



**PRESCRIPTION MEDICATION ABUSE SUBCOMMITTEE
 MEETING MINUTES**

DATE: March 19, 2015

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

COMMITTEE MEMBERS PRESENT: Ramon Castellblanch, PhD, Chairperson
 Darlene Fujimoto, PharmD, Volunteer
 Rosalyn Hackworth, Board Member
 Lavanza Butler, PharmD

COMMITTEE MEMBERS NOT PRESENT: Gregory Murphy, Board Member

STAFF PRESENT: Anne Sodergren, Assistant Executive Officer
 Joyia Emard, Public Information Officer
 Laura Hendricks, Staff Analyst
 Laura Freedman, Board Counsel

Call to order

Chairperson Ramon Castellblanch called the meeting to order at 10 a.m. Committee members present were Darlene Fujimoto, Lavanza Butler, and Rosalyn Hackworth.

1. FOR INFORMATION: Report on CURES, California’s Prescription Drug Monitoring Program

Mike Small, DOJ Administrator II, is program administrator of the Department of Justice’s Law Enforcement Services Program which oversees CURES. Robert Sumner, Deputy Attorney General in Legislative Affairs, is a Department of Justice legislative advocate and has been involved in implementing SB809. Both presented information on CURES.

Mr. Small said efforts to increase registration have been successful, which he said was helped by the Board’s efforts to register pharmacists. He said CURES staff members have increased

their outreach to register prescribers and dispensers. He said in 2013, pharmacist registration increased and the number of patient queries increased. He said the total pharmacist registration since December 2011 is 13,148. Half of those registrations occurred in 2014. He also said that 1.4 million patient activity reports were delivered to pharmacists in 2014, up from 909,000 in 2013. Mr. Small reported that total prescriber registrations from 2010 to 2014 are 22,605. He said dispenser and prescriber registrations are up 346 percent since 2011.

Mr. Small reported the new CURES 2.0 computer system is on budget and on time and is expected to be launched on June 30, 2015. He said it will have an online registration process with the initial implementation of CURES 2.0. The system will be fully functional by October 2015.

He said CURES now has three student interns and four retired annuitants on staff and they have been able to dramatically improve customer service. Mr. Small explained that DOJ is requesting approval for seven permanent personnel for the CURES program and five for CURES IT, which would be funded in the new fiscal year.

Discussion

Chair Castellblanch asked who will approve the funding of the additional CURES staff positions. Mr. Small said the Department of Finance approves these and the funding is provided in SB809.

Dr. Fujimoto asked about the number of registrants for CURES versus the number of DEA controlled substance certification licenses, Mr. Small said CURES does not have staff to take the time to create that report, but they will once positions are approved and filled. She then asked if clinical pharmacists who do not hold DEA certifications to dispense controlled substances need to register in CURES. Mr. Small said the statute states that all pharmacists must register in CURES, whether or not they furnish controlled substances. Anne Sodergren, board assistant executive officer, said the board could decide to seek legislation to change the requirement so that clinical pharmacists do not need to register in CURES.

Dr. Fred Mayer, with the Marin County Drug Abuse Task Force, said that at the October Prescription Medication Abuse Subcommittee meeting he asked why the CURES program has taken so long to get off the ground. He said he was told to write a letter to Attorney General Kamela Harris, which he did in November. He said he has yet to hear back. He said there is an emergency and 42,000 people have died from prescription overdose and he doesn't understand why it will take until July to get the CURES system fully functional. Mr. Sumner said he has heard great things about the Marin Task Force's efforts to curb prescription abuse and overdose and he applauds that, but he said that the implementation of SB809 was scheduled to be functional and funded in July 2015.

Dr. Fujimoto said they have been told in the past that the CURES system would not be funded until it was fully operational. She said this has been discussed several times in past meetings. Mr. Small said the legislature had an option to front the money for CURES and have it be paid

back as fees were collected, but instead decided to allow fees to accumulate for a few years before they would authorize staff.

When asked what the board could do to support the efforts to garner approval for the proposed staff positions, Mr. Small suggested the board send the Department of Finance a letter of support for CURES funding.

Jillian Hacker, director of government affairs for California Society of Health Systems Pharmacists (CSHSP), said they also have questioned the requirement for all pharmacists to be registered in CURES. She said CSHSP would like that requirement amended. Dr. Fujimoto asked her if she knew how many pharmacists are not involved in the furnishing of scheduled drugs and Ms. Hacker said she did not.

The committee discussed that this could be an agenda item for another meeting.

An audience member said the CURES system blocks users if their password has not been updated and there is not much help on the website to correct that. Mr. Small said the new system will make it very clear when the passwords need to be changed. He said the new system will be state-of-the-art in regards to user friendliness.

Dr. Fujimoto asked Mr. Small if he could provide a presentation to the board or at a committee meeting before CURES is implemented. Mr. Small said he will work with board staff to provide a presentation in May or June.

Attachment 1 contains a copy of Mr. Small's PowerPoint presentation.

2. FOR INFORMATION: Report on a Pharmacist's Corresponding Responsibility in Regards to Dispensing Prescription Medications

Joyia Emard, Board of Pharmacy Public Information Officer, presented information on three recent disciplinary actions taken by the board, which involved corresponding responsibility. She said the completed cases all involved the furnishing of controlled substances and are available on the board website. She said Health & Safety Code 11153 requires pharmacists to demonstrate a corresponding responsibility in the furnishing of controlled substances to ensure they are for a legitimate purpose and are not for abuse. She said there are a number of red flags that pharmacists should look for which could indicate the drugs are not for legitimate medical purposes.

She said one of the cases involved an Anaheim pharmacy in which both the pharmacist's and the pharmacy's licenses were revoked and they were required to pay \$7,000 for the cost of the investigation. She said corresponding responsibility was cited because the pharmacist did not review patient profiles and filled prescriptions for patients coming from a distance, with prescriptions written by physicians prescribing the same therapy to multiple patients and prescriptions for the same medications written for the same patient by different physicians. She

said in this case the pharmacy also had large amounts of controlled substances that they could not account for, were not reporting to CURES on a weekly basis, were not reviewing CURES data when filling prescriptions for patients who used multiple prescribers and multiple pharmacies to obtain controlled substances, did not verify prescriber's status to fill controlled substances, and dispensed early refills on dozens of prescriptions.

Another case involved an Irvine community pharmacy where the pharmacist in charge received suspension and probation and the pharmacy license was surrendered. She said the enforcement action also included an order to pay almost \$15,000 for the cost of the investigation. She said in this case the board inspector found that most schedule II controlled substance prescriptions came from the same five doctors, that patients traveled a distance and paid in cash and that some patients arrived as a group in vans and all received controlled substances. She said the inspector also found that these prescriptions were not properly verified with the prescriber and that pharmacy staff were presented with what they thought were fake identifications by patients, but the pharmacist in charge directed them to fill the prescriptions even with the questionable identification documents.

The final case Ms. Emard presented involved a Rite Aid pharmacy in Downtown Los Angeles where the pharmacy and pharmacist in charge both received 5-year probations and the pharmacist also received a suspension and was directed to pay more than \$8,000 for the cost of the investigation. The pharmacist recently surrendered her license. The pharmacist had been providing many early refills for controlled substances, some up to 28 days early. Many of the patients were doctor shoppers and had visited up to 45 doctors and seven pharmacies. This case prompted media attention and the Los Angeles City Attorney and the Los Angeles Police Department are working with the DEA and Board of Pharmacy on a presentation to Downtown Los Angeles pharmacists to educate them on corresponding responsibility and the problem of prescription drug abuse.

Discussion

Chair Castellblanch said he was impressed with the board's enforcement actions regarding controlled substances. Dr. Fujimoto said she thought the board was doing a good job on utilizing corresponding responsibility and said she likes the corresponding responsibility brochure developed by the board.

Chair Castellblanch asked if information on corresponding responsibility would be in the upcoming issue of the *Script* and Ms. Emard said there is an article on the corresponding responsibility brochure and information on the revised pain management guidelines created by the Medical Board. She said the *Script* also contains a list of enforcement actions with links to the board website and the case documents.

Dr. Fujimoto said she did not like to highlight negative issues regarding the pharmacy profession and that enforcement actions should be used as teachable moments for pharmacists. She said she would like pharmacists to understand that the enforcement actions

are taken for egregious cases. She said most pharmacists are professionals and are trying to do what is right. She said pharmacists should use the checklist for red flags, but if they make a mistake one time that is not grounds for enforcement. She said enforcement actions are warranted when there is a repeated pattern of actions.

Chair Castellblanch said that he is not as concerned about the profession of pharmacy as he is about public protection. He said there is an epidemic of prescription drug abuse and he thinks that policies and enforcement actions by the board can cut down on abuse and reduce harm to the public.

Dr. Mayer, representing Pharmacists Planning Services and the Marin County Task Force, said he wrote a letter to the board and received no response. He said in his letter that some pharmacies that were investigated now have a protocol which includes a list of questions a pharmacist needs to ask before dispensing scheduled drugs. He said pharmacists must be given time in their work schedule for these protocols. He said there are also patients who have a legitimate need for pain medications who are not receiving them because pharmacists are refusing to fill their prescriptions. He asked that the board make it mandatory that pharmacies have a protocol in place in regards to furnishing scheduled pain medications. He said he has sent the board a copy of protocols that some of the chain pharmacies have put in place after being reprimanded for opioid dispensing practices. He said he will resend that information.

3. FOR INFORMATION AND POSSIBLE ACTION: Board Requirements For Continuing Education on Pain Management

Chair Castellblanch said he was recently at a presentation in San Diego and there are still many pharmacists who don't know about the prescription drug abuse crisis. He is recommending that the board require pharmacists to take at least two units of continuing education (CE) on pain management and that in the training they learn about CURES, corresponding responsibility, red flags and board enforcements and the seriousness of the opioid epidemic.

Ms. Butler said pharmacists are already educated on pain medication, and Chair Castellblanch revised the motion to require continuing education on the topics of CURES, corresponding responsibility, red flags and board enforcements and the seriousness of the opioid epidemic.

Rosalyn Hackworth made the motion and it was seconded by Lavanza Butler.

Discussion

Dr. Fujimoto said there is already a requirement for substance abuse continuing education in 1732.5. Ms. Sodergren said the board has long discussed course area requirements and substance abuse is one area that was recently approved by the board. She said the board has not been specific as to what should be included in the course content in each area. She said the board voted to approve 1732.5 in January 2015. Dr. Fujimoto said she did not want the board to be prescriptive about course content. She mentioned the requirement for CE in the category of maintaining the pharmacy's drug inventory and didn't understand what it meant and thought it

did not apply to many pharmacists. Ms. Sodergren said that item came from the board's enforcement committee because they are seeing huge drug losses because pharmacies are not properly maintaining their inventory.

Chair Castellblanch said that he would like the committee to recommend to the board that the subcommittee's request be incorporated in the list of continuing education requirements. Dr. Fujimoto said this is very new for the board to be requiring specific CE. She said the board should keep the requirements in broad terms. Board counsel Laura Freedman interjected that the motion needed to be amended based on the discussion.

Ms. Hackworth amended the motion to recommend to the board that as part of the section on substance abuse that the board adds the topics of corresponding responsibility and red flags.

Dr. Painter said the subcommittee needs to be careful in how it words this requirement because some pharmacists may want to take a course on personal substance abuse and also there are many pharmacists who don't dispense opioids and this would not be appropriate CE for them.

Ms. Freedman clarified that the subcommittee would be voting on a recommendation to the board that in the current draft of 1732.5 , subsection d, subsection 5 that the topic of substance abuse wording be revised to include corresponding responsibility and red flags.

Chair Castellblanch called for the vote and the recommendation was approved.

4. FOR INFORMATION: Report on Naloxone Emergency Regulations to Prevent Opioid Overdose Deaths

Ms. Sodergren said that at the March 9, 2015 Board Meeting, minor changes were made to the naloxone protocol language, which has been determined to be non-substantive. She said legislation that mandated the use of naloxone allowed for an emergency regulation to be in place for 180 days or upon full adoption by the Office of Administrative Law. She said the regular rule making process is lengthy because of the public comment periods followed by review to determine if changes are going to be made. Staff is now working on the timing of the release of the protocol because the emergency regulation could expire before the regular rule-making is complete and there would be a period of time between them where there was no regulation and pharmacists would be unable to furnish naloxone. She referred to the most current version of the regulation distributed at the meeting where an order change was made to the nasal naloxone information. She said the other change to either include the patient or recipient's name on the label would be included in the formal rulemaking process. That change would need to go before the Medical Board for approval.

Attachment 2 includes a copy of the final version of the emergency regulation.

There was no discussion.

5. FOR INFORMATION: Presentation on University of California, San Diego Webinar and Other Activities Related to Prescription Drug Abuse

Nathan A. Painter, Pharm.D., CDE and Associate Clinical Professor at the University of California, San Diego Skaggs School of Pharmacy and Pharmaceutical Science, presented information on what is being done in the University of California system to provide education about prescription drug abuse.

He shared an overview of a webinar presentation that will be given to UC Student Health physicians, physician assistants, nurse practitioners, pharmacists, pharmacy technicians, psychologists and therapists through the UC health clinics. He said most of the attendees will be pharmacists and physician assistants.

He said the presentation provides an overview of prescription drug abuse in the college population. During the presentation, drug-seeking behavior will be identified with case examples and information on aberrant drug seeking behaviors and red flags. He said they will explore tools to use with patients at risk of prescription drug abuse, and other topics will include stimulant/benzos and naloxone. He said they will also discuss using CURES to identify patients at risk, setting limits, limiting the amount on the prescription, and referring to psychiatry or other campus resources for follow-up.

He said UCSD Skaggs School of Pharmacy has about 15 points where courses in the curriculum address controlled substances, pain management and opioid abuse including law and ethics, therapeutics, and a prescription drug abuse elective. He said many pharmacy schools address the issue of prescription drug abuse.

He said the San Diego opioid abuse prevention group recently began a campaign, One San Diego, to encourage opioid patients to use one physician and one pharmacy. He said this policy is for patients who are receiving chronic opioid therapy.

Discussion

Chair Castellblanch asked Dr. Painter for more information about One San Diego. Dr. Painter said two years ago the San Diego emergency departments (EDs) adopted guidelines for furnishing opioids and these policies have been adopted by EDs in many parts of the state. He said they are now trying to push that out beyond the EDs by encouraging patients to go to one doctor for prescriptions and one pharmacy to have them filled. He said many pain management prescribers have contracts with their patients and seeing one doctor for pain medications and having them filled at one pharmacy is usually included in those contracts.

Steve Grey commented that he and two past board presidents teach the ethics class and that it impresses students about the importance of proper furnishing of opioids.

6. FOR INFORMATION: Proposal to Prepare a Draft Report on the Subcommittee’s Findings and Recommendations on the Opioid Epidemic

Chair Castellblanch said the subcommittee has been meeting for more than a year and has heard from many presenters. He said through testimony it has been shown that there really is an epidemic with prescription pain medication abuse. He said the committee has learned about the demographics of opioid overdose, which predominantly occurs to middle-aged men. He said it has been shown that there is a link between the opioid epidemic and the increase in heroin abuse. He said the committee has also heard about innovative work being done by a number of counties and groups. He said he would like to put together a report about the committee’s findings.

Discussion

Dr. Fujimoto said she thought it would be a good idea for him to create a draft that would be circulated for comment within the subcommittee. Chair Castellblanch asked that the committee submit to him any ideas for what they considered most important to include in the report.

7. FOR INFORMATION: Review of Activities to Promote Prescription Drug Abuse Awareness Month, ACR 26 (Levine)

Ms. Sodergren reported that staff is looking to leverage ACR 26 to conduct an outreach to licensees about what the board has available in regards to prescription drug abuse prevention materials including the website, public service announcement videos and corresponding responsibility materials. She said staff would utilize the Department of Consumer Affairs’ social media outlets and subscriber alerts to inform licensees and consumers.

There was no discussion.

8. FOR INFORMATION: Report on Conversion of the Board of Pharmacy Website

Chair Castellblanch said the board’s website is outdated and that staff is upgrading it to a more user-friendly format. Ms. Sodergren reported that board IT staff is updating the board website to make it more consistent with other state agencies. She said a screenshot of a draft home page was included in the meeting materials to show the progress being made. She said staff is striving to have the website update completed in six months. She said that progress on the website update will be presented at the July board meeting. She said that initially staff was planning to upgrade the website when BreEze was implemented and to roll them out at the same time, but BreEze implementation has been lagging so staff is proceeding with the website upgrade.

Discussion

Chair Castellblanch said the progress on updating the board website is good news and he is hoping that there will be less of the running lists of materials on the web pages and that it will be more user friendly. He said he hopes that prescription drug abuse prevention will be highlighted on the home page.

9. FOR INFORMATION: Discussion of Articles Documenting the Issues of Prescription Drug Abuse

Ms. Sodergren said that news articles pertaining to prescription drug abuse were included in the meeting materials for committee review and included articles on 2013 drug overdose mortality data, the failure of abuse-deterrent opioids, a *Consumer Reports*-commissioned review of the research used to approve Zohydro, an article on a lack of evidence that opioids work for chronic pain and another on the FDA urging caution in prescribing pain medications for pregnant women.

There was no discussion.

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

Ms. Sodergren said that presentations listed in the meeting materials detail the outreach being done by the board and include workgroup meetings that Board Executive Officer Virginia Herold and Ms. Emard participate in with other state agencies with a goal to establish a statewide policy on opioid abuse. She said staff continues to provide education on corresponding responsibility whenever possible. She said Ms. Herold has spoken to some of the pharmacy school classes about board issues and corresponding responsibility. Ms. Sodergren said the board will continue to partner with the DEA on presentations as time and staffing allow.

Discussion

Chair Castellblanch asked Ms. Hackworth to speak on the educational program she organized in the San Diego area. She said Ms. Herold was a presenter and a Department of Justice representative spoke on diversion, and that Steve Grey spoke on pharmacy law. She said the board approved providing three hours of CE for pharmacists attending the program. Ms. Hackworth said CURES registration was also provided. She said she would like to provide the program in Los Angeles.

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

There was no public comment for items not on the agenda.

The meeting was adjourned at 12 p.m.