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

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

COMMUNICATION AND PUBLIC EDUCATION COMMITTEE MEETING MINUTES

Date: September 8, 2016

Location: Department of Consumer Affairs
1st Floor Hearing Room
1625 N. Market Blvd.
Sacramento, CA 95834

Committee Members Present: Victor Law, RPh, Chair
Debbie Veale, RPh, Vice Chair
Ryan Brooks, Public Member

Staff Present: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Laura Freedman, DCA Staff Counsel
Debbie Damoth, Staff Services Manager
Bob Dávila, Public Information Officer

1. Call to Order and Establishment of Quorum

The meeting was called to order at 9:34 a.m. Roll call was taken, and a quorum was established.

2. Public Comment for Items Not on the Agenda, Matters for Future Meetings

There were no public comments.

3. Update and Discussion on the Development of a Revised Patient Consultation Survey Questionnaire

a. Review and Discussion of Similarly Conducted Surveys on Patient Consultations

Chairperson Law noted that President Gutierrez asked the committee at the October 2015 board meeting to develop a broader survey for licensees about patient consultation. At the July 2016 board meeting, the board directed staff to research previously conducted patient consultation surveys.

Board staff contacted the Institute for Safe Medication Practices (ISMP) and the National Council on Patient Information and Education (NCPIE). Chairperson Law reviewed the following information that was provided by ISMP and NCPIE, which also was included in the meeting materials:

- Pharmaceutical Consultation in UAE Community Pharmacies, N. M. Hamoudi, A. A. Shirwaikar, H. S. Ali, and E. I. Al Ayoubi, Indian J Pharm Sci. 2011 Jul-Aug; 73(4): 404–408 – Provides sample questions on pharmacists' opinions on patient counseling and the use of consumer product information (CPI) and patient information leaflet (PIL).
    - Patient counseling and giving out CPI/PIL is my professional responsibility.
    - PIL and CPIs will ease my counseling tasks.
    - Patient counseling and giving out CPI to customers will enhance my financial costs.
    - I should get paid for counseling and giving out PILs.
    - Counseling and information leaflets have no role in my practice.
    - Counseling will increase my dispensing workload and thus I need extra staff
    - Patient counseling and giving out CPI/PIL is the responsibility of the prescriber.
    - Customers will experience medication side effects when I give out CPI.
    - Patient counseling will improve my sales and reputation of my pharmacy.
    - For effective counseling act, I need training.
    - Customers do not show any interest toward counseling or PIL.
    - Patient counseling and information leaflets contain more information which contradicts with the prescriber's information.

- Counselling Practices in Community Pharmacies in Riyadh, Saudi Arabia: A Cross-Sectional Study, Sinaa Alaqeel and Norah O. Abanmy, Alaqeel and Abanmy BMC Health Services Research (2015) 15:557 – Provides statements from pharmacists regarding barriers to counseling.
    - Pharmacists have limited drug resources.
    - Pharmacists are too busy.
    - Pharmacists do not have the patient history.
    - Pharmacists lack confidence in their knowledge.

- Attitude of Community Pharmacists towards Patient Counseling In Saudi Arabia, The Internet Journal of Pharmacology. 2010 Volume 9, Number 2 – Provides several topics of interest.
    - Pharmacists' attitudes to items about the professional responsibilities of the community pharmacist.

        - The pharmacist should counsel patient about prescribed medication.
        - The community pharmacist should counsel patients about OTC medication.
        - The community pharmacist should keep up-to-date knowledge of current drug information.
        - The community pharmacist should attend continuing education regularly.
        - The community pharmacist should have good working relationships with health care providers.
        - The community pharmacist should be committed with the rules and regulation governing the practice of pharmacy.
    - Pharmacists' attitudes towards items about reasons for deciding to counsel.
        - Medications are more likely to be taken as they should be taken.
        - With regular customers, I know enough about them to be able to counsel effectively.
        - I am a respected member of community and expected to give advice.
        - Counseling improves patient compliance.
        - Counseling improves patient/pharmacist relationship.
        - Counseling brings more people into the pharmacy.
        - Counseling increases provisional relationships.
        - Customers appreciate extra care and interest I show in them.
        - Counseling enables me to become an active member of the health care team.
        - Counseling may prevent the patient from experiencing an adverse drug effect.
        - Counseling reduces drug wastage.
        - Counseling increases sales.
        - Counseling increases job satisfaction.
        - Counseling improves my knowledge and practicing ability.
    - Pharmacists' attitudes towards items about reasons against deciding to counsel.
        - I should not counsel without adequate medical history.
        - People do not respect the advice of a pharmacist.
        - I am too busy.
        - I am not paid for counseling.
        - I do not like talking to consumers.
        - Counseling does not lead to a significant improvement in health care.
        - Counseling may not be necessary.
        - Counseling is not my responsibility beyond but should be

performed by the doctor.
    - Counseling increases professional responsibility beyond which I am prepared to accept.
    - I lack confidence in my knowledge.
    - There is a lack of feedback from people.
    - Customers do not perceive the benefit.
    - I do not know enough about drugs and their effects.
    - I do not know how to approach people.
    - I am worried about contradicting doctors.

- A comparison of patients' and pharmacists' satisfaction with medication counseling provided by community pharmacies: a cross-sectional survey, Yang et al. BMC Health Services Research (2016) 16:131 – Provides statements for reasons why community pharmacists' perceive barriers to patient consultation.
    - Pharmacists' lack of time.
    - Patient's lack of time.
    - Low level of patient demand and expectation.
    - Lack of educational programs.
    - Lack of communication skills.
    - Lack of patients' information.
    - Lack of continuing education for counseling.

- Risk-Informed Interventions in Community Pharmacy: Implementation and Evaluation, Cohen, Michael R. and Judy L. Smetzer, Institute for Safe Medication Practices, September 14, 2009.

Ms. Veale asked if these were the only studies that ISMP and NCPIE could provide and whether any studies of patient consultation were available that were done recently in the United States. Ms. Veale stated the board feels that something must be done to increase pharmacist consultations with patients and that the board was looking for a study that could be the backbone of the board's efforts. Ms. Damoth replied that she could not find studies in her own research, so she reached out to ISMP and NCPIE. She said that the groups directed her to these studies – mostly from ISMP, because information provided by NCPIE was not relevant.

Mr. Brooks said an earlier board survey on why pharmacists do not do consultations provided answers that the board already knew. He asked what jurisdiction the board has other than enforcement and noted that the board cannot force pharmacies to pay more money or change their structure to increase consultations. He expressed uncertainty about where the board was going with this.

Chairperson Law said that the board could enforce patient consultation requirements but has not really done so. He said the licenses of both the pharmacist and the pharmacy could be disciplined if the board found that they were not doing consultations. Mr. Brooks said the board does not need a survey; the board simply needs to enforce the requirement for patient consultations. Chairperson Law agreed but added that board members feel that having a study showing that that doing patient consultations can improve patient compliance and reduce medication errors would be helpful.

Ms. Veale said that the board is doing some enforcement but that members also want to consider legislation. Ms. Herold pointed out that the board already has a requirement in place for consultation.

Ms. Veale said the board is not looking at consultation itself but how to make the pharmacist more available in the pharmacy for patients. She said that the board's study showed that pharmacists feel that they are not available because board regulations are keeping them away from the consultation and forcing them to do tasks that are non-discretionary. She said the purpose of this survey was to look at regulations and that perhaps the issue should be handled by the Licensing Committee. She added that at the last board meeting, members seemed to come to the conclusion that maybe another study is not needed. She said that all the studies seem to reach the same conclusion, so maybe the issue should simply be handed to Licensing.

Chairperson Law said that there is nothing in the board's regulations to impose a severe punishment on violators and asked if the board needs a statutory change. Ms. Herold noted that the board currently has the ability to revoke a license if the board wanted to take formal discipline against a pharmacist for failing to consult or if there were evidence that an error would not have happened if the pharmacist had taken time to consult.

As an example, Ms. Herold cited an example that would not have happened if the pharmacist had provided a patient consultation. She said that, at the board's request, staff has been citing and fining for a long time where there is proof of failure to consult. Staff has cited and fined three chains – Walgreens, CVS and Rite Aid – for failure to consult. She said that eventually it may become more expensive to chains to not consult than to provide consultations. She added that, under a "three strikes and you're out" policy, if there are three violations for failure to consult, the case is referred to the Attorney General's office for formal discipline.

Chairperson Law said that he agreed with a "three strikes" rule because even if the pharmacy or pharmacist or pharmacy management gets a first strike, they would make sure that any pharmacist working on the shift does consultations. In addition, he said, they would tell pharmacists that their main job is giving consultations, not filling prescriptions.

Mr. Brooks asked what barriers are placed on pharmacies that the board could remove or change to make pharmacies more efficient. He said that is the important question and that a questionnaire about patient consultations probably could not provide the answers.

Ms. Veale said that there are some tasks that the board has burdened the pharmacist with that could be offloaded to others. She said that was the reason the board was going through the process of looking for studies to back up the board's efforts. She said that during the last few committee and board meetings, members were getting comfortable with not having a survey to move forward.

Ms. Veale said maybe the board should compile a list of non-discretionary tasks that are keeping pharmacists from providing consultations to patients and consider whether they can be offloaded to the pharmacy technicians. Mr. Brooks suggested that the board direct staff to put together the regulations on one side and recommendations on how to streamline them on the other side, and then the board could act on that.

Ms. Veale said the committee should recommend to the board that the issue be passed to the Licensing Committee to look at the regulations. Chairperson Law said that he agreed and that there is no point in getting more surveys. Mr. Brooks seconded Ms. Veale's proposed recommendation.

Public comment: Paige Talley of the California Council for the Advancement of Pharmacy said that she believes more counseling is done in situations when a parent is picking up medication for a child or at a compounding pharmacy or specialty pharmacy. She also thanked the board for fining chains for not complying with counseling requirement. She said that her pharmacy now gives a consultation each time she picks up medications, and she suggested that pharmacies display signs informing patients that they must be counseled about their medications. Ms. Herold replied that patients will not demand a meaningful consultation until they begin receiving it; once they start demanding it, it will be built into their health care plan.

Lori Hensic of Kaiser Permanente agreed that additional surveys of pharmacists regarding patient consultation would not be helpful for increasing patient consultation. To find ways to ensure that patient consultations are meaningful, she said that it could be more useful instead to collect information from patients. She suggested asking customers why they did not get a consultation when picking up a prescription.

Motion: Recommend that the board re-direct the subject of patient consultation to the Licensing Committee; recommend that the Licensing Committee focus on regulations that could be streamlined to increase pharmacist availability for consultations; and recommend that no survey be conducted.

M/S: Veale/Brooks

Yes: 3 No: 0 Abstain: 0

Name	Yes	No	Abstain	Not Present
Brooks	x			
Law	x			
Veale	X			

b. Review and Discussion of the Department of Consumer Affairs Developed Patient Consultation Survey

Chairperson Law reported that, at the May 2016 Communication and Public Education Committee Meeting, Division of Program & Policy Review Chief Tracy Montez, Ph.D., of the Department of Consumer Affairs addressed the committee and her office's ability to develop the patient consultation survey for the board's licensees. During the meeting, the committee provided basic parameters to Dr. Montez regarding the survey, including intent, privacy for participants, and various practice settings that must be addressed.

Chairperson Law said the committee directed board staff to work with Dr. Montez's team on the development, administration and completion of the survey. The committee agreed to a target date of September 2016 for the committee to review the survey.

Chairperson Law noted that, at the July 2016 board meeting, the board directed staff to review the proposal submitted by the Department of Consumer Affairs. Board staff met with Dr. Montez and her team in the beginning of September 2016.

Ms. Herold told the committee that staff contacted various health foundations including the Kaiser Foundation, but none was interested in doing a survey. She said staff also reached out to DCA. Ms. Damoth said DCA estimated a contract price of $15,000 to $20,000 for staff work, plus $1 for each pharmacist surveyed. Ms. Herold said DCA suggested reaching 10,000 to 20,000 pharmacists. Ms. Herold said perhaps the board could use that money to find a better way to encourage patient consultation.

Motion: Recommend canceling the pharmacist survey by the Department of Consumer Affairs.

M/S: Veale/Brooks

Yes: 3 No: 0 Abstain: 0

Name	Yes	No	Abstain	Not Present
Brooks	x			
Law	x			
Veale	x			

4. Update and Discussion on the Final Rule Implementing Section 1557 of the Affordable Care Act (ACA) Regarding Nondiscrimination in Health Programs and Activities, Specifically Including its Impact on Pharmacy Translations and Interpretations

a. Overview and Summary

Chairperson Law said that a new rule issued by the U.S. Department of Health and Human Services requires pharmacies to provide "meaningful access" to customers with limited English proficiency – including posting taglines written in at least 15 languages advising the public that interpreter and translation services are available free of charge.

Chairperson Law said that the regulation implements Section 1557 of the Affordable Care Act, which forbids discrimination in health care on the basis of race, color, national origin, age, disability and sex. The rule went into effect on July 18, 2016. A copy of the board's draft newsletter article on this requirement, the APHA summary documents and Federal Rule itself were included in the committee meeting materials.

Chairperson Law told the committee that the rule appears to pre-empt the board's rules and regulations on prescription label translations.

b. Board Statutes and Regulations Impacted

Chairperson Law noted that a cursory review indicates the following statutes and regulations may be impacted by the new federal rule:

Business and Professions Code Sections:

- 4076 – Prescription Container – Requirements for Labeling
- 4076.5 – Standardized, Patient-Centered Prescription Labels; Requirements
- 4076.6 – Dispenser Shall Provide Translated Directions for Use Printed on Container Label or Supplemental Document Upon Request; Dispenser Responsible for Accuracy of Translation; Veterinarian Excepted
- 4122 – Required Notice at Availability of Prescription Price Information, General Product Availability, Pharmacy Services; Providing Drug Price Information; Limitations on Price Information 16 California Code of Regulations Sections:
- 1707.5 – Patient-Centered Labels for Prescription Drug Containers; Requirements
- 1707.6 – Notice to Consumers

Ms. Freedman asked if there are any pharmacies that do not receive federal funds and therefore would not be affected by the new federal rule. Chairperson Law and Ms. Veale said that some specialty compounding pharmacies might not receive Medicare or

Medicaid funds, but they would constitute a small percentage of all pharmacies. Ms. Herold noted that it would be unfair to have separate standards of care for consumers by defining a benefit based on reimbursement.

In addition, Ms. Herold agreed that the federal rule appears to pre-empt the board's requirements for label translations. She added that, although the effective date was June 19, there is a 90-day implementation period – so the implementation date would be Oct. 19. But she said that she asked a couple of large chains what they were doing to comply with the law, and they told her that they were astounded when the new rule came out because no one saw it coming. She said that the board learned of the new law right before it took effect. She recommended that the board move in the direction of creating a single standard of care for the state, and Ms. Freedman agreed.

Ms. Herold asked Chairperson Law if he were ready to implement the federal rule in his pharmacies. Chairperson Law replied that he was not prepared to handle 15 languages and would need time to work with a software company.

Ms. Veale noted that the federal law refers to the top 15 languages in each state. She noted that the board previously had identified the top 12 languages in the state for Medi-Cal purposes. Ms. Herold said the data on the top 15 languages is available and that the California Pan-Ethnic Health Network has been helpful in this area.

Ms. Herold said that existing telephone interpreter services will help with the oral requirements of the new law, but translated label instructions will require more work. Ms. Veale noted that the board already provides label translations in five languages and asked if the board now must provide them in 15 languages. She suggested that the board could consider doing label translations in 15 languages or simply not provide the label translations for the current five languages anymore.

Ms. Veale said that many pharmacies have access to translation software that could be expanded. She said that perhaps the board should "pull off" the label directions currently provided in five languages and let pharmacies do their own translations.

Ms. Herold suggested that the board invite pharmacists to the October board meeting to talk about how they are complying with the new federal rule. Committee members said that was a good idea and suggested that software vendors also be invited. Ms. Herold said the discussion would give the board time to developed a reasoned approach to complying with the federal rule.

Chairperson Law said that software programs make it easy to translate label directions into other languages. Mr. Brooks noted that Google apps do not always provide accurate language translations. Ms. Veale said that pharmacies generally have translation software systems that are more sophisticated and accurate than Google.

Ms. Veale said she agreed with Ms. Herold that the board should take some time and set up a stakeholder meeting. Ms. Herold said that hearing from pharmacists about what they are doing or plan to do to comply with the federal regulation will give the board information to determine the direction the board would like to go and how to proceed. Ms. Veale said it would be helpful for staff or Ms. Freedman to advise the board on specific board regulations that pose issues for the federal regulation and to draft language for possible solutions.

Mr. Brooks expressed concern that, unlike major chains, small local pharmacies might not be able to afford or might not want to spend money on software translation services and instead rely on Google apps.

Ms. Herold said that a key subject for a board discussion is how pharmacies are complying with the new federal rule – especially since they will be subject to audits to ensure compliance and could be in trouble if they are not in compliance by the October implementation date. She said that she was not aware that any other boards of pharmacy had discussed this issue. She added that complying with the new federal rule would be a major project for pharmacies nationwide as well as other health-care providers who receive federal funding.

Motion: Bring the federal rule implementing Section 1557 of the Affordable Care Act to the board's attention at the September board meeting and ask the board to invite stakeholders to the October board meeting for a discussion about how they are complying or plan to comply with the rule.

M/S: Brooks/Veale

Yes: 3 No: 0 Abstain: 0

Name	Yes	No	Abstain	Not Present
Brooks	x			
Law	x			
Veale	x			

Ms. Freedman clarified with the committee members that the intent of the motion was put the item on the September board agenda to discuss only the logistics – not the substance – of a board meeting with stakeholders that is to be held in October.

c. Development of Prescription Label Translations of Directions for Use Pursuant to Business and Professions Code section 4076.6

Ms. Veale noted that this subject was discussed by the Communication and Public Education Committee in May and reported to the full board in July. A staff report noted

that the far broader provisions in the Affordable Care Act (ACA) now pre-empt the board's planned activities in this area.

Chairperson Law said that any discussion of future public education activities in relation to AB 1073 should be postponed pending the final outcome of the board's discussions on the new federal rule on label translations.

Lori Hensic of Kaiser Permanente asked for clarification on the committee's plan for addressing the issues raised by the new federal rule and bringing those issues to the full board's attention. Ms. Herold replied that before changing any regulations and statutes, board members want to hear from licensees about what they feel is needed, what they can do, and what they can't do to comply with the new federal rule. Ms. Freedman noted that the committee is recommending that in September the board discuss how it would have that meeting in October.

5. Update and Discussion on Development of FAQs Received from ask.inspector@dca.ca.gov

Chairperson Law noted that, currently, the board has available to its licensees and the public the option to call and ask general questions to one of the board's pharmacist inspectors. This service is available Tuesdays and Thursdays from 8:00 am to 4:30 pm. In addition, licensees may submit an email request to a pharmacist inspector at ask.inspector@dca.ca.gov. Emails are responded to during business days. To ensure that all licensees receive the benefits of service, the board is developing an FAQ to be posted on the board's web site concerning the most frequent questions and issues.

Chairperson Law said that, while the questions and answers are not intended as, nor should they be construed to be, legal advice, the information is intended to provide guidance to the reader on relevant legal sections that should be considered when using professional judgment to determine an appropriate course of action. Should a licensee require legal advice or detailed research, the licensee is encouraged to contact an attorney or other source.

Chairperson Law said that board staff had drafted an initial collection of FAQs that were sent for review by the board's legal counsel. Ms. Damoth told the committee that board staff received the FAQs along with comments from counsel. She added that they would be posted on the board's website as soon as the FAQs and comments are synthesized.

Chairperson Law asked if the final FAQs would be posted online without committee members reviewing them first. Ms. Sodergren said that decision was up to the committee. Committee members said that they did not need to see them again before they are posted.

Motion: Direct the Executive Officer to post the FAQs online after staff has finished them.

M/S: Brooks/Veale

Name	Yes	No	Abstain	Not Present
Brooks	x			
Law	x			
Veale	x			

6. Discussion and Consideration of Naloxone-Related Matters

a. Communication to the California Healing Art Boards Regarding Naloxone

Chairperson Law reported that, at previous committee meetings, committee members have expressed interested in reaching to out to California healing arts boards regarding naloxone access, regulation and protocol.

Chairperson Law told the committee that board staff drafted an article about pharmacists and naloxone to be shared with the other California Healing Arts Boards. He said that the article would be provided to the other California Healing Arts Boards with a cover letter from California State Board of Pharmacy Executive Officer Virginia Herold. A copy of the article was included in the meeting materials.

Ms. Damoth told the committee that the cover letter was under review and that it would be sent to all the healing arts boards. Chairperson Law thanked board staff and said that it is important that other healing arts practitioners know what is going on in the pharmacy profession.

b. Naloxone FAQs

Chairperson Law reported that, at previous committee meetings, committee members have expressed the need for a naloxone FAQ. He said that board staff drafted naloxone FAQs that were under legal review. Ms. Damoth told the committee that the FAQs would be posted as soon as staff has finished synthesizing them with comments from legal counsel. Chairperson Law replied that the committee recommends that the FAQs be posted as soon as they are ready.

c. SB 833 (Committee on Budget and Fiscal Review, Health, Chapter 30, Statutes of 2016)

Chairperson Law reported that SB 833 (Committee on Budget and Fiscal Review, Health, Chapter 30, Statutes of2016) requires the State Department of Public Health, subject to an appropriation for this purpose in the Budget Act of 2016, to award funding to local health departments, local government agencies, or on a competitive basis to community-based organizations, regional opioid prevention coalitions, or both, to support or establish programs that provide Naloxone to first responders and to at-risk opioid users through programs that serve at-risk drug users, including, but not limited to, syringe exchange and disposal programs, homeless programs, and substance use disorder treatment providers.

Chairperson Law said that there is approximately $3 million available from this law. But he added that the board is not eligible to apply for the funding.

Ms. Herold said that pharmacies that want to provide naloxone should apply to the Department of Public Health for this money. She said that she belongs to a committee with CDPH members and that she would disseminate information about application guidelines to pharmacies as soon as it is available. She urged pharmacists to apply for the money especially now that they have authority to furnish naloxone and added that she also notified the California Pharmacists Association to inform its members about this funding.

Ms. Veale asked if information about the available funding could be disseminated as a subscriber alert. Ms. Herold said yes but added that she wants to wait so that the board can also let subscribers know at the same time how to apply for the funding.

Ms. Veale told the committee that many pharmacies are not dispensing naloxone. She suggested that subscriber alerts also be sent out every so often to remind pharmacists that they now can provide naloxone and direct them to the protocol on the board's website. She said that she recently was at a CE session and that there were a lot of pharmacists who do not know what they are supposed to be doing with naloxone.

Ms. Herold said board staff could develop an article that could be sent out as a subscriber alert to pharmacies about this. She said the article could remind pharmacists that, with an hour of CE, they can dispense naloxone on their own authority. She said staff could develop a statement about it that could be sent out as a subscriber alert and perhaps do the same for immunizations and hormonal

contraceptives.

Ms. Damoth noted that the upcoming issue of *The Script* would include an article about the regulations authorizing pharmacists to furnish naloxone. Ms. Herold said staff could repurpose or refocus the article and send it out as a subscriber alert. She also expressed support for Ms. Veale's suggestion about sending subscriber alerts to remind pharmacists that taking an hour of CE in furnishing naloxone would enable them to meet the health care needs of their patients who are receiving opioids.

d. Discussion on Federal Legislation: US S. 524 – Comprehensive Addiction and Recovery Act of 2016

Chairperson Law reported that, on July 22, 2016, President Obama signed into law US S. 524 – known as the Comprehensive Addiction and Recovery Act (CARA) of 2016 – in an effort to combat the national epidemic of prescription opioid abuse and heroin use. A copy of the enacted law was included in the meeting materials.

There were no comments from committee members or the public.

i. Lali's Law

Chairperson Law reported that, according to Congressman Bob Dold's website, Lali's Law was passed by the House by a vote of 415-4 on May 12, 2016, and the bill was signed into law as part of the Comprehensive Addiction and Recovery Act of 2016 on July 22, 2016. A copy of the press release was included in the meeting materials.

Chairperson Law said that Lali's Law will increase access to naloxone throughout the United States. The bill is named in memory of Alex Laliberte, a Buffalo Grove, Ill., resident and Stevenson High School graduate, who passed away seven years ago from a drug overdose.

Chairperson Law said that Lali's Law creates a competitive grant program that will help states increase access to naloxone. The primary purpose of the grant is to fund state programs that allow pharmacists to distribute naloxone without a prescription. Many states use these programs to allow local law enforcement officers to carry and use naloxone.

Chairperson Law asked if the grants were available to everyone in California and all the states. Ms. Herold said that awarding grants is a competitive process and that state agencies such as the Justice Department and the Department of Public Health both pursue grants for purposes such as this. She said that she did not know if the Board of

Pharmacy would be a potential grantee but added that the board could consider applying.

Ms. Herold asked Ms. Freedman if the board would need status as a 501(c)(3) organization to apply for grants. Ms. Freedman replied that she had not yet reviewed that aspect of the law and whether the board could apply for grants would depend on how the law is written. She said that she also would also want to review the board's authority, because the board is authorized to do only certain things.

Ms. Freedman said that the board might be better suited to facilitate or get the word out about Lali's Law. Ms. Herold said that perhaps staff could add the information to the subscriber alert and suggested contacting the lawmaker's office for information on how they expect grants to be distributed. She added that, if the grants are part of the budget, the federal budget year begins in October.

There were no comments from the public.

ii. Provisions regarding Partial Fills for Schedule II

Chairperson Law reported that, as one of the many provisions of the Comprehensive Addiction and Recovery Act of 2016, the CARA provides for partial fills of Schedule II Controlled Substances as outlined below:

SEC. 702. PARTIAL FILLS OF SCHEDULE ll CONTROLLED SUBSTANCES.

(a) IN GENERAL.-Section 309 of the Controlled Substances Act (21 U.S.C. 829) is amended by adding at the end the following:

"(f) PARTIAL FILLS OF SCHEDULE II CONTROLLED SURSTANCES.

"(1) PARTIAL FILLS.-A prescription for a controlled substance in Schedule II may be partially filled if-

"(A) it is not prohibited by State law;

"(B) the prescription is written and filled in accordance with this title, regulations prescribed by the Attorney General, and State law;

"(C) the partial fill is requested by the patient or the practitioner that wrote the prescription; and

"(D) the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.

"(2) REMAINING PORTIONS.-

"(A) IN GENERAL.-Except as provided in subparagraph (B),

remaining portions of a partially filled prescription for a controlled substance in Schedule II

"(i) may be filled; and

"(ii) shall be filled not later than 30 days after the date on which the prescription is written.

"(B) EMERGENCY SITUATIONS.-In emergency situations, as described in subsection (a), the remaining portions of a partially filled prescription for a controlled substance in Schedule II-

"(i) may be filled; and

"(ii) shall be filled not later than 72 hours after the prescription is issued.

"(3) CURRENTLY LAWFUL PARTIAL FILLS.-Notwithstanding paragraph (1) or (2), in any circumstance in which, as of the day before the date of enactment of this subsection, a prescription for a controlled substance in schedule II may be lawfully partially filled, the Attorney General may allow such a prescription to be partially filled.".

(b) RULE OF CONSTRUCTION.-Nothing in this section shall be construed to affect the authority of the Attorney General to allow a prescription for a controlled substance in schedule III, IV, or V of section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) to be partially filled.

Chairperson Law noted that Section 702 (f)(2)(A)(ii) conflicts with California law, which is 6 months or 30 days once partially dispensed.

Ms. Veale said that the federal law is more restrictive but added that California must follow the federal law. Ms. Herold noted that the board also has other provisions dealing with partially filling Schedule II drugs, but the federal law appears to be more restrictive. She added that the board needs to bring this to the attention of pharmacists.

Ms. Herold said that this should be discussed in an article in *The Script* rather than a subscriber alert so that that pharmacist can consult the information on an ongoing basis. She said that *The Script* was expected to be released that day, so the article could be in the next newsletter.

There was no comment from the public.

7. <u>Discussion on the Development of FAQs for SB 493 Related Items</u>

Chairperson Law reported that Senate Bill 493 (c. 469, Hernandez) was enacted in 2013 and established a new license for an Advanced Practice Pharmacist (APP). The board is currently promulgating regulations to specify certification program requirements and other requirements. There were two rulemakings. One was approved by the Office of

Administrative Law (OAL). The other was disapproved and returned to the board for modification.

Chairperson Law said that, at the April 2016 board meeting, the board requested that the Communication and Public Education Committee coordinate the development of a Frequently Asked Questions (FAQs) for SB 493 related items. Board staff drafted SB 493 FAQs for legal review.

Ms. Damoth told the board that the FAQs would be posted online as soon as possible.

8. Discussion on CE Courses Available for Naloxone, Self-Administered Hormonal Contraception and Nicotine Replacement Therapy under Protocols

Chairperson Law and committee members reviewed a handout chart summarizing options for CE that are available specific to naloxone, self-administered hormonal contraception and nicotine replacement therapy under protocols.

Ms. Veale asked if the handout would be posted somewhere. Chairperson Law said the handout indicates that nicotine replacement therapy requires two hours of CE upon renewal; meanwhile, naloxone and self-administered hormonal contraception do not require CE education – only CE training prior to being allowed to furnish naloxone or self-administered hormonal contraception. Ms. Herold said a statute requires CE education for nicotine replacement.

Ms. Sodergren told the committee that the chart could be updated to show what is required before initiating one of these three tasks – and then, if there are additional requirements as a condition of renewal, those could be added and highlighted in a separate column.

Ms. Herold said the updated chart will be posted on the board's website under the SB 493 Implementation tab. Ms. Damoth asked if the committee wanted to see the chart again or just post it. Committee members directed staff simply to post the information as soon as it is ready.

Public comment: Lori Hensic of Kaiser Permanente said that adding links to CE providers with the chart would be helpful for pharmacists. Ms. Veale replied that adding links to CE providers could be seen as promoting those specific providers, which the board cannot do.

9. Update and Discussion on Resources Available on the Board's Website

Chairperson Law reported that, at prior meetings, the committee reviewed multiple items for posting on the board's website as a resource for consumers and licensees. At the May

2016 meeting, the committee directed board staff to develop a draft policy for posting resources on the board's website and bring back to the committee.

Chairperson Law reported that board staff consulted with other boards within DCA and state agencies and drafted the California State Board of Pharmacy's Website Guidelines: Developed by the Communication and Public Education Committee. A copy of the draft policy was included in the meeting materials.

Ms. Veale explained that the policy issue came up because the board was receiving general requests to post items on the board's website. Chairperson Law agreed that the board should have posting guidelines.

Mr. Brooks said that the draft policy is reasonable, but he added that the challenge for websites is how useable they are: Can users search the site for documents? How long does posted information remain on the site? Is the information relevant? He said that "less is more," and he added that the board's site does not reflect that idea.

Ms. Veale agreed that the board's website has a lot of "stuff" on it, which members tried to address during the recent redesign. She said the problem is that the board does not want to keep things off of the site that should be on it. Ms. Herold said that the board provides both public education and licensee education, which requires the board to maintain a site that is interactive as much as possible.

Committee members agreed that the draft policy is a good place for the board to start and see how it works and make changes as necessary. The committee directed staff to move forward with the policy and post on the board's website.

10. Discussion of a Board-Developed Bulletin Board Message and Related Communication Materials

Staff provided the committee with an overview of a board-developed bulletin board message and related communication materials.

Ms. Herold unveiled photos of two draft concepts for a billboard intended to encourage parents to talk to their children about prescription drug abuse. She said the draft concepts were developed by staff at Mr. Brooks' firm. The first draft included drawings of pills around the message "Unattended Drugs are the Leading Killer of Kids." The second draft featured "Kid KILLER" with capital letters superimposed on a prescription drug pill.

After discussing both concepts, committee members agreed to recommend that the board proceed with the first draft concept, which committee members said was eye-catching and self-explanatory. Committee members also said the billboard should tell the public that the message is sponsored by the Board of Pharmacy and provide information on how to contact the board. Ms. Freedman added that any billboard and message attributed to the

board must be reviewed for compliance with legal requirements.

Public comment: Paige Talley of the California Council for the Advancement of Pharmacy expressed hope that the message not deter parents from getting needed prescription drugs for their children. Committee members replied that the billboard message text refers to "unattended" drugs.

Motion: Add the board's website and sponsorship to the billboard message and move forward with the concept to the full board.

M/S: Brooks/Veale

Yes: 3 No: 0 Abstain: 0

Name	**Yes**	**No**	**Abstain**	**Not Present**
Brooks	x			
Law	x			
Veale	x			

11. <u>Update and Discussion on SB 1193 (Hill) Requiring Pharmacists, Intern Pharmacists, Pharmacy Technician and Designated Representatives Licensed in California Join the Board's E-mail Notification List</u>

Chairman Law reported that, at the April 2016 board meeting, the board requested the Communication and Public Education Committee discuss the possible requirement to collect pharmacists' email addresses. At the May 2016 committee meeting, the committee directed board staff to draft language for consideration at the July 2016 board meeting to require pharmacists' emails addresses to be collected at time of renewal.

Chairperson Law said that, at the July 2016 board meeting, the board was advised that this requirement was added to the board's Sunset bill SB 1193 (Hill) was amended to include this provision. A copy of the relevant provisions of SB 1193 (Hill) as amended in Assembly August 18, 2016, was included in the meeting materials.

Chairperson Law asked for an update on the status SB 1193. Ms. Herold replied that the bill was on the governor's desk and that he was expected to sign it. She said the bill would give the board authority to require individuals who have email addresses to provide the addresses to the board and to keep the information current.

There were no comments from the public.

12. Communication Plan for Consumers and Licensees

In accordance with the board's strategic plan, staff developed and provided committee members with copies of a draft communication plan that included aspects for both board consumers and licensees.

Chairperson Law complimented the plan. Ms. Veale said the plan was a good start and said the committee would continue working with it. She said the committee should revisit it at the committee's next meeting.

Public comment: Lori Hensic of Kaiser Permanente asked what is the board's plan for communicating impending new pharmacy requirements contained in current legislation. Ms. Herold replied that the board would use subscriber alerts, mailings and various other methods to keep licensees informed. She added that the next edition of *The Script* would focus on the new legislation.

The board took a break at 11:30 a.m.

The board reconvened at 11:38 a.m.

13. Update and Discussion on the Forty-Fifth Annual Report of the Research Advisory Panel of California for 2015 Regarding Controlled Drugs Research

Chairperson Law reported that the Research Advisory Panel of California recently submitted its annual report to the Legislature and Governor. A copy of the Forty-Fifth Annual Report of the Research Advisory Panel of California 2015 was included in the meeting materials.

There were no comments from committee members or the public.

14. Board Publications – Review and Recommendations for changes

a. Counterfeit Prescription Drugs: Protect Yourself, Your Family and Your Pets

b. Buying Prescription Medications Online: Are the Drugs You Buy Real or Fake?

Chairperson Law reported that Department of Consumer Affairs requested that the board assess the two board produced publications listed above. He said the committee could determine if the pamphlets should be updated or removed from publication. A copy of both documents was included in the meeting materials.

Chairperson Law said the pamphlets contained good information but perhaps they were not hitting the proper target audience. He suggested asking retailers associations to distribute the pamphlets to customers when they fill their prescriptions. Ms. Herold said staff could ask the California Retailers Association if it is interested in helping out. She added that copies also could be made available at board meetings and speaking engagements.

Chairperson Law asked that the pamphlets also be translated into the top five languages and that pharmacies should be notified that they are available so they can be distributed to customers.

Ms. Sodergren suggested updating the pamphlets to include information about the .pharmacy domain. Ms. Herold agreed.

Lori Hensic of Kaiser Permanente asked if online pharmacies could be required to post this type of information on their websites. Ms. Herold said that was a good idea and that staff could look into that. Ms. Hensic added that perhaps online sites that use the .pharmacy domain also could be required to disseminate this type of information, because their customers are obviously seeking out and using online pharmacy sites.

15. Update on *The Script* Newsletter

Chairperson Law reported that the Summer 2016 edition of *The Script* was being formatted for publishing. He added that board staff was currently working on articles for the Winter 2016/17 edition of *The Script*.

Ms. Herold and Ms. Damoth informed the committee that *The Script* was ready for publication within days.

16. Update on Media Activity

Chairperson Law reported that the board's executive officer (unless otherwise noted) participated in the following media interviews and requests for information.

- **MPA Media,** July 14, 2016: Kathryn Feather, regulation of acupuncture needle distributors.
- **Capitol Television Network News,** July 27, 2016: Jonathan Underland, drug-take back regulations.
- **KPIX,** Aug. 16, 2016: Molly McCrea, opioid compound U-47700
- **Veterinary Information Network News Service,** Aug. 29, 2016: Edie Lau, unlicensed business selling veterinary prescription drugs online.

There was no comment from committee members or the public.

17. Update on Public Outreach Activities Conducted by the Board

Chairperson Law reported a list of major public outreach activities provided by the board's staff:

- July 18: Supervising Inspector Christine Acosta presented HD compounding for CPhA.
- August 9: Inspector Jennifer Hall provided a review of new laws to the board's competency committee.
- August 18: Supervising Inspector Christine Acosta presented the new compounding regulations to Tenet health.
- August 24: Inspector Trang Song presented at the Vietnamese Pharmacist Association

There was no comment from committee members or the public.

18. Review and Discussion of News or Journal Articles

Chairperson Law reported that several items of potential interest for the committee were included in the meeting materials.

There were no comments from committee members or the public.

19. Review and Discussion of the California Department of Public Health's Comparison Between the Centers for Disease Control and Prevention's *Guidelines for Prescribing Opioids for Chronic Pain* and the Medical Board of California's *Guidelines for Prescribing Controlled Substances for Pain*

Chairperson Law reported that a copy of the California Department of Public Health's Comparison Between the Centers for Disease Control and Prevention's *Guidelines for Prescribing Opioids for Chronic Pain* and the Medical Board of California's *Guidelines for Prescribing Controlled Substances for Pain* was included in the meeting materials.

Ms. Herold told the committee that the Medical Board's goal is to not have duplicate guidelines out in the community. She noted that the Medical Board put out its guidelines two years before the CDC acted. She added that the good news is the information is out there for prescribers to see what both organizations believe is appropriate pain treatment with opioids, which is the same in most cases and is beneficial information for prescribers.

There were no comments from the public.

20. <u>Future Meeting Dates</u>

a. December 1, 2016

Chairman Law reported that the committee's next meeting date is December 1, 2016.

The meeting adjourned at 11:54 a.m.