



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

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

DATE: May 28, 2014

LOCATION: 1350 Front Street
Room: B-109
San Diego, CA 92101

COMMITTEE MEMBERS

PRESENT: Ramon Castellblanch, PhD, Chairperson
Amarylis Gutierrez, PharmD
Darlene Fujimoto, PharmD, Volunteer
Stan Weisser, RPh, Board President

COMMITTEE MEMBERS

NOT PRESENT: Rosalyn Hackworth, Public Member

STAFF

PRESENT: Virginia Herold, Executive Officer
Joyia Emard, Public Information Officer
Laura Hendricks, Staff Analyst
Michael Santiago, Staff Attorney

Call to order

Chairperson Ramon Castellblanch called the meeting to order at 10 a.m. and conducted a roll call.

Subcommittee members present were Dr. Castellblanch, Dr. Amarylis Gutierrez, Dr. Darlene Fujimoto and Board President Stan Weisser.

Subcommittee member Rosalyn Hackworth was not present.

1. PRESENTATION: Honoring Pharmacist John Robertson For Saving His Patient's Life

President Stan Weisser, on behalf of the Board of Pharmacy, presented John Robertson, PharmD of Ramona, with a commendation plaque and board pin honoring him for saving a patient's life.

Dr. Robertson is a pharmacist at Sav-On pharmacy inside Ramona's Albertsons supermarket and he saved a patient's life by going to his home to check on him when the man failed to pick up his prescription medication and didn't answer his phone. With the aid of sheriff's deputies, Dr. Robertson found the man collapsed inside where he had fallen two to three days earlier and was unable to get up. The man was hospitalized.

Dr. Robertson thanked the board and said it had been a humbling experience. He said he doesn't think his actions are out of the ordinary and he has heard of similar actions from other pharmacists. He said pharmacists really are here to help patients.

2. FOR INFORMATION: Prescription Drug Abuse Materials Currently Available on the Board of Pharmacy's Website

Dr. Castellblanch reported there are materials, links and videos on the board's website page on Prescription Drug Abuse Prevention. He said materials are available for teens, college students, parents and educators. He said these are new materials and, unfortunately, prescription drug abuse is a widespread problem with teens and college students.

Executive Officer Virginia Herold said board Public Information Officer Joyia Emard was responsible for the web page development and she took the project and ran with it. She said Ms. Emard has been working with some of the community groups. Ms. Herold said the website materials came mostly from government agencies. She said the goal is to provide materials to people who need the information.

Ms. Herold said the Prescription Opioid Misuse and Overdose Workgroup has been formed by the Department of Public Health and is chaired by the director of Public Health. The workgroup is made up of representatives from various state agencies and meets monthly. She said the goal of the group is to unify a focused policy that can be articulated by the state agencies in efforts on opioid abuse education and prevention.

Dr. Castellblanch asked Ms. Emard for comment on the website materials. Ms. Emard encouraged people to utilize the web page and said materials would be regularly updated and added.

Dr. Gutierrez asked if materials from coalition presenters at subcommittee meetings were included on the website. Ms. Herold said no, but some of the board-developed materials were based on coalition materials. Ms. Herold said the board is not aware of

all of the groups. She said there seems to be a lot of activity at county levels as parents try to grapple with the problem of prescription drug abuse.

Ms. Emard said she expects to receive contact information on the various coalitions. She said most of the coalitions are funded by SAMSHA, whose materials have been included on the board web page.

Ms. Herold said subcommittee member Dr. Fujimoto is active in the San Diego coalition group. Dr. Fujimoto said the San Diego coalition members have varied backgrounds. She said the San Diego Medical Society is involved along with representatives from law enforcement and medical and insurance fraud companies. She said coalition group materials need to be reviewed to ensure they are scientifically accurate before putting them on the board website.

Dr. Castellblanch said the board needs to be extremely careful about materials placed on the website and asked the committee members to review the materials.

Dr. Castellblanch said he liked the idea of providing links to the various drug abuse prevention coalitions on the website. He said that the Board of Pharmacy may become a nexus for these groups to provide a link to these programs. He said three of those groups have presented to the subcommittee.

President Weisser asked if the presentations from the subcommittee groups that presented were recorded and if they could be made available on the board website. However, because the meetings are not webcast, there is no video record available.

3. FOR INFORMATION: Prescription Drug Abuse Prevention Materials by Rabia Atayee, PharmD, Assistant Professor of Clinical Pharmacy, UCSD School of Pharmacy; and Nathan Painter, PharmD, Associate Clinical Professor, UCSD School of Pharmacy

Dr. Atayee and Dr. Painter presented information for both health care professionals and patients/consumers on medication abuse. Dr. Painter is a member of the San Diego prescription drug abuse task force in San Diego County.

Dr. Atayee said there is quite a bit of focus these days on opioid abuse, but there are many other prescription drugs that contribute to morbidity and mortality when abused, including benzodiazepines and stimulants.

She said she'd like to see information on drug interactions on the website, such as when opioids are combined with other drugs. She said pharmacists need to be aware of red flags that indicate a prescription could be for abuse. She said not all of her pharmacy colleagues are aware of the red flags.

Dr. Painter said some of the websites they recommend are the Medicine Abuse Project, which is geared to consumers and parents; Aware RX, which has a heavy focus on

parents; a link to DEA Drug TakeBack; and Wake UP Now, which focuses on high school-age students and allows them to share their information on use and misuse of drugs.

Dr. Atayee said health care professionals can find information at Ohio State University's GenerationRX, which provides tools for prescribers or pharmacists; The National Institute on Drug Abuse for current trends and health effects; and the White House Office of Drug Control for national strategies.

Dr. Painter and Dr. Atayee mentioned some articles that could be shared with pharmacists.

Dr. Atayee said CURES is a very valuable resource for dispensing pharmacists. She said there is doctor shopping, even within closed health care systems, and it would be helpful to have CURES information on the board website. Dr. Painter said group sign-ups are available, which eliminates one of the barriers of CURES registration – getting documents notarized.

Dr. Painter said he had lists of controlled substances that are abused including opioids, benzodiazepines and stimulants.

Dr. Atayee shared the list of red flags regarding corresponding responsibility from the board website. She suggested giving pharmacists the proper words to use with patients and prescribers when questioning prescriptions.

Dr. Castellblanch asked to receive a list of all of the suggestions they had made. He suggested that if handouts had been given to the subcommittee members, they could have formulated better questions.

President Weisser said there are some constraints with adding items to the website, such as staff time and budget constraints. He asked how often items should be updated. Dr. Atayee said probably every three years.

Dr. Gutierrez asked about the corresponding responsibility brochure and Ms. Herold said staff is working with the attorney to determine what verbiage a pharmacist could use to decline to fill a prescription.

Ms. Herold said what is important to remember is that the red flags listed are just some of the warning signs the board would look at, but it is not an all-inclusive list. She said just one or two of those red flags may be enough to warrant not filling the prescription. She said she doesn't want pharmacists to use the list of red flags as a checklist where all have to be met.

Dr. Castellblanch asked for the funding sources of some of the websites they mentioned. Dr. Painter said the Ohio State program was originally funded by a grant from Cardinal

Health. Dr. Castellblanch asked for the source of the articles and Dr. Painter said it was from MedScape. Dr. Castellblanch wanted to know who funds MedScape.

Dr. Gutierrez asked if the two speakers thought there were any red flags not on the board's list that should be included. Dr. Painter said anytime a patient comes in asking for certain brands, then that is a red flag. The big cocktail he said is an opioid with a benzo, but also they can throw in a muscle relaxant, which is the tripecta for problems. Dr. Atayee said there is a lot of media attention about the triad being lethal. She said pharmacists do have to keep an open mind in that there are patients who do better with specific drugs. Dr. Painter suggested other terms could be used besides "red flags."

Ms. Herold interjected that the term "red flags" comes from the board's precedential decision. She said when the board does an inspection and is going to discipline for excessive dispensing and failure to observe corresponding responsibility on the early refills that there are whole patterns of the same patients coming up with hundreds of days per year of early dispensing and multiple patients doing this. Then, she said, it becomes a willful pattern.

Dr. Atayee said she finds in these cases there is a lack of communication between the prescriber and pharmacist for the same patient. Ms. Herold said the board has been working with the Medical Board for two years on this issue.

Dr. Castellblanch asked about the idea of a CURES tutorial to help with enrollment. Dr. Painter said a CURES tutorial could be just a series of screenshots on the website with information underneath them.

Dr. Atayee said a statewide school of pharmacy volunteer effort where volunteers show pharmacists how to use CURES could be initiated.

Dr. Fujimoto said this would be a good state initiative. She said the system itself is the problem. She said registrations sit on the system for six weeks before being processed. She said the Department of Justice's processing has been the biggest problem and there are problems within the CURES system.

Ms. Herold said the board is writing a letter to the Department of Justice to request they dedicate some staff time to assist with CURES registration. She said board staff developed an information sheet on the three ways to sign up for CURES, which now includes a pharmacist personally giving it to a board inspector or personally delivering it to the board's office in Sacramento. She said 17% of California pharmacists have registered for CURES.

Dr. Castellblanch suggested that Drs. Atayee and Painter put together a tutorial.

Dr. Gutierrez said the CURES system is not that hard to use, but getting registered on it is difficult.

Sam Shimomura, associate dean of Western University College of Pharmacy, asked if students could be registered at the time of graduation. Ms. Herold said no, because they have to be licensed pharmacists to register, but the board has worked out with the DOJ that a pharmacist doesn't have to submit a pharmacy number when applying for CURES if they aren't employed by a pharmacy, so that new pharmacists can now register once they are licensed.

President Weisser said it would be good if during schooling, pharmacist students studied a small section on CURES to explain its importance and the importance of signing up and using it.

Dr. Gutierrez said that when educating pharmacist students on CURES, they must be told that accessing CURES has to be for real patient information and not just to see what people are taking.

John Cronin, pharmacy attorney and retired pharmacist, said NAPB has produced a video on red flags. He asked if the board is planning to connect prescription drug abuse with the internet sales of drugs on its website.

Mr. Cronin asked about the board's approach for materials for pharmacists and consumers and was concerned that consumers not be given the red flag information. Ms. Herold said the board has a tremendous duty to educate pharmacists and every time you educate, you run the risk that an astute patient uses it to get around the system. She said the focus needs to remain on educating pharmacists about what red flags mean.

Dr. Gutierrez said it is a good thing to let patients know that this is what you are going to be subject to. She said pharmacists are going to be educating the patients, as well.

Genevieve M. Clavreul, RN, Ph.D., said people who want to abuse medications know the red flags already. She said she's concerned about CURES because the system is very antiquated and poorly designed. She said people won't use it until it is redesigned. She is also concerned because CURES doesn't communicate with the 23 other states that also have PDMPs. In regards to material being placed on the board website, she said the board needs to carefully review materials from Ohio State because they are very politically aligned.

Dr. Castellblanch said NAPB gave a presentation on the system they are designing to be used by two bordering states and California is not planning on using that system. He said one sole person is working on CURES, but most states don't have prescription monitoring systems operating under a law enforcement agency. He said other state PDMPs are run by a public health agency or the state board of pharmacy. He said an SB 809 stakeholder meeting was recently held and it was not publicly announced and the Board of Pharmacy was not invited to participate. He told Ms. Clavreul that he shares her concerns.

Dr. Fujimoto said the pharmacy diversion cases the board tries are for large amounts of diverted tablets, not just a minor mistake here and there – the board wouldn't waste time pursuing those.

4. FOR INFORMATION: Educational Curriculum Materials for Teachers Developed by Purdue Pharma

Purdue Pharma provided a grant to the National Educator Association Health Information Network to create two books which are available without charge to educators. One is geared to grades 5-8 and the other is for grades 9-12. The books each contain more than 100 pages and meet educational curriculum requirements.

Ms. Herold said she found out last week that the Department of Education had to cut funds for drug education and had to use the money in other areas, so they've cut back on drug education for students. She said the DEA is creating a program, but they are not yet ready to roll it out. Ms. Herold said she plans to forward the materials to the Department of Education.

Dr. Fujimoto said Purdue Pharma didn't develop the materials, they funded their creation. She said they tried to address the problem without bias.

Dr. Castellblanch said the board would need to let educators know up front that the company making money off Oxycontin has funded the materials.

Ms. Herold said the materials seem to be relatively complete. She said part of the board's job is to share information on the resources that are available.

5. FOR INFORMATION: Use of/Education about Naloxone as an Overdose Antidote

Naloxone is used in cases of opioid overdose and acts as an antidote. It neutralizes the effects of opioids, allowing drug users to breathe during an overdose. Naloxone is an opioid antagonist—meaning that it binds to opioid receptors and can reverse or block the effects of other opioids. It can very quickly restore normal respiration to a person whose breathing has slowed or stopped as a result of abusing heroin or prescription opioids, or accidentally ingesting too much pain medication.

Naloxone has been routinely used in emergency care and in anesthesiology for decades. It can be administered by injection or in a nasal form of the drug, known commonly by its trade name, Narcan.

A California law took effect January 1, allowing family and friends of heroin and painkiller users to obtain the antidote from doctors, so it is available in case a loved one overdoses.

Assembly Bill 1535, currently pending in the California Legislature, would allow a pharmacist to furnish naloxone hydrochloride to a person pursuant to a standardized procedure or protocol developed by the Board of Pharmacy and the Medical Board of California. Pharmacists furnishing naloxone would be required to complete specified training.

Ms. Herold said the board recently took a “support” position on this bill.

President Weisser said other states picked up the gauntlet and have implemented similar programs and they are saving lives. He said the bill is sponsored by the California Pharmacists Association and is a good bill.

Ms. Herold said as far as she knows there is no opposition to the bill.

Dr. Gutierrez said standardized procedures would be developed for pharmacists and patient education on how to use it.

Dr. Fujimoto said that she believed that some San Diego Police Department officers are carrying it and eventually all of them will have it.

6. FOR INFORMATION: CURES Registration Procedures for Board of Pharmacy

In an effort to register pharmacists in the Department of Justice’s CURES Program, pharmacists will be able to give completed packets to a board inspector or they can deliver them in person at the Board of Pharmacy office.

CURES is California’s prescription drug monitoring program for controlled substances and is operated under the California Department of Justice. Effective January 1, 2016, all California licensed pharmacists must be registered to access CURES (as required by section 209 of the California Business and Professions Code).

Ms. Herold said staff sought ways to augment the efforts of DOJ to register pharmacists in CURES. She said that the board must be able to document who an applicant is when the board registers pharmacists. She said staff has developed an information sheet on how to do it. She said she hopes it will help increase the number of pharmacists registered. Dr. Gutierrez wanted to know if pharmacists could register at board and committee meetings.

Dr. Castellblanch said they can earn six units of CE and sign up for CURES at a board meeting. He said inspectors will have information on how to sign up for CURES when they visit a pharmacy.

Pharmacist Joanne Kozel said she went to a CE recently on CURES, sponsored by the San Fernando Valley Pharmacist Association, and she and her husband were the only ones registered. She said pharmacists in the San Fernando Valley don't know about CURES.

Ms. Herold thanked her for the information and said the board would rather educate pharmacists than have to discipline them.

Dr. Gutierrez asked if staff could do a subscriber alert to pharmacists about the CURES sign-up opportunities.

7. FOR INFORMATION: Implementation of SB 809 (DeSaulnier, Chapter 400, Statutes of 2013)

This bill established the CURES Fund within the State Treasury to receive funds from California licensed prescribers and dispensers to be allocated, upon appropriation by the Legislature, to the Department of Justice for the purposes of funding CURES. On April 1, 2014, the Board of Pharmacy began charging on renewals an annual fee of \$6 on licensees who administer, furnish or dispense controlled substances. The bill requires the proceeds of the fee to be deposited into the CURES Fund for the support of CURES, as specified.

Dr. Castellblanch said pharmacists are required to be signed up in CURES by January, 1 2016; however, more CURES staff won't be available until six months prior to this. He said the board voted at an earlier meeting to send a letter to the DOJ and wanted to know the progress and when it would go out. Ms. Herold said staff is still working on the letter and it should be out by the next board meeting.

President Weisser said there is another issue with CURES because it is getting tied into the issue of the ballot measure on the Medical Injury Compensation Act (MICRA) cap on medical malpractice pain and suffering settlements. Dr. Castellblanch explained the MICRA cap issue on the November ballot.

8. FOR INFORMATION: Report on CURES Data Report of Controlled Substances Dispensed in California

Ms. Herold reported that from 4/1/13 to 3/31/14 data reported in CURES indicates that the number of prescriptions filled were as follows: 9,049,441 Schedule II; 19,043,970 Schedule III; and 19,809,330 Schedule IV. She said there are 650,000,000 total prescriptions filled in California every year.

9. FOR REVIEW AND DISCUSSION: Development of Corresponding Responsibility Brochure

Board staff presented a draft brochure on corresponding responsibility being developed for pharmacists.

Ms. Herold said the board wanted to create a brochure alerting pharmacists about the precedential decision. She said Ms. Emard put the draft together and it still needed more review and she wanted to emphasize that there could be other red flags not listed that would warrant further investigation of a prescription by a pharmacist.

Dr. Castellblanch asked how the brochure would be distributed. Ms. Herold said the information would be in an article in the upcoming "Script" newsletter; the brochure would be on the board website and would be distributed at various meetings.

10. FOR INFORMATION: Results of DEA's April 2014 National Drug TakeBack Day

Dr. Castellblanch said the three DEA field divisions in California collected 78,495 pounds of unwanted, used and expired drugs during the TakeBack Event on April 26. The second Drug TakeBack event of the year will be held in October. He said the board will disseminate the information when the October date is announced.

Ms. Herold said there is a bill pending in the state legislature that would establish parameters for drug take back. She said the current version requires that CalRecycle establish these guidelines and the Board of Pharmacy would enforce them. CalRecycle agreed to add an amendment that the board be the co-author of the regulation requirement. Ms. Herold said there haven't been any federal regulation changes to allow this and all states have to wait until the DEA announces their guidelines.

11. FOR INFORMATION: Board Comments Submitted on a Proposed Federal Rescheduling of Hydrocodone From Schedule III to Schedule II

The Board of Pharmacy sent a letter to the DEA on April 28 with comments in support of the rescheduling of hydrocodone from Schedule III to Schedule II.

President Weisser said there is legitimate need for a timetable to taper into the higher level restrictions on prescribing and dispensing CII drugs.

12. FOR INFORMATION: Report on The Medical Board of California's Prescribing Task Force

The task force met in February and will meet again June 19, 2014, in Sacramento to finalize revisions to the Medical Board's pain management guidelines. An agenda for this meeting is not yet publicly available.

Ms. Herold said the Medical Board hasn't revised their pain management guidelines since the 1990s and the task force met once and they hope to finalize the revised guidelines at the June meeting. She said there is a draft of the guidelines that will be made public prior to the meeting. Ms. Herold said if the guidelines are adopted by the Medical Board, then they and the Board of Pharmacy will plan a two-day seminar similar

to the one done in February 2013, to introduce those guidelines, and emphasize CURES, drug take back, prescription drug abuse and other issues.

13. FOR INFORMATION: Review of the Medical Board of California's Public Service Announcement Developed for Prescription Drug Abuse Awareness Month.

The subcommittee viewed a video developed by the California Medical Board on prescription drug abuse was presented that can be found at <https://www.youtube.com/watch?v=mGmn8pQwiUU>.

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

Dr. Castellblanch requested articles be included in the packet that show prescription drug abuse is a huge problem with Workers Compensation. He said the vast majority of prescription overdose deaths are in men age 35-55; there are considerably more men than women; and there are more whites than nonwhites. He said this is very much a working person's epidemic. He pointed out an article on prescription drugs and older people and one on pregnant women and opioid use. Ms. Herold gave credit to Ms. Emard for compiling the articles. Dr. Castellblanch said doctors are prescribing opioids to pregnant women. He said the tentacles for this epidemic are spreading far and wide and the articles show how widespread the epidemic is.

Dr. Fujimoto said she used to work with UCSD's geriatric department and she said the problem lies not with the senior patients, but with the prescribers. She said the seniors get put into hospitals and care facilities and they get over-medicated. She said there are a few who are purposely misusing their medications, but mostly it is overprescribing and mis-prescribing. She said the seniors are often being prescribed for by numerous doctors who are not communicating with each other.

President Weisser said there is a stigma – people don't want to take away a 70-year-old's medication.

Ms. Clavreul said in regards to Workers Comp, that if they would treat the patient right away the patient wouldn't need to be on pain medication. She said it can take up to one year to get treatment. She said during that waiting time there is no other alternative besides pain medication. She said if you remove the pain, people won't use the pain medications.

15. FOR INFORMATION: Report on Public Outreach to Address Prescription Drug Abuse

The committee reviewed recent public speaking events where the board or staff made presentations.

Ms. Herold said at the CPhA meeting, the Department of Justice attended for two hours to sign pharmacists up on CURES.

At a Bay Area forum convened by the U.S. Attorney's Office, there were six elected district attorneys sitting in one room at the same time, which she has never seen – all to address prescription drug abuse. President Weisser said he and the Medical Board representative who presented were very well received. He said families of prescription drug overdose victims and law enforcement also attended. He said there were very many moving presentations, it was very informative and it was well-attended. He thanked Ms. Herold and Ms. Emard for the support they gave in putting together his presentation.

Ms. Herold said she and Dr. Castellblanch spoke at a Medi-Cal Drug Utilization Board meeting. Dr. Castellblanch spoke about prescription drug abuse and the work of the committee, while she spoke about drug diversion thefts from pharmacies and corresponding responsibility. She said Medi-Cal, which pays for prescription drugs, has now limited the quantity of some pain medications that they will cover at one time. Dr. Castellblanch said Ms. Herold's presentation on corresponding responsibility was very enlightening.

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

Dr. Castellblanch stated that he would like the pharmacist exams to incorporate test questions on prescription drug abuse to create awareness by ensuring this subject is taught in the schools.

Dr. Gutierrez said she'd like to see a monthly CURES report on how many pharmacists have signed up to see if the efforts of the board are increasing registration. She said she'd also like the numbers by county to see if there is a need for more efforts in any specific area. Ms. Herold said she thought those numbers could be broken out.

Dr. Fujimoto said she'd like to look at CURES data to see if those who signed up are actually using it. She said sign-ups are a good goal, but she'd like to see what percentage of those registered are actually using CURES. Ms. Herold asked the committee members to let her know what data they are interested in receiving and she can see if it is available.

Dr. Gutierrez asked if the board knows which chains are directing their pharmacists to sign up. Dr. Castellblanch said staff could send a letter to the chains asking them about their CURES policy. Dr. Fujimoto said she doesn't think it's the chains that are not signing up, but the small pharmacies.

Adjournment: 12:27 p.m.