine replacement therapy, or an equivalent curriculum-based training program completed ~~on or after the year 2000~~within the last two years in an accredited California s~~S~~chool of p~~P~~harmacy.

Additionally, pharmacists who participate in this protocol must complete ongoing continuing education focused on smoking cessation therapy from an ~~Board-~~approved provider once every two years.

(9) Patient Privacy: All pharmacists furnishing nicotine replacement products in a pharmacy or ~~pharmacy~~ health care facility shall operate under the pharmacy or ~~pharmacy's~~ facility's policies and procedures to ensure that patient confidentiality and privacy are maintained.

10) Nicotine Replacement Therapy Medications for Smoking Cessation
Insert chart

Note: Authority cited: Section 4052.9, Business and Professions Code. Reference: Section 4052(a)(10), Business and Professions Code.

Protocol Sources

Centers for Disease Control and Prevention, "Quitting Smoking," *available at* http://www.cdc.gov/tobacco/data_statistics/fact_sheets/cessation/quitting/index.htm.
This resource describes the methods of quitting smoking and their effectiveness.

CPhA/CSHP, "Pharmacists Protocol for Dispensing Nicotine Replacement Products."
This draft protocol was consulted in development of the Board's recommended protocol.

Frank Vitale, "Brief Intervention Protocol for Assisting Patients with Tobacco Cessation," 64 AM. J. HEALTH-SYST PHARM. 2583 (2007).
This commentary provides important resources and specific dialogue for a pharmacists' procedure for assisting patients with tobacco cessation.

Nicole Van Hoey, "Opportunities for Smoking Cessation Services in Emerging Models of Care," America's Pharmacist (Oct. 2014).
This Continuing Education provided helpful referral resources, especially smartphone resources.

University of California, San Francisco, "Smoking Cessation Leadership Center," http://smokingcessationleadership.ucsf.edu/.
This site offers evidence-based resources for providers as well as continuing education opportunities in smoking cessation for CME and CEU credit.

University of California, San Francisco, "Rx for Change," http://rxforchange.ucsf.edu/.
This site offers evidence-based resources for providers and non-providers.

Accreditation Council for Pharmacy Education, "Basic Tobacco Intervention Workshop," P.L.A.N. Search Detail, *available at* https://www.acpe-accredit.org/pwtool/plan/DetailResultsPLAN.aspx?progtype=1&id=267501&cosp=289079&fromdate=10/27/2014.
This website shows ACPE-approved education involving smoking cessation.

Agency for Healthcare Research and Quality, "Treating Tobacco Use and Dependence: 2008—Clinical Practice Guideline," *available at* http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/tobacco/clinicians/index.html.
This site provides tobacco reference materials and guides for health care providers.

Nicotine Replacement Therapy Medications for Smoking Cessation

	Nicotine Replacement Therapy (NRT) Formulations Used as Monotherapy					Combination NRT
	Gum	**Lozenge**	**Patch**	**Nasal Spray**	**Inhaler**	
Product	**Nicorette[1], Generic** OTC 2 mg, 4 mg original, cinnamon, fruit, mint	**Nicorette Lozenge,[1]** **Nicorette Mini Lozenge,[1]** **Generic** OTC 2 mg, 4 mg cherry, mint	**NicoDerm CQ[1], Generic** OTC (NicoDerm CQ, generic) Rx (generic) 7 mg, 14 mg, 21 mg (24-hour release)	**Nicotrol NS[2]** Rx Metered spray 0.5 mg nicotine in 50 mcL aqueous nicotine solution	**Nicotrol Inhaler[2]** Rx 10 mg cartridge delivers 4 mg inhaled nicotine vapor	**Combinations with demonstrated efficacy** Nicotine patch + nicotine gum Nicotine patch + nicotine lozenge Nicotine patch + nicotine nasal spray Nicotine patch + nicotine oral inhaler
Precautions	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Temporomandibular joint disease ▪ Pregnancy[3] and breastfeeding ▪ Adolescents (<18 years)	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Pregnancy[3] and breastfeeding ▪ Adolescents (<18 years)	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Pregnancy[3] (Rx formulations, category D) and breastfeeding ▪ Adolescents (<18 years)	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Underlying chronic nasal disorders (rhinitis, nasal polyps, sinusitis) ▪ Severe reactive airway disease ▪ Pregnancy[3] (category D) and breastfeeding ▪ Adolescents (<18 years)	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Bronchospastic disease ▪ Pregnancy[3] (category D) and breastfeeding ▪ Adolescents (<18 years)	▪ See precautions for individual agents
Dosing	*1st cigarette ≤30 minutes after waking:* 4 mg *1st cigarette >30 minutes after waking:* 2 mg Weeks 1–6: 1 piece q 1–2 hours Weeks 7–9: 1 piece q 2–4 hours Weeks 10–12: 1 piece q 4–8 hours ▪ Maximum, 24 pieces/day ▪ Chew each piece slowly ▪ Park between cheek and gum when peppery or tingling sensation appears (~15–30 chews) ▪ Resume chewing when tingle fades ▪ Repeat chew/park steps until most of the nicotine is gone (tingle does not return; generally 30 min) ▪ Park in different areas of mouth ▪ No food or beverages 15 minutes before or during use ▪ Duration: up to 12 weeks	*1st cigarette ≤30 minutes after waking:* 4 mg *1st cigarette >30 minutes after waking:* 2 mg Weeks 1–6: 1 lozenge q 1–2 hours Weeks 7–9: 1 lozenge q 2–4 hours Weeks 10–12: 1 lozenge q 4–8 hours ▪ Maximum, 20 lozenges/day ▪ Allow to dissolve slowly (20–30 minutes for standard; 10 minutes for mini) ▪ Nicotine release may cause a warm, tingling sensation ▪ Do not chew or swallow ▪ Occasionally rotate to different areas of the mouth ▪ No food or beverages 15 minutes before or during use ▪ Duration: up to 12 weeks	*>10 cigarettes/day:* 21 mg/day x 4–6 weeks 14 mg/day x 2 weeks 7 mg/day x 2 weeks *≤10 cigarettes/day:* 14 mg/day x 6 weeks 7 mg/day x 2 weeks ▪ May wear patch for 16 hours if patient experiences sleep disturbances (remove at bedtime) ▪ Duration: 8–10 weeks	1–2 doses/hour (8–40 doses/day) One dose = 2 sprays (one in **each** nostril); each spray delivers 0.5 mg of nicotine to the nasal mucosa ▪ Maximum – 5 doses/hour or – 40 doses/day ▪ For best results, initially use at least 8 doses/day ▪ Do not sniff, swallow, or inhale through the nose as the spray is being administered ▪ Duration: 3–6 months	6–16 cartridges/day Individualize dosing; initially use 1 cartridge q 1–2 hours ▪ Best effects with continuous puffing for 20 minutes ▪ Initially use at least 6 cartridges/day ▪ Nicotine in cartridge is depleted after 20 minutes of active puffing ▪ Inhale into back of throat or puff in short breaths ▪ Do NOT inhale into the lungs (like a cigarette) but "puff" as if lighting a pipe ▪ Open cartridge retains potency for 24 hours ▪ No food or beverages 15 minutes before or during use ▪ Duration: 3–6 months	*Reserve for patients smoking ≥10 cigarettes/day:* **Long-acting NRT**: to prevent onset of severe withdrawal symptoms ▪ **Nicotine patch** 21 mg/day x 4-6 weeks 14 mg/day x 2 weeks 7 mg/day x 2 weeks **PLUS** **Short-acting NRT**: used as needed to control breakthrough withdrawal symptoms and situational urges for tobacco ▪ **Nicotine gum (2 mg)** 1 piece q 1–2 hours as needed *OR* ▪ **Nicotine lozenge (2 mg)** 1 lozenge q 1–2 hours as needed *OR* ▪ **Nicotine nasal spray** 1 spray in each nostril q 1–2 hours as needed *OR* ▪ **Nicotine inhaler** 1 cartridge q 1–2 hours as needed

	Nicotine Replacement Therapy (NRT) Formulations Used as Monotherapy					Combination NRT
	Gum	Lozenge	Patch	Nasal Spray	Inhaler	
Adverse Effects	▪ Mouth/jaw soreness ▪ Hiccups ▪ Dyspepsia ▪ Hypersalivation ▪ Effects associated with incorrect chewing technique: – Lightheadedness – Nausea/vomiting – Throat and mouth irritation	▪ Nausea ▪ Hiccups ▪ Cough ▪ Heartburn ▪ Headache ▪ Flatulence ▪ Insomnia	▪ Local skin reactions (erythema, pruritus, burning) ▪ Headache ▪ Sleep disturbances (insomnia, abnormal/vivid dreams); associated with nocturnal nicotine absorption	▪ Nasal and/or throat irritation (hot, peppery, or burning sensation) ▪ Rhinitis ▪ Tearing ▪ Sneezing ▪ Cough ▪ Headache	▪ Mouth and/or throat irritation ▪ Cough ▪ Headache ▪ Rhinitis ▪ Dyspepsia ▪ Hiccups	▪ See adverse effects listed for individual agents
Advantages	▪ Might serve as an oral substitute for tobacco ▪ Might delay weight gain ▪ Can be titrated to manage withdrawal symptoms ▪ Can be used in combination with other agents to manage situational urges	▪ Might serve as an oral substitute for tobacco ▪ Might delay weight gain ▪ Can be titrated to manage withdrawal symptoms ▪ Can be used in combination with other agents to manage situational urges	▪ Once daily dosing associated with fewer adherence problems ▪ Of all NRT products, its use is least obvious to others Can be used in combination with other agents; delivers consistent nicotine levels over 24 hours	▪ Can be titrated to rapidly manage withdrawal symptoms ▪ Can be used in combination with other agents to manage situational urges	▪ Might serve as an oral substitute for tobacco ▪ Can be titrated to manage withdrawal symptoms ▪ Mimics hand-to-mouth ritual of smoking ▪ Can be used in combination with other agents to manage situational urges	▪ Provides consistent nicotine levels over 24 hours and patients can titrate therapy to manage withdrawal symptoms and situational urges for tobacco ▪ Research studies suggest combination therapy provides a small, but meaningful increase in success rates compared to single agent NRT ▪ Attractive option for patients who have previously failed treatment with monotherapy ▪ See advantages listed for individual agents
Disadvantages	▪ Need for frequent dosing can compromise adherence ▪ Might be problematic for patients with significant dental work ▪ Proper chewing technique is necessary for effectiveness and to minimize adverse effects ▪ Gum chewing might not be acceptable or desirable for some patients	▪ Need for frequent dosing can compromise adherence ▪ Gastrointestinal side effects (nausea, hiccups, heartburn) might be bothersome	▪ When used as monotherapy, cannot be titrated to acutely manage withdrawal symptoms ▪ Not recommended for use by patients with dermatologic conditions (e.g., psoriasis, eczema, atopic dermatitis)	▪ Need for frequent dosing can compromise adherence ▪ Nasal administration might not be acceptable or desirable for some patients; nasal irritation often problematic ▪ Not recommended for use by patients with chronic nasal disorders or severe reactive airway disease	▪ Need for frequent dosing can compromise adherence ▪ Cartridges might be less effective in cold environments (≤60°F)	▪ Combination therapy is more costly than monotherapy ▪ See disadvantages listed for individual agents

[1] Marketed by GlaxoSmithKline.
[2] Marketed by Pfizer.
[3] The U.S. Clinical Practice Guideline states that pregnant smokers should be encouraged to quit without medication based on insufficient evidence of effectiveness and theoretical concerns with safety. Pregnant smokers should be offered behavioral counseling interventions that exceed minimal advice to quit.

Abbreviations: NRT, nicotine replacement therapy; OTC, over-the-counter (non-prescription product); Rx, prescription product.

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