



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

PRESCRIPTION MEDICATION ABUSE SUBCOMMITTEE REPORT

Ramon Castellblanch, PhD, Chairperson

Darlene Fujimoto, PharmD, Volunteer

Rosalyn Hackworth, Public Member

Lavanza Butler, PharmD

Greg Murphy, Public Member

A Report on the Prescription Medication Abuse Subcommittee meeting held on August 26, 2014, in San Diego.

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

Background

The Prescription Opioid Misuse and Overdose Work Group was formed by the State Department of Public Health and is chaired by the department director. The work group is made up of representatives from various state agencies and meets monthly. 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.

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. 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. 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.

Committee Discussion

Committee members asked if others could join the work group, but at this time it is only state agencies of which there are state leaders taking part who are physicians and CURES is represented.

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

Background

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. Three representatives from each state were in attendance.

During the meeting, national officials encouraged that prescription drug monitoring programs be fully implemented with operability across state lines. Participants were asked to set goals for their state that would help with abuse prevention. 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.

Committee Discussion

Committee members said the report showed that the data for California is not accurate, possibly because the proper information is not getting reported or used. Committee members also expressed concern because CURES is run by law enforcement - one of only three states doing that – and the system doesn't meet the needs of health care providers.

The committee discussed the timeliness of CURES data and was informed the requirement is that within seven days the information has to be entered by dispensers. It then goes to an outside company, which sends it to the Department of Justice, so it's almost a three-week lag time between when a pharmacist enters the data and when it shows up in CURES. However, once data is in the CURES system, it is fully accessible.

The committee discussed that the board finds the CURES data invaluable and a CURES report on a pharmacy is generated before a pharmacy inspection is conducted; although not all pharmacies are inputting the controlled substance data.

It was pointed out that input in CURES has been required for years; however, prescribers and pharmacists will need to be registered to access the data by January 1, 2016. It was pointed out that Proposition 46, (Medical Injury Compensation Reform Act) now on the ballot, has a provision that would require that prescribers check the system before giving controlled substance prescriptions.

Discussion also was held regarding the difficulty to register on the CURES system and the ability of pharmacy customers to “work” the system.

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.

Background

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

Committee Discussion

The committee discussed that more than one billion hydrocodone pills were distributed to patients last year in California and that 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)

Background

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

Background

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 were expected to be adopted by the Medical Board this fall and 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

Background

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 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 besides opioids for the treatment of pain.

Committee Discussion

The committee discussed that *Consumer Reports* gets no funding from the pharmaceutical industry and relies on independent grants and in-kind funding and the reports are provided for free to consumers.

There was discussion as to whether the board planned to include these materials on the board website. However, questions arose as to the article’s statement that there is a “small chance” of addiction if opioid medications are taken as directed because the American Journal of Public Health states it’s as high as 50 percent for those taking opioids long-term. They were told the information in the article was from 2012 and is in the process of being updated.

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

Background

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 challenges and the goals of the PDMPs, providers, prescribers and regulatory agencies. This allowed NCPDP to propose solutions and to develop applicable enhancements that could be standardized across the industry.

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 range from daily to monthly and the current systems are burdensome to providers and pharmacists. Other issues include inconsistent patient identification requirements and the lack of an easy way to share information.

She reported the group is now finalizing an implementation guide to incorporate every state's needs and is recommending a national PDMP administrator, which would provide an integrated system for prescribers and pharmacists. She said they believe accessing the PDMP should be within the current workflow of prescribers and pharmacists.

Committee Discussion

The committee suggested that it already may be too late to have a national tracking system because so many states already have PDMPs in place.

Attachment 1 contains a copy of Ms. Russell's 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

Background

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 described and discussed opioid side effects and 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 suggested it is best 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.

Committee Discussion

The committee discussed that Dr. Crispo received no funding from any pharmaceutical companies and the project was conducted with Dr. Atayee at U.C. San Diego School of Pharmacy. Committee members expressed that pharmacy schools across the state could incorporate this information into their programs.

Committee members discussed that there is better adherence with consultation and this type of consultation can be done in 5-10 minutes, based on what the patient already knows.

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

Background

Jason Smith, writer, business owner and pain medication addict, is in recovery and has been sober for two years. He recently wrote a series of three articles on heroin and opioid abuse and 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 cutting into the supply side of prescription drug abuse is meaningless unless the demand side is also cut. He said it would have been 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. 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 it is not true that if you take opioids as directed that you will not become addicted.

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 doctors they think they might be addicted, then the doctors cut 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 turn to 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.

In regards to getting his questionable prescriptions filled, he said pharmacists were the most difficult to fool because doctors can be charmed during their 10 minutes with a patient, but the pharmacist doesn't know the patient and a pharmacist looks at the prescription and the patient's age and questions whether the patient 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 who he could get talking and 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 filled prescriptions against his will because he didn't want to go through withdrawals. He said if at that point he had information on detoxing and rehabilitation, he might have used it.

He said he is a byproduct 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.

Committee Discussion

The committee said Mr. Smith's presentation showed another side of prescription drug abuse that had not been heard at the meetings. Committee members said they

recognize prescription abuse is connected to heroin abuse; however, a committee member commented that weren't research studies to demonstrate it. 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

Background

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. The SB 493 committee is already developing protocols for hormone contraception distribution and will also be assigned to develop this protocol once the governor signs the bill. At the time, the bill was on the governor's desk for signature.

Committee Discussion

Committee members suggested 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 maintain consistency.

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

Background

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." Continuing education units would be provided to pharmacists and pharmacy technicians who attended. CURES registration would also be available during this presentation.

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

Background

Take backs are normally held in April and October, but the DEA moved it to September this year. A link on the board's website was available to find a nearby location for disposal on September 27.

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

Background

A list of outreach activities is available in the attached minutes.

Committee Discussion

The committee discussed that the executive officers from the Medical Board and the Board of Pharmacy met with the Dental Board because the Dental Board is setting up a prescription drug abuse committee. Dentists are the number three prescriber of opioids and the California Dental Board is interested in learning more about the topic.

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.

Minutes from the August 26, 2014 meeting are provided in **Attachment 3**.

Attachment 1

NCPDP PDMP Solution for a National Problem

Nicole Russell
Government Affairs Specialist
August 26th 2014



Why it matters

Prescription drug abuse is a patient safety issue and a public health crisis:

- Unintentional overdose deaths, resulting in approximately one hundred preventable deaths each day, have been classified as epidemic by the CDC;
- Drug-induced overdose deaths now surpass homicides and car crash deaths in America at a cost of more than \$193 billion annually;
- Abuse of opioids results in \$72 billion in medical costs each year.



Benefit of current PDMP programs

- Using web tools to access state PDMP data
- Interconnecting state PDMP's
- Decreasing fraud and abuse
- Future of state PDMP programs:
 - **Now** is the time to take advantage of new technologies and capabilities



State PDMPs lack uniform best practices:

- Lack standards to share drug abuse information effectively, resulting in programs that could be more effective at addressing timely potential drug abuse and diversion, or evaluating patient risk;
- Burdensome and does not effectively provide information at the point of care and in a timely manner.
- Not leveraging current technology and standards
- State specific program requirements need to be consistent



Overcoming Barriers

- Share real-time information at the point of care through the use of existing, interoperable industry standards.
- Reduce burden on providers by incorporating drug abuse information within pharmacy and prescriber workflows
- Enable prescribers and pharmacies to make clinical decisions prior to writing and dispensing medications for proactive intervention
- Ensure access for patients with valid medical needs



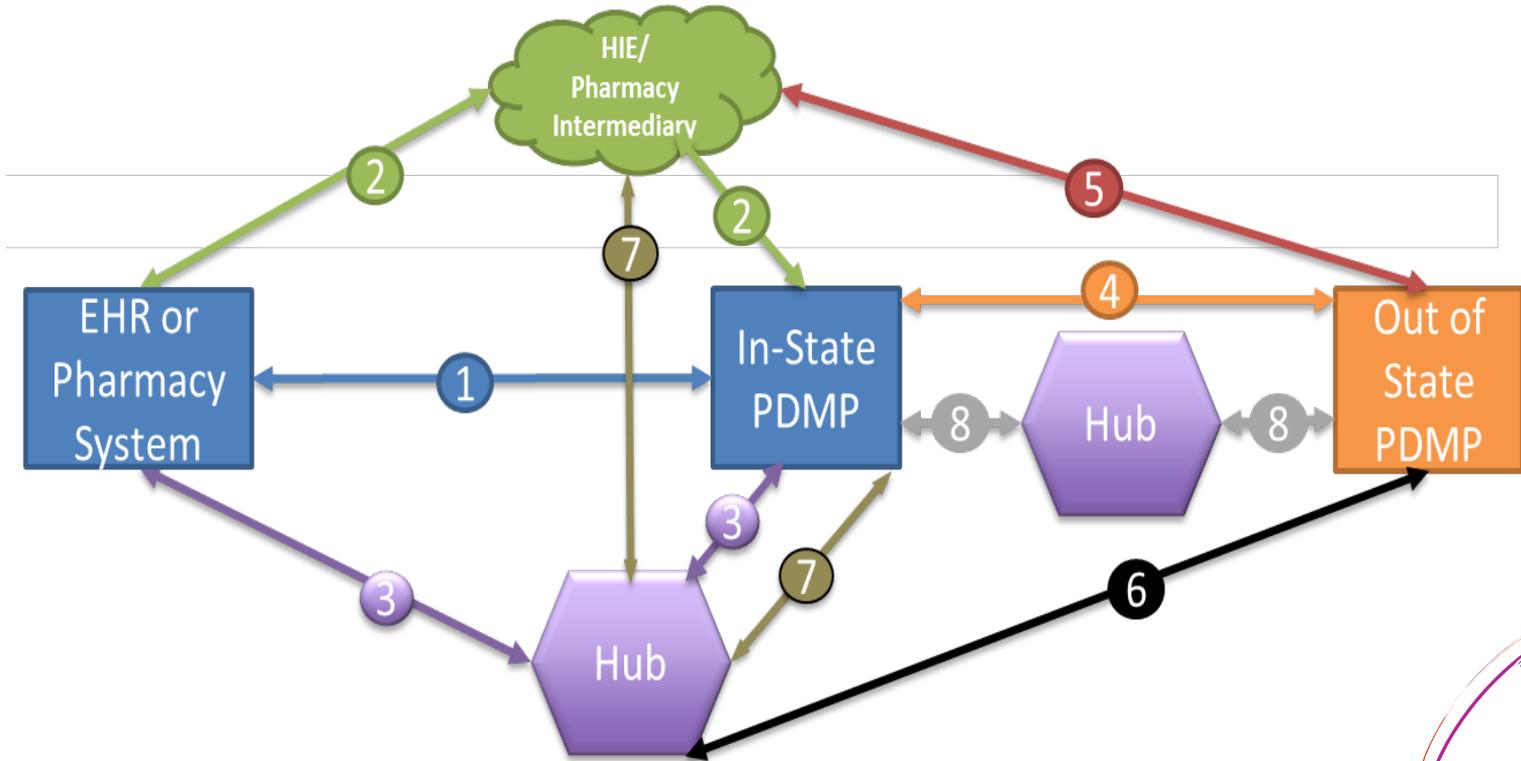
NCPDP White Paper

- A Strategic Action Group meeting on Prescription Drug Monitoring Programs (PDMPs) was held in Baltimore, MD on October 18, 2012. Goals and Objectives of the strategic action group were to identify the current and future issues and needs regarding PDMPs
- At the request of the PDMP Strategic Action Group, during the November 2012 NCPDP Work Group meeting, a PDMP Task Group was formed, with the initial task of developing a White Paper to:
 - Examine the problem
 - Identify future needs
 - Recommend solutions for PDMP data access and role of NCPDP

<http://www.ncdp.org/NCPDP/media/pdf/wp/NCPDP-PDMP-WhitePaper-201303.pdf>



ONC Framework



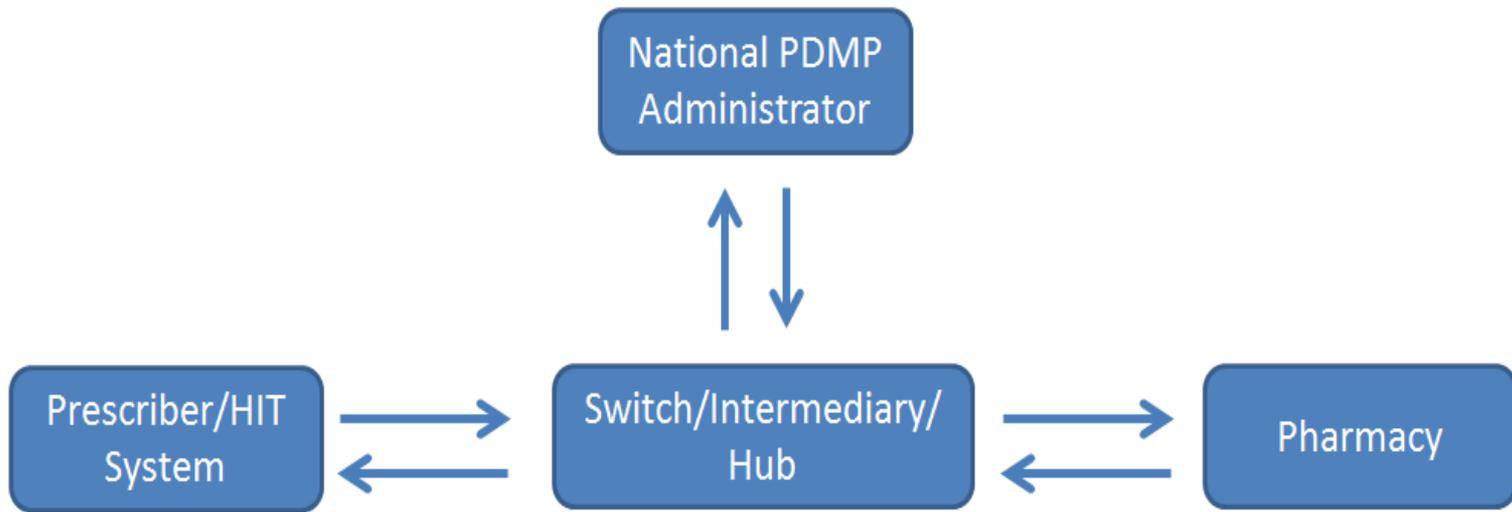
Integrated workflow solution

- **Pharmacy** reports controlled substance dispensing in real time to **National PDMP Administrator** using **Telecommunication Standard**
 - Currently is done via separate batch process
- **Prescriber/HIT System** queries PDMP data from **National PDMP Administrator** at point of care using the **SCRIPT Standard** to make appropriate clinical decisions before the medication is prescribed.
- **Pharmacy** receives clinical alerts from **National PDMP Administrator** via the **Telecommunication Standard** during claim processing that PDMP data needs to be checked prior to dispensing.
- **Pharmacy** queries PDMP data from **National PDMP Administrator** at point of service using the **SCRIPT Standard** to enable appropriate clinical decisions before the medication is dispensed.



Existing NCPDP industry standards

NCPDP's PDMP Transaction Flow



A Sustainable, National Solution for Prescription Drug Monitoring Programs

Utilization of NCPDP's existing standards will enable healthcare providers to deter prescription drug abuse and ensure access for patients with a valid medical need before controlled substances are prescribed – using real-time alerts and responses. This **sustainable, national** approach eliminates data silos and promotes **interoperability**, provides **actionable and timely** information to prescribers and pharmacists using **existing workflows** to ease adoption, and **supports patient safety** efforts to curb a public health crisis.



A Sustainable, National Solution for Prescription Drug Monitoring Programs

Discussion



Attachment 2

Pharmacist Counseling Tips for Opioid Prescriptions

Angela Crispo, PharmD

8/26/14

Constipation

All patients consistently taking opioids are at risk for developing constipation. All opioids have the same risk for causing constipation. Constipation can occur at any dose and if taken consistently the risk increases. Opioids cause the gut to slow down. It is therefore recommended to take a **stimulant laxative**, such as senna or bisacodyl, to help maintain normal bowel function. This side effect does NOT improve over time, so patients will continue to need laxatives for the duration of opioid therapy.

Nausea

Some patients may experience nausea after taking an opioid. This may be worsened if they are also experiencing constipation. This side effect will improve over time, but if they are having severe nausea, providers may be able to prescribe medications to help with nausea related to opioids, e.g. prochlorperazine or metoclopramide.

Sedation

All opioids can cause drowsiness, dizziness and some altered mental status. This is most likely to occur at the beginning of therapy or if doses are increased. For this reason, patients should be encouraged to not drive or participate in any activity that requires full attention and alertness. This side effect will improve over time.

Respiratory depression

In addition, opioids can also cause slow breathing. Though this is rare in patients with chronic opioid use, those who are just starting therapy should be cautious and only take them as prescribed to avoid heavy sedation and slowed breathing.

Addiction

Because opioid abuse and overdose stories are so prevalent in the media, some patients may be frightened and have some misconceptions about them. Here are a few definitions that may be used to help reassure your patients.

- *Tolerance* = requiring a markedly increased dose of the substance to achieve the desired effect or a markedly reduced effect when the usual dose is consumed^{2,3}
 - Example: "Your doctor may need to increase your dose to achieve the same pain relief."
- *Dependence* = physical and chemical changes in the body that causes withdrawal if the substance is stopped abruptly^{2,3}
 - Example: "Your body may get used to the drug so that when it's not present, the body goes through withdrawal. Some common symptoms of withdrawal may be increased blood pressure, sweating, diarrhea and pain."

- *Pseudoaddiction* = abnormal behavior developing as a direct consequence of inadequate pain management⁴
 - Example: "Some people may have behaviors that can be misinterpreted as addiction, such as frequently requesting more or higher doses, to gain attention if they are not getting enough pain relief."
- *Abuse* = any pattern of use that is not as intended for that substance^{2,3}
 - Example: "Using opioids as a sleep aid because they can cause sedation instead of using them for pain."
- *Addiction* = a psychological disease that causes compulsive substance use despite harmful consequences^{2,3}
 - Example: "Some signs of addiction include cravings for the drug despite having no pain, not attending to home, work or school responsibilities due to spending too much time getting, using or recovering from the drug, or continuing to use the drug despite knowing it is causing harm either physically or socially."

This may be a difficult and uncomfortable conversation for both parties. While it is important to relay all risks of any drug with a patient, it is essential to not make the patient feel as if they are being judged and understand they do not have to be labeled an addict simply by taking these medications. Simple ways to approach the topic include:

- "Do you have any concerns about this medication?"
- "What kind of information do you already know about this medication?"
- "I would like to take a moment to talk to you about what can happen with the long-term use of this medication."

References

1. Zichterman A. Opioid pharmacology and considerations in pain management. Continuing education program. Postgraduate Healthcare Education, LLC. 2009.
2. O'Brien CP. Drug addiction. In: *Goodman and Gilman's The pharmacological basis of therapeutics. 12th edition*. New York: McGraw Hill. 2011.
3. American Psychiatric Association. *Diagnostic and statistical manual of mental disorders* (5th ed.). Washington, DC: American Psychiatric Publishing; 2013.
4. Weissman DE, Haddox JD. Opioid pseudoaddiction – an iatrogenic syndrome. *Pain*. 1989;36(3):363-6.

Attachment 3

**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.

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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

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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.