



California State Board of Pharmacy

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

**COMMUNICATION AND PUBLIC EDUCATION COMMITTEE
MEETING MINUTES**

Date: January 20, 2016

Location: Department of Consumer Affairs
1625 N. Market Blvd., El Dorado Room
Sacramento, CA 95834

Committee Members Present: Debbie Veale, RPH, Chair
Ramón Castellblanch, PhD, Vice Chair, Public Member
Ryan Brooks, Public Member
Lavanza (Cheryl) Butler, RPH

Committee Members Not Present: Ricardo Sanchez, Public Member

Board Members Present in the Audience: Amy Gutierrez, PharmD, President

Staff Present: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Laura Hendricks, Staff Analyst
Debbie Damoth, Staff Services Manager

Board members present: Debbie Veale and Ramón Castellblanch.

Note: Lavanza Butler arrived at 10:41 am and Ryan Brooks arrived 10:43 am.
Board members not present: Ricardo Sanchez.

The meeting was called to order at 10:30 a.m. Chairperson Debbie Veale welcomed those in attendance. Chairperson Veale announced that as two board members were on their way to the meeting, items on the agenda would be taken out of order. Ms. Veale began the meeting with Agenda Item 8.

Item 8 - Final Report on the Prescription Drug Abuse Subcommittee

Prescription Drug Abuse Subcommittee Chair Castellblanch provided the final report on the subcommittee's work to the committee. Dr. Castellblanch provided an overview of the mission of the subcommittee and the frequency of the meetings. Dr. Castellblanch also provided an overview of the groups the subcommittee received testimony; education tools made available on the board's website; professional educational information available about pain killers; public education on pain killers; and CURES 2.0.

Chairperson Veale thanked Dr. Castellblanch for his work on the subcommittee and encouraged Dr. Castellblanch to continue pursuit these items through his continued participation and involvement on the Communication and Public Education Committee.

Chairperson Veale conducted another roll call. Committee members present: Lavanza Butler, Ramón Castellblanch, Debbie Veale, and Ryan Brooks.

Fred Mayer on behalf of Pharmacy Planning Services, Inc. (PPSI), CARA, and RX Safe from Marin County provided handouts to the committee. Mr. Mayer encouraged the committee keep the subcommittee. Chairperson Veale explained by keeping prescription drug abuse as a focus of the Communication and Public Education Committee the issue will be addressed in a more efficient manner.

Item 5 - Update on Information on the Board's Website Regarding the State's Emergency Contraception Protocol

Chairperson Veale welcomed to the committee via telephone conference Dr. Sally Rafie, BCPS, from UCSD's School of Pharmacy. At the October 2015 committee meeting, Dr. Rafie requested that the committee reevaluate the emergency contraception information provided on the board's website. The committee requested Dr. Rafie provide letters of endorsements from reproductive organizations supporting her position that posting such information on the board's website would assist in public education. Additionally, the committee asked Dr. Rafie to provide the educational materials without reference to brand names, so as not to confuse the posting on the board's website with an endorsement for a particular brand of emergency contraception.

Dr. Rafie presented the letter of support from Executive Director Kelly Cleland, MPA MPH of the American Society for Emergency Contraception (ASEC); President and CEO Jessica Arons of the Reproductive Health Technologies Project (RHTP); and Chair Brooke Griffin, PharmD, BCACP of the American College of Clinical Pharmacy Women's Health Practice & Research Network as well as updated educational material for the board's website without brand name identification or pricing information. Chairperson Veale thanked Dr. Rafie for the letter of support validating the information provided.

Chairperson Veale called for questions from the committee and public. There were no questions for Dr. Rafie.

Motion: Recommend to post information provided by Dr. Rafie on the board's website.

M/S: Brooks/Butler

Chairperson Veale called for comment from the board and public. There was none.

Support: 4 Oppose: 0 Abstain: 0

Item 1 – Presentation by Department of Health Care Services Pharmacist James Gasper Promoting Naloxone and Buprenorphine Access and Subsequent Discussion

Chairperson Veale reviewed Assembly Bill 1535 (Chapter 326, Statutes of 2014), which allows pharmacists to furnish naloxone without a prescription under a protocol developed by the Medical Board and the Board of Pharmacy.

The board promulgated emergency regulations to establish a protocol for pharmacists furnishing naloxone hydrochloride. The emergency regulation was approved by the Office of Administrative Law and became effective 4/10/15. The board readopted the emergency regulation with an expiration date of 4/6/16 while the board sought to establish the non-emergency regulation through the normal regulatory process. The non-emergency regulation was noticed on 5/22/15 for a 45-day comment period and a subsequent 15-day comment period on 9/5/15. [Note: The non-emergency regulation was recently approved on 1/27/16.]

Chairperson Veale introduced Dr. James Gasper, BCPP, Psychiatric and Substance Use Disorder Pharmacist, Pharmacy Benefits Division, California Department of Health Care Services. Dr. Gasper provided a presentation on the current state of opioid addiction and opioid overdose deaths both in California and nationally. Dr. Gasper discussed potential interventions that pharmacists can make today to reduce opioid overdoses by providing patients with the opioid overdose antidote naloxone and other forms such as buprenorphine.

Dr. Gasper highlighted the fact that there has been an increase in drug overdose deaths in the US including prescription opioids and heroin. Dr. Gasper explained that when opioids are being restricted without offering treatment alternatives, there is an addiction that exists which is left without direction. Often times, people turn to heroin in these cases because it is cheaper than prescription opioids.

Dr. Gasper reported that in California, the counties with the highest overdose death rates are in the rural northern counties. The data provided by Dr. Gasper was from 2012, he indicated that

the 2013 data was similar and the 2014 data is currently being compiled. According to his data the average statewide overdose death rate is 4.9 overdose deaths per 100,000 from opioids and heroin in California. However, in the northern rural counties, the averages range from 11 to 23.9 deaths per 100,000. This pattern emerges due to the fact that there is no infrastructure for treatment and providers in these rural counties.

Committee member Ryan Brooks inquired if the prescription data in CURES reflects these statistics. Dr. Gasper noted that CURES data does indicate an elevated opioid prescription volume in these areas. Dr. Gasper indicated the difficulty is in identifying the legitimate prescriptions for opioids. He added that pharmacist often struggle to identify when a prescription is for a legitimate medical purpose. Dr. Castellblanch noted that a pharmacist may believe they are filling a legitimate prescription, when in fact the prescriber is overprescribing opioids to their patient.

Mr. Brooks asked if the board investigates more licensees in these identified counties. Executive Officer Virginia Herold indicated that most investigations are initiated based on complaints received by the board. She added that complaints may be generated by someone who sees a family member being overprescribed opioids or suspects they may be selling their opioid medications. Ms. Herold also reported that the board also conducts proactive prescription drug abuse investigations by using data from CURES. Ms. Herold stated that the board can analyze CURES data by county, but staff will also look statewide.

Mr. Brooks noted that the board should continue to investigate through the complaint process as well as identify areas statewide with high opioid overdose deaths per capita. Chairperson Veale added that the committee can assist with communication and education. Dr. Gasper added that many communities do not have the resources to help people with opioid addictions.

Chairperson Veale indicated pharmacists are receiving new legitimate prescriptions for pain; however, they are unable to take on the new patient because of limitations on opioids drugs. Ms. Herold explained that pharmacists are having difficulties obtaining opioids from wholesalers because many are being investigated by the DEA.

Ms. Herold noted that it is important to remember that people need treatment for their legitimate pain. Dr. Gasper added that because the opioid supply is sequestered some end-of-life patients do not receive pain treatment, which is a tragedy.

Committee member Lavanza Butler recalled that at a Prescription Drug Abuse Subcommittee meeting there had been a presentation by a group of attorneys who were filing a lawsuit based on deceptive marketing practices by pharmaceutical companies. The lawsuit alleged that doctors are prescribing opioids for chronic pain, rather than acute pain (for which opioids are

intended) because the pharmaceutical representatives are falsely stating that opioid use for chronic pain is appropriate.

Dr. Gasper provided a map of California which illustrated that methadone clinics are not available in over 20 rural counties. Chairperson Veale asked why a county would not have a methadone clinic. Dr. Gasper indicated the county board of supervisors may not approve it or there may not be a “business need” to open the treatment program.

Dr. Gasper explained that buprenorphine was the first drug that could be used outside a methadone clinic to treat an opioid addiction. It has been on the market for 13 years.

Dr. Gasper noted the solutions to the opioid epidemic include safe prescribing practices, naloxone distribution, and increasing access to treatment for opioid addiction. He noted the barriers for naloxone include knowledge of training available for providers, adoption of pharmacies’ policies and procedures, and proactive patient selection by pharmacists. Dr. Gasper recommended a compendium of Naloxone courses acceptable by the board would be helpful. Ms. Herold stated the board would be happy to post this information on the board’s website. A representative from CPhA offered to provide information to the board about their Naloxone training. It was noted that Rx Consultant also has training available.

President Amy Gutierrez added from the audience, that the White House Office of National Drug Control Policy issued a statement saying public agencies (including state and counties) can get the Narcan nasal spray at 40% discount.

Dr. Gasper noted that opioid addiction is not comfortable topic for many pharmacists; educational literature is a first step. Dr. Gasper reported that patient behavior changes when naloxone is received with opioids, because they realize that their opioid prescription needs to be used with caution and monitored. Dr. Gasper added pharmacists are the front line in identifying what patient may need naloxone. Dr. Castellblanch noted this assessment could be part of the red flag process.

Dr. Steve Gray of Kaiser noted a point of confusion for pharmacists is whether or not naloxone is covered if it is dispensed by a pharmacist rather than prescribed by a prescriber. The other point of confusion is if naloxone is covered by the purchaser’s insurance if it is for another person who may be at risk for overdose. Staff noted that this information is not available and needs to be clarified at a future meeting.

Dr. Gray further noted that under the protocol, if a pharmacist provided Naloxone to a patient, that information cannot be communication to the physician without explicit consent from the patient. For organizations that share information across medical records this would require some pharmacies to undergo significant modification of dispensing systems.

Dr. Gasper stated that one of the reasons naloxone has not been as well received is the affordable version of naloxone requires an atomizer that does not have an NDC. This atomizer can't be paid for by health plans and historically, pharmacies were unable to obtain atomizers. He noted that if there is one product that is both affordable and available, it will help pharmacies provide Naloxone to more patients.

Dr. Gasper continued that there has been a lot of confusion on who is the prescriber of record. Ms. Herold explained that pharmacists are able to furnish Naloxone. Dr. Gasper added that should be clarified that the prescriber on record is the pharmacist.

Ms. Herold, Ms. Sodergren and Dr. Gutierrez left the meeting at approximately 10:47 a.m.

Dr. Gasper stated that having written information available on the furnishing of Naloxone would be helpful to pharmacists and healthcare providers. Chairperson Veale added that a Naloxone Frequently Asked Questions (FAQs) section of the board's website would be helpful.

Dr. Gasper provided that buprenorphine is a long acting opioid and partial agonist which means there is a limit to the opioid effect it has; treats withdrawal; and, stops the patient from using opioids. It is not constrained to the methadone clinic. Chairperson Veale added the limiting factor is the prescription from a prescriber that is required.

Dr. Castellblanch asked what the board could do to promote this. Dr. Gasper added pharmacists in these communities need education and make them the proponents. Chairperson Veale added pharmacists need to be comfortable discussing addictions, naloxone and drug treatment programs. The committee discussed possible options including a roadshow in these counties.

Dr. Gasper continued pharmacies may be methadone dispensaries in collaboration with the prescribing physicians. This is a way to get the methadone maintenance to the outlying counties. Mr. Brooks added the methadone registration will be the most difficult part. Local board of supervisors or councils need to be educated.

Chairperson Veale thanked Dr. Gasper for his presentation and asked for public comment.

2. Discussion on Development of Regulations to Allow for the Waiver of Patient-Centered Label Requirements (Business and Professions Code Section 4076.5(d))

Chairperson Veale reviewed the requirements for the waiver of patient-centered labels pursuant to Business and Professions Code section 4073.5(d). Currently, the process for a licensee requesting the waiver is to come before the committee and full board. The development of the proposed regulation would allow for this decision to be made at the staff

level, provided the licensee has demonstrated meeting the required elements of section 4073.5(d).

Dr. Gray discussed possible issues with the accrediting requirement as there are accreditations agencies other than the Joint Commission.

Dr. Gray also stated that there may be a problem with the use of the word “parenteral” included in (g)(2). He explained that “parenteral” is defined as medication administered in a manner other than through the digestive tract. He also noted that the compounding regulation now includes eye drops, ear drop, or vaginal suppository.

Chairperson Veale asked that board staff modify the proposed language in response to the issued raised by Dr. Gray before the next board meeting.

Motion: Recommend to the full board:

- (1) Add language to the appropriate subsection of section 1707.5 to allow waiver requests to be submitted to board staff for review and approval;
- (2) Incorporate the definition of parenteral;
- (3) Add “include other accrediting agencies”; and,
- (4) Provide the Executive Officer and board staff the authority to sign off on waivers.

M/S: Brooks/Castellblanch

Chairperson Veale called for comment from the board and public. There was none.

Support: 4 Oppose: 0 Abstain: 0

3. Consideration of Request for Waiver of Requirements for Patient-Centered Labels as Provided in California Business and Professions Code section 4076.5(d) from Access IV

Ramona Moenter, R.Ph., MBA, of Access IV presented the request for waiver of requirements for patient-centered labels as provided in California Business and Professions Code section 4076.5(d). Pharmacist Moenter confirmed that Access IV meets the requirements for exemption as outlined in section 4076.5(d).

Pharmacist Moenter reported that the directions provided in 12 point font are currently being cut off because they are too long to fit on the label. To remedy this staff manually truncate the directions for use so that they will fit on the label, this results in unclear directions for the patient. Ms. Moenter stated Access IV would go back to the original size font of 10 point if the waiver is approved. Access IV services agreed to be in compliance with the patient-centered labels and translation requirements.

Motion: Recommend to the board that Access IV be granted a two-year conditional waiver and require Access IV to self-report complaints to the board.

M/S: Brooks/Butler

Chairperson Veale called for comment from the board and public. Steve Gray requested clarification on if the waiver would be granted for a specific site or it would be an enterprise wide approval. Chairperson Veale confirmed an approved waiver would be site specific to the four sites listed in the request from Access IV.

Support: 4 Oppose: 0 Abstain: 0

4. Consideration of Issuing a Revised Patient Consultation Survey Questionnaire

At the July 2015 Board Meeting, the board reviewed the results of a short questionnaire made available to licensees via Survey Monkey regarding patient consultation. At the October 2015 board meeting, President Gutierrez asked the committee to develop a broader survey on patient consultation.

The committee determined Dr. Castellblanch to be the point of contact for quality control. The committee discussed options within the Department of Consumer Affairs, schools of pharmacies, and associations for the survey to pharmacists.

Steve Gray of Kaiser mentioned he had many contacts for survey formulation including the UCSB graduate school, Kaiser Family Foundation, and the USC School of Business. Chairperson Veale directed staff work with Dr. Castellblanch and research survey options with the entities Dr. Gray's mentioned.

6. Update on the Redesign of the Board's Website

Chairperson Veale provided that she and Dr. Castellblanch met with Webmaster Victor Perez. The new website design is scheduled for release in late spring 2016.

7. Discussion on .Pharmacy Domain

a. Options for the Board to Distribute Public Information via the Board's Website

Chairperson Veale deferred this item until the board's website has been updated.

b. Option of Sending a Letter of Support for .Pharmacy Domain

Chairperson Veale reported that board staff worked with NABP staff to draft a letter of support for the .Pharmacy program. She explained that if the committee approves the letter it will be forwarded to the full board for approval.

Fred Mayer of PPSI had to leave the meeting early and requested the issue of medical marijuana and the drug issue pertaining to pharmacy consultation be added to the next committee agenda.

The committee discussed the requirements for pharmacies who wish to participate in the .Pharmacy program. Chairperson Veale called for public comment.

Dr. Steve Gray indicated he has attended many meetings and believes the intent is good but didn't recall the criteria used by .Pharmacy. He recommended reviewing the criteria and then providing recommendation to the board.

Chairperson Veale researched online during the meeting and found information about the standards used by .Pharmacy. The non-recommended sites were found to have accepted non-valid prescriptions; issued prescriptions by online consultants or questionnaires only without a medical doctor involved; offered foreign or non-FDA approved medications and dispensed controlled drugs; and lacked a secure website. Chairperson Veale and the committee briefly reviewed the .Pharmacy standards.

A representative from CPhA added that they have received a lot of complaints of bad pharmacy websites and would support the idea of providing a letter of support to the .Pharmacy program.

Motion: Recommend to the board the letter of support be sent to NABP for their .pharmacy domain initiative.

M/S: Brooks/Butler

Support: 3 Oppose: 1 Abstain: 0

9. Discussion Regarding Prescription Label Translations of Directions for Use

Chairperson Veale reported that Assembly Bill 1073 was approved by the Governor on October 11, 2015. The bill requires a pharmacist to use professional judgment to provide a patient with directions for use of a prescription, consistent with the prescriber's instructions. AB 1073 also requires a prescriber to provide translated directions for use, if requested, and authorizes the dispenser to use the translations made available on the board's website to comply with the requirement. Dispensers are not required to provide translated directions for use beyond what the board has made available. However, the bill does authorize a dispenser to provide his or her own translated directions for use to comply with the requirement. Veterinarians are exempt from the requirement to provide translated directions for use. The provisions of the bill went into effect on January 1, 2016.

Ms. Sodergren returned to the meeting at 1:12 pm. Committee member Brooks left the meeting at 1:12 pm. The committee took a break at 1:13 pm and resumed at 1:25 pm.

Chairperson Veale posed the high level question as to what the committee thinks will be necessary to educate the public on translations. Dr. Castellblanch indicated a sign informing patients of their right to translations in the five languages identified would be helpful. The committee discussed other possible means of communication.

Ms. Sodergren offered various ideas such as a drafting a public service announcement, posting information on Facebook, Tweeting about the availability of translations, or developing a communication plan. Chairperson Veale asked staff to form a communication plan and bring it the next committee meeting for review and approval.

Ms. Sodergren offered a drafting and releasing a PSA in the interim while developing a communication plan and regulation. Chairperson Veale requested the PSA be released in advance of the committee meeting.

Kim Chen from CPEN indicated her willingness to partner with the board in educating licensees and the public about translation services. Ms. Chen indicated the “Point to your Language” poster is a place to start and recommended reaching out to Assembly member Ting’s office for additional help in publicizing translation services.

Dr. Castellblanch thanked Ms. Chen for her assistance.

10. Report on Development of FAQs Received From ask.inspector@dca.ca.gov

Chairperson Veale reported the board has implemented a program which gives licensees the opportunity to call and ask general questions to one of the board’s pharmacist inspectors. This call-in 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.

Ms. Sodergren reported the board is working on developing the FAQs for the licensees as well as consumers as both populations ask different types of questions. The board has developed the first FAQs for licensees and will be posting them to the board’s web site as well as including them in the next newsletter.

Chairperson Veale indicated posting the FAQs on the website once approved would be acceptable. Ms. Veale asked for public comment. There was none.

11. CURES 2.0 Update on Communication to Licensees

Chairperson Veale reported that the Department of Justice (DOJ) recently announced another milestone in its conversion to CURES 2.0. Specifically, the DOJ announced that beginning January 8, 2016, the upgraded prescription drug monitoring program is available. As part of

this transition, on or after January 8, 2016, all current registrants are required to update their registration in the new 2.0 environment to ensure access to the system. This can be done electronically.

Ms. Veale stated that according to the DOJ, CURES 2.0 will be available to all registrants that use Microsoft Internet Explorer Version 11.0 or greater, Mozilla FireFox, Google Chrome, or Safari when accessing the system. Registrants that do not currently have access to one of those specified internet browsers will be able to continue to access the prior version of CURES until the legacy system's retirement, at that time the updated browser must be used.

Ms. Veale reminded the committee and public that all pharmacists are required to be registered to use CURES no later than July 1, 2016. On or after January 8, 2016, pharmacists can register using an automated system by visiting www.oag.ca.gov/cures and clicking on the Registration link and following the instructions.

Chairperson Veale reported the board is working with the DOJ to develop "Frequently Asked Questions" to assist registrants with understanding CURES 2.0. The board will send out updates via its subscriber alert system as it learns additional information from the DOJ. Questions regarding these changes should be directed to cures@doj.ca.gov.

Dr. Castellblanch asked if CURES was working. A representative of CPhA reported to the committee that at least 10 pharmacists are having issues logging in and added that CPhA has limited contact with DOJ. The representative explained that the pharmacists are prompted to enter a new password; however when they attempt to enter a new password there is an error screen. It was noted that some pharmacists were able to log-in after waiting 1-2 days after receiving the error message.

Ms. Sodergren provided that after January 8th, everyone has to re-register online in a streamlined fashion in CURES 2.0 environment. Ms. Sodergren asked CPhA for a screenshot of the error message their members are receiving. Ms. Sodergren reported that the board has requested that the DOJ produce a tutorial, however it is unclear if that occurred. She added that the DOJ has requested that all issues be addressed to DOJ via email. The board has requested a list of common issues from DOJ so that an FAQ can be developed to help direct people who are experiencing problems. Chairperson Veale asked for an update on CURES 2.0 at the next meeting.

Dr. Castellblanch asked for the status of the applications pending in the CURES 1.0 environment. Ms. Sodergren indicated she would find out the status of the applications and report back to the committee.

Dr. Castellblanch asked for CURES 2.0 issue to be earlier on the agenda at the next committee meeting.

12. Update on the Educational Information on Board's Website Regarding Opioids, Naloxone, Red Flags, Consumer Information, and Prescription Drug Abuse Prevention for 13/14/15 Year Olds, and UCSD/Consumer Reports

Dr. Castellblanch requested the information be posted on the website. Board staff Debbie Damoth indicated she would work on this request.

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

13. Update on *The Script* Newsletter

Chairperson Veale reported Board staff has written the Winter issue of *The Script* newsletter. The Winter issue is currently under legal review, and will be issued soon.

Dr. Castellblanch requested an article in the next issue about the CDC report on opioid related deaths. Ms. Veale asked Dr. James Gasper to write an article on the opioid epidemic for the next newsletter.

14. Update on Media Activity

Chairperson Veale reported on the media activity for the board.

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

Chairperson Veal requested agenda item #16 – Review and Discussion of News or Journal Articles be postponed to the next meeting. Dr. Castellblanch requested articles from the New York Times about opioid abuse be included for discussion at the next committee meeting.

Chairperson Veale recapped requests for future agenda items provided throughout the meeting.

Steve Gray requested the Department of Consumer Affairs' publication entitled "*Consumer's Guide to Healthcare Providers*" be updated to include pharmacists as pharmacists are now considered healthcare providers with the enactment of SB 493.

Fred Mayer of PPSI requested the issue of medical marijuana and the drug issue pertaining to pharmacy consultation be added to the next committee agenda.

Ms. Veale adjourned the meeting was adjourned at 1:52 pm.