

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
PRESCRIPTION MEDICATION ABUSE SUBCOMMITTEE
MEETING MINUTES**

DATE: August 26, 2014

LOCATION: Department of Public Health
1500 Capitol Ave.
Building 172 – Auditorium
Sacramento, CA 95814

**COMMITTEE MEMBERS
PRESENT:** Ramon Castellblanch, PhD, Chairperson
Darlene Fujimoto, PharmD, Volunteer
Lavanza Butler, PharmD

**COMMITTEE MEMBERS
NOT PRESENT:** Rosalyn Hackworth, Board Member
Gregory Murphy, Board Member

**STAFF
PRESENT:** Virginia Herold, Executive Officer
Joyia Emard, Public Information Officer
Laura Hendricks, Staff Analyst

Call to order

Chairperson Ramon Castellblanch called the meeting to order at 11 a.m.

1. FOR INFORMATION: Report on California Prescription Opioid Misuse and Overdose Work Group Headed by the Director of the State Department of Public Health

Executive Officer Virginia Herold reported that the Prescription Opioid Misuse and Overdose Work Group was formed by the State Department of Public Health and is chaired by the department director. She said the work group is made up of representatives from various state agencies and meets monthly. She said work group members include the Medical Board, Dental Board, Pharmacy Board, Department of Public Health, Department of Health Care Services, Department of Justice CURES, Emergency Medical Services Authority, Department of Education and the California Conference of Local Health Officers.

She said the goal of the group is to unify a focused policy that can be articulated by state agencies in efforts on opioid abuse education and prevention. She said the next meeting was to be held on August 29, 2014. She said the Medical Board is revising its Guidelines For Prescribing Controlled Substances For Pain and the goal of the work group is to provide a unified message to both the medical community and the public on the new policy once it is completed. She said the Medical Board's new guidelines and the rescheduling of Tramadol as schedule IV drug and Hydrocodone from schedule III to schedule II are leading the way for changes in how opioids are used for pain management. For example, with the new scheduling, hydrocodone will no longer be available by verbal prescription and will only be dispensed with written prescription in hand.

Chair Castellblanch asked if others could join the work group and Ms. Herold said at this time it is only state agencies. Dr. Darlene Fujimoto asked if CURES was a focus of this group and if health care providers were involved. Ms. Herold said CURES is part of the group, but not its focus; and there are medical doctors who are in the group because they hold leadership positions with state agencies.

2. FOR INFORMATION: Report on 50-States Meeting Addressing Opioid Abuse Recently Held in Washington D.C.

Ms. Herold said the executive officers of the Medical Board and Board of Pharmacy, along with a representative from the California Department of Public Health, recently attended a federal Department of Health and Human Services working meeting with state officials from across the country to share best practices and discuss how federal and state governments can work together to address the opioid abuse epidemic. She said there were three representatives from each state in attendance. Ms. Herold stated that the materials provided during the meeting made it appear that California doesn't have a prescription drug abuse problem when compared with other states, but she said California officials know there is a problem.

She said that during the meeting, national officials encouraged that prescription drug monitoring programs be fully implemented with operability across state lines. She reported that participants were asked to set goals for their state that would help with abuse prevention. Ms. Herold said the California representatives concurred that there was a need for better, timely and more readily available information from the prescription drug monitoring program; a need to provide some means for prescribers to have information on alternatives to pain treatment besides opioids; and a need for revision of the evaluation mechanisms for physicians on pain treatment because the current process puts too much emphasis on pain.

Dr Fujimoto said the report shows that the data for California is not accurate, possibly because the proper information is not getting reported or used. She said because CURES is run by law enforcement - one of only three states doing that - the system doesn't

meet the needs of health care providers. Ms. Herold said in time she hopes CURES will meet those needs.

Dr. Castellblanch said he would like someone to speak on the New York e-prescribing system at the next meeting.

Dr. Dorothy Uzoh asked how timely the CURES data is and how it compares to other states. Ms. Herold said the requirement is that within seven days the information has to be entered by dispensers. She said it then goes to an outside company, which sends it to the Department of Justice, so she expects it's almost a three-week lag time between when a pharmacist enters the data and when it shows up in CURES. She said some small states can have their data live in their PDMP within five minutes. However, once in the CURES system, the data is fully accessible.

Ms. Herold said the board finds the CURES data invaluable. For example, before the board conducts a pharmacy inspection, a CURES report on that pharmacy is generated. She said not all pharmacies are inputting the controlled substance data. Chair Castellblanch asked how real the data is and Ms. Herold said patients can change their name, birth date or other information to not have it line up in the system. Dr. Fujimoto said she hoped the new system would be better.

Jason Smith said it would take a doctor shopper about a day to get around the CURES system and asked what was required with the January 1, 2016 deadline. Ms. Herold said input in CURES has been required for years, what's new is that prescribers and pharmacists will need to be registered to access the data by January 1, 2016.

Dr. Ivan Petrelka said CURES is very user unfriendly and it was difficult to register his staff. He said there is also a significant lag time between entries and their appearance on the system. He said the data can be inaccurate. He said his office has submitted data that never appears in the CURES system and they've contacted the third party vendor that handles the data, which confirmed they received the data, but it still never appeared in CURES. Dr. Petrelka asked if physicians will be required to check CURES on patients receiving scheduled medication prescriptions. Ms. Herold said there is no requirement at this time, but Proposition 46, (Medical Injury Compensation Reform Act) now on the ballot, has a provision that would require it.

3. FOR INFORMATION: Report on CURES Data of Controlled Substances Dispensed in California and Controlled Substance Diversion for Fiscal Year 2013-14; and CURES Board Funds.

Ms. Herold said board staff compiled CURES data on controlled substances dispensed and the number of pills dispensed per California adult; controlled substances drug loss; top drugs lost or stolen; and board expenditures on the CURES system. The information was provided in the meeting materials.

She said more than one billion hydrocodone pills were distributed to patients last year in California. She said night break-ins, losses in transit and employee pilferage are the biggest reasons for losses reported by community pharmacies.

4. FOR INFORMATION: Red Flags Video Regarding Corresponding Responsibility Produced by the National Association of Boards of Pharmacy (NABP)

Ms. Herold said the National Association of Boards of Pharmacy (NABP) produced a video for pharmacists on red flags that could indicate abuse of prescription medications. The group then filmed board of pharmacy executive officers introducing the video. The California version is now available on the board website at:

<https://www.youtube.com/watch?v=jdeQ0GeJjAM&feature=youtu.be>.

5. FOR INFORMATION: Medical Board of California's Prescribing Task Force

Ms. Herold said the Medical Board's Prescribing Task Force met in June 2014 to make revisions to the Medical Board's pain management guidelines. Another meeting was slated for late September. The guidelines are expected to be adopted by the Medical Board this fall and Ms. Herold said once the new guidelines are approved, the board will then hold another joint conference with the Medical Board in Southern California.

6. FOR INFORMATION: *Consumer Reports* Articles on the Dangers of Painkillers Presented by Doris Peter, PhD, Director of Consumer Reports Health Ratings Center

Consumer Reports recently published a special report on the dangers of painkillers. Doris Peter, PhD, Director of Consumer Reports Health Ratings Center, presented by telephone information from their research. She said the publication has printed articles about prescription drug abuse for 10 years and a rigorous process is used to produce these reports. She reported that they take drug effectiveness reviews and translate complex information into formats consumers can understand to provide information on options for treatment and effectiveness, safety and cost. She said they try to identify "best buy" choices for consumers. A copy of the report was included in the meeting materials.

Dr. Peter said they also provided information on pain medications in their September issue of their magazine and included different options for pain treatment instead of opioids.

Chair Castellblanch asked if *Consumer Reports* gets any funding from the pharmaceutical industry and Dr. Peter said no and that the reports are available for free to consumers. She said *Consumer Reports* relies on independent grants and in-kind funding. She said

consumers prefer the longer versions of their documents and they like getting more information if they have the condition.

Dr. Fujimoto asked whether the board planned to include these materials on the board website. Chair Castellblanch said he would like to do that and Dr. Peter said the board has permission to include them on the website. Dr. Fujimoto said that current data shows that opioids are not effective in the treatment of long-term pain and that is pointed out in the “Five Surprising Facts” article included in the meeting materials.

Mr. Smith asked about the question posed in the Consumer Reports piece - “Will I become addicted?” He said the article states the answer is that there is a “small chance” of addiction if the medication is taken as directed. He questioned the validity of that statement when the American Journal of Public Health states it’s as high as 50 percent for those taking opioids long-term. Dr. Peter said they are in the process of updating that information, which is from 2012, and it depends on whether the patient hasn’t taken opioids before or has had any addiction issues.

7. FOR INFORMATION AND DISCUSSION: Recommendations Developed by National Council for Prescription Drug Programs (NCPDP) for Improving Prescription Drug Monitoring Programs (PDMP)

Nicole Russell, Government Affairs Specialist with NCPDP, presented their white paper by telephone.

She said the National Council for Prescription Drug Programs formed a focus group whose goals and objectives were to identify the current and future issues and needs regarding the exchange of information for Prescription Drug Monitoring Programs (PDMPs). The group identified the specific industry challenges and the goals of the PDMPs, providers, prescribers and regulatory agencies. This allowed NCPDP to propose efficient solutions, which leverage existing standards and methodologies, and to develop applicable enhancements that could be standardized across the industry.

She said prescription drug abuse is classified as both a public health crisis and a patient safety issue. She said it requires a national solution and every state, except Missouri, has a PDMP in place. She said states can and should remain active in this area. She said the current programs don’t effectively allow sharing of information across state lines and don’t relay information in real time. She said pharmacy reporting requirements ranges from daily to monthly. Ms. Russell said the current systems are burdensome to providers and pharmacists and current technology is not being leveraged. She said other issues include inconsistent patient identification requirements; lack of communication between states; and there is no easy way to share information. She said NCPDP wants prescribers to be able to be proactive in dispensing by being able to access PDMP information.

She said the white paper took 1.5 years to produce and numerous agencies and NCPDP staff served on the task force. She said they identified problems, needs and future solutions. She reported the group is now finalizing an implementation guide to incorporate every state's needs and they are recommending a national PDMP administrator, which would provide an integrated system for prescribers and pharmacists. Currently, there is no national administrator. She said they believe accessing the PDMP should be within the current workflow of prescribers and pharmacists.

Chair Castellblanch said he worries that the train has already left the station in regards to having a national tracking system and asked how their efforts fit into other efforts currently underway. Ms. Russell said this program would enhance the current systems, but details have not yet been worked out. She said they are looking to collaborate with NABP and not take away from any work states have been doing.

Ms. Russell invited anyone with an interest to join their group.

Attachment 1 contains a copy of Ms. Russell's PowerPoint presentation.

8. FOR INFORMATION: Presentation by Angela Crispo, PharmD, Pharmacy Resident, PGY2 Psychiatric, University of California San Diego Health System, on Counseling Tips for Pharmacists on Opioid Prescriptions

Dr. Crispo presented "Pharmacist Counseling Tips for Opioid Prescriptions" with information that pharmacists can utilize when counseling patients on new or changed opioid prescriptions. She said her residency has allowed her to work with pain patients in a variety of settings and her goal is to assist pharmacists by providing information on educating patients about the safe use of opioids.

She said opioid side effects include long-term constipation, which will require the use of laxatives. She also said opioids can cause nausea, which will eventually get better and there are medications which can help with nausea. She said sedation is another side effect, which will get better as the patient adjusts to the medication. She said respiratory depression can occur at the start of taking the medication and again with increased dosage. She said patients need to be advised to take the medication as prescribed to decrease this risk.

She said pharmacists need to have a conversation with patients about abuse and tolerance. She said tolerance is defined as the body needing more of the substance to provide the same therapeutic response, whereas dependence would result in the patient going through withdrawals if the substance is abruptly stopped. She said pseudo-addiction is behavior that can present as addiction when the patients really are in pain. She explained that abuse is defined as the misuse of a drug, such as using the drug to help a patient sleep at night, instead of taking it for pain management.

She said addiction is defined by the American Psychiatric Association as a psychological disease that causes compulsive substance use despite harmful consequences, such as patients who know it is harming them, but they still go to great lengths to get more and more of the substance that is not for pain-related use. She said she found patients were much more understanding about their pain management and can have better conversations about the medications when a pharmacist gives them this information. She said her handout provided ways to start a conversation (See Attachment 2). She said the best way is to ask the patient what he or she already knows about the medication. The pharmacist could then dispel incorrect information or add onto what the patient already knows.

Chair Castellblanch asked if Dr. Crispo received any funding from any pharmaceutical companies. Dr. Crispo said she did not. She said she did this project with Dr. Atayee at U.C. San Diego School of Pharmacy. Chair Castellblanch said he thinks pharmacy schools across the state should incorporate this information into their programs.

Ms. Herold asked if patients are given all of this information during a first-time consultation with a pharmacist. Dr. Crispo answered yes. Ms. Herold asked if there was better adherence with consultation and Dr. Crispo said yes. Ms. Herold said she completely supports a thorough consultation and asked how long it takes to do this type of consult. Dr. Crispo said she never timed it, but it can be done in 5-10 minutes, based on what the patient already knows. Chair Castellblanch said he'd like this information integrated in the pharmacy exam and Ms. Herold said it may already be and it is probably in the national exam. She said exam construction is not done in a public meeting.

Attachment 2 contains a copy of the counseling tips developed by Dr. Crispo that were distributed at the meeting.

9. FOR INFORMATION: Opioid Addiction and Recovery and the Personal Experiences of Jason Smith

Jason Smith, writer, business owner and pain medication addict, is in recovery and has been sober for two years. He is also knowledgeable about opioid recovery and the ongoing support process.

Mr. Smith said he recently wrote a series of three articles on heroin and opioid abuse. He said one of his articles chronicles the switch from pain medications to heroin. He said heroin use rose when Purdue Pharmaceutical made Oxycontin crush-proof. He said there was much discussion during the meeting about cutting into the supply side of prescription drug abuse, but he said it is meaningless unless the demand side is also cut. He said it is becoming more difficult for people to get opioid pain medications. He asked what is to be done when someone is caught doctor shopping. He said it would have

been much more effective for him when he was abusing pain medications if a pharmacist would have pulled him aside and offered information on treatment and recovery instead of calling the police. He suggested suspected abusers be given a list of where they could go locally for help detoxing and recovering and that they be treated like human beings instead of criminals. He said abuse is costing people's lives. He said it is not true that if you take opioids as directed that you will not become addicted. He said Dr. Crispo did a good job of describing the difference between dependence and abuse. He said there was a contradiction between how Dr. Crispo and Dr. Peter defined addiction.

Mr. Smith said his use of opioids began after a car accident when he was prescribed pain medications. He said the first time he took the drugs he loved the feeling they gave him. Mr. Smith said his story is not unique and when patients tell their doctor they think they might be addicted, then the doctor cuts them off. He said when patients get cut off or get caught doctor shopping they are not going to magically stop taking drugs. He said they are more likely to buy them off the street and then dealers turn them to heroin. He said people buy heroin because it is cheaper and more readily available.

He said doctors should be required to show some sort of competency to prescribe scheduled drugs and they should know about addiction. He said his prescribing doctor was educated on opioids by the pharmaceutical sales reps.

He said initially he was put on the medication because he was in pain and then eventually his brain produced pain that wasn't real in order to get the medication. Once he got off the opioids, he realized his back had gotten better and he was in less pain than he was when he was on opioids.

He said he is a byproduct or collateral damage of pain treatment and he suggested that the pharmaceutical industry should help fund the mess they created, just like gambling addiction information is funded by casinos because it is a byproduct of their industry.

Ms. Herold thanked Mr. Smith for his presentation and said it is another side of the issue that the committee had not heard about. She asked if he had any advice for pharmacists when they encounter a doctor shopper and she asked how he scammed pharmacists. He said the pharmacists were the most difficult to get past because doctors can be charmed during their 10 minutes with a patient, but the pharmacist doesn't know the patient and they look at the prescription and the patient's age and question whether he or she really needs the opioid prescription. He said he dealt mostly with pharmacy technicians and he said he could watch and see who was letting things go, who didn't check ID on a prescription or which ones he could get talking so they didn't pay close attention to a prescription. He said he never got caught in the U.S. by a pharmacist. He said people have a misconception about what a drug addict is, but he said addicts are regular, everyday people.

He said during his abuse period, he probably wouldn't have been receptive to a pharmacist suggesting he get help. However, he said there were many times when he didn't want to fill the prescriptions, but he also didn't want to go through withdrawals. He said if at that point he would have information on detoxing and rehabilitation, he might have been more receptive.

Dr. Fujimoto said she read his three articles and found them very informative and that the board recognizes prescription abuse is connected to heroin abuse. Dr. Castellblanch said there isn't good research available to demonstrate the connection between opioid abuse and heroin abuse. Mr. Smith cited a study from the American Journal of Medicine that stated the number of people going to rehab for Oxycontin dropped by 70 percent when it was made abuse proof and the exact same number increased for heroin abuse. He said the JAMA study is also very good.

10. FOR INFORMATION: Legislative Approval of Drug Overdose Prevention Bill (AB 1535, Bloom), Permitting Pharmacists to Furnish Naloxone

Ms. Herold said Assembly Bill 1535, Assembly member Richard Bloom's drug overdose prevention bill, was recently passed by the Legislature and would permit pharmacists to furnish the opiate overdose antidote naloxone, pursuant to procedures developed by the Board of Pharmacy and the Medical Board of California. She said the SB 493 committee is already developing protocols for hormone contraception distribution and will probably also be assigned to develop this protocol once the governor signs the bill. She said it was on the governor's desk for signature at that time.

Dr. Fujimoto said it would be good to get the protocols now being used by families and law enforcement that could be shared with the committee developing the protocols to keep them consistent. Ms. Herold agreed.

Dr. James Gasper said he was involved in the pilot of Naloxone in San Francisco and worked with CPHA on the language for this. He said he would like to be involved in the process.

11. FOR INFORMATION: Upcoming Joint DOJ and Board of Pharmacy CE Program in Santa Barbara

Ms. Herold said a free, joint training for pharmacists by the California State Board of Pharmacy and the Los Angeles Field Division of the Drug Enforcement Administration would be held on September 3 and 4 in Santa Barbara on "What every pharmacist should know to prevent drug diversion." She said continuing education units would be provided to pharmacists and pharmacy technicians who attend. CURES registration would also be available during this presentation.

12. FOR INFORMATION: The Next DEA Drug TakeBack on September 27, 2014

Ms. Herold said the take backs are normally held in April and October, but the DEA moved it to September this year. She said there was a link on the board's website to find a nearby location for disposal on September 27.

13. FOR INFORMATION: Public Outreach to Address Prescription Drug Abuse

Ms. Herold said the executive officers from the Medical Board and Board of Pharmacy had just met with the Dental Board because the Dental Board is setting up a prescription drug abuse committee. She said dentists are the number three prescriber of opioids and the California Dental Board is interested in learning more about the topic.

- July 10: Executive Officer Virginia Herold and Public Information Officer Joyia Emard attended the California Prescription Opioid Misuse and Overdose Work Group meeting
- July 15: Board Inspector Brandon Mutrux, PharmD, spoke on prescription drug abuse and other pharmacy issues at a Senior Scam Stopper program held in Southern California
- August 21: Executive Officer Virginia Herold provided a presentation at the California Conference of Local Health Officers monthly meeting regarding the board's implementation of SB 493 and the state's immunization registry
- August 25: Executive Officer Virginia Herold provided a presentation about the board's activities regarding prescription drug abuse to the first meeting of the Dental Board of California's prescription drug abuse committee

14. FOR INFORMATION: Additions to the Board of Pharmacy Prescription Drug Abuse Prevention Website Page

Due to time constraints, this item was deferred to the next meeting.

15. FOR INFORMATION: Articles Documenting the Issues of Prescription Medication Abuse

Due to time constraints, this item was deferred to the next meeting.

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

Megan Maddox, with the California Pharmacy Association, asked if the committee was aware of the recent lawsuit by Santa Clara and Orange Counties and wondered if the committee would be addressing it.

Chair Castellblanch asked if there were future agenda items from committee members. He said he'd like to add the Santa Clara and Orange County lawsuits. He also wanted to discuss New York's e-prescribing law; and how to bypass the limitations of the board website and suggested Facebook might be an option.

Dr. Fujimoto asked for clear direction and focus on future agendas. She said there are a lot of informational and educational items on the agenda, but she wants to know what the committee is doing with this information and if there will be future action items. She wants to know what pharmacists would want on the agenda. She has concern that the prescription drug abuse prevention portion of the board website is getting too long. She said it needs to be more focused and there needs to be a reason for putting the information on the board website. She wants to cut down what is on the site and set up parameters to review the website. She asked that at future meetings, slides be provided to go with the presentations; and she wants the setting of naloxone protocol to be tied into this committee.

Dr. Butler asked for information at the next meeting on e-prescribing and drug take back. She also wanted to put information on the website that pharmacists can refer people to who may have abuse issues.

Chair Castellblanch said the committee would meet again in November.

Adjournment

2:12 p.m.