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STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
ENFORCEMENT AND COMPOUNDING COMMITTEE
MEETING MINTUES
MARCH 26, 2015

DATE: March 26, 2015

LOCATION: DCA Headquarters Building Two
1747 North Market Blvd., Room 186
Sacramento, CA 95834

COMMITTEE MEMBERS PRESENT:
Amy Gutierrez, PharmD, Chair, Professional Member
Greg Lippe, Public Member

COMMITTEE MEMBERS NOT PRESENT:
Rosalyn Hackworth, Public Member
Greg Murphy, Public Member
Allen Schaad, RPh, Professional Member

STAFF PRESENT:
Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Janice Dang, PharmD, Supervising Inspector
Desiree I. Kellogg, Deputy Attorney General
Laura Freedman, DCA Staff Counsel
Michael Santiago, DCA Staff Counsel
Susan Cappello, Enforcement Manager

Call to Order

Dr. Gutierrez, chair of the committee, called the meeting to order at 10:16 a.m.

Dr. Gutierrez welcomed those in attendance. Roll call of the board members present was taken and a quorum of the committee was not established.

I. PUBLIC COMMENT FOR ITEMS NOT ON THE AGENDA/AGENDA ITEMS FOR FUTURE MEETINGS

No public comments were received.

II. ENFORCEMENT MATTERS

a. PRESENTATION: Kim Fleming on EMD Serono's Program to Permit Patients to Authenticate Medication Via Checking a Serial Number on a Medication Container Against a Manufacturer's Data Base

Background

At this meeting, Ms. Fleming requested the opportunity to provide information about EMD Serono's smartphone application that allows a patient to scan the two dimensional barcode to verify the authenticity of a prescription.

Discussion and Comment

Ms. Fleming provided a brief explanation of EMD Serono's background and its affiliation with Merck KGaA in Germany.

Ms. Fleming also provided an overview of the "Check My Meds" smartphone application that helps you and your healthcare professional verify the integrity of EMD Serono prescriptions. This application was developed to meet the requirements of the U.S. Food and Drug Administration's (FDA) effort to verify the authenticity of all drugs dispensed to patients regarding product integrity to safeguard patients against counterfeiting.

Ms. Fleming stated that the application would allow a patient to scan the two dimensional barcode. The two dimensional barcode includes the global trade identification number, expiration date, lot number and serial number encoded into the barcode which is then generated and printed on each package during the packing process.

Ms. Fleming further explained the different messages that would appear on the application and options within the application.

Mr. Lippe inquired if the application would indicate if there was a recall on a drug. Ms. Fleming indicated that a message would appear on the screen directing the patient as to what steps to take next.

Ms. Herold stated that this application was what the e-pedigree project was all about. Dr. Gutierrez asked how many medications are available to be serialized and was advised that the application only verifies EMD Serono's medications.

Ms. Fleming also provided a demonstration on how to use the application and also noted that the application would not scan a linear barcode.

Dr. Gutierrez asked if the application was available today and was advised that it was. Dr. Gutierrez also inquired on how many calls EMD Serono receives and was advised by Ms. Fleming that the calls being receiving were regarding the application itself and not counterfeiting.

Mr. Lippe asked if EMD Serono would be licensing this application with other companies. Ms. Fleming advised that EMD Serono has received calls from other companies that are excited about the application and would like to come together for a single application but are not yet ready to start this process.

Ron Bone inquired if a recall message was the same as a discontinued message. Ms. Fleming indicated that if EMD Serono was no longer marketing a particular product the message with alert the patient to contact EMD Serono.

Dr. Dang stated that most pharmacies are moving towards automation and that prescriptions are not always being dispensed in its original packaging and was concerned that the application would not account for this. Ms. Fleming advised that most of EMD Serono's medications are packaged in a 30-day or 90-day supply and that the patient would most likely be receiving the original container. Dr. Dang further indicated that most chain stores have automation and the product is being removed from its original container when dispensed and repackaged into a prescription vial.

Dr. Dang also inquired if EMD Serono uses any of the personal information the patient used to register and was advised that only a username and password were required and EMD Serono didn't have access to that information.

Dr. Gutierrez requested clarification on the packaging and where the barcode is located if the patient didn't receive the entire package. Ms. Fleming indicated that if a patient didn't receive a full package product, that EMD Serono would then verify the lot number and expiration date.

Pharmacist Tony Wong asked what type of advice EMD Serono was providing in regard to counterfeit or illegitimate products. Ms. Fleming advised that EMD Serono would ask for the product to be returned for internal testing to be conducted and a replacement product would be provided. RPH Wong also inquired if the patient would be referred to a health care provider and was advised that a patient would be directed to the drug safety group that has medical professionals available.

There was no further public or committee comment.

b. PRESENTATION: Michael Galloway of MatchRx on Its Model to Enable the Transfer of Prescription Medication in Short Supply Between Two Pharmacies

Background

At this meeting, a PowerPoint presentation was provided by Michael Galloway regarding the transfer of prescription medication in short supply between two pharmacies.

MatchRx is a private web-based inter-pharmacy marketplace for non-controlled, non-expired overstocked prescription drugs and drugs in short supply. MatchRx maintains safe, secure and detailed electronic transaction records, providing track and trace compliance for dispenser-to-dispenser transactions.

Discussion and Comment

Ron Bone stated that he thought the service provided by MatchRx was a great way for people to maintain the data that has to be maintained as part of the drug security act.

John Kello provided an overview of MatchRx's services which connects independent pharmacies in resolving three longstanding problems; 1) eliminate costly overstock before it expires; 2) locating small quantities of difficult to find medications; and 3) minimize pharmaceutical waste. Members of MatchRx would purchase small quantities of non-controlled, non-expired overstock from other members to satisfy specific patient requirements, locate items temporarily in short supply, supplement limited buying resources, and mitigate dramatic price increases of certain drugs.

Michael Galloway explained that no controlled substances were allowed on the web site and that only non-controlled and unexpired drugs were offered and are validated through Medi-Span. Dr. Gutierrez inquired if HIV and Hepatitis C medications were allowed and she was advised that HIV medications were allowed unless the manufacturer has a restriction that prevents a pharmacy from reselling.

Mr. Galloway indicated that only community pharmacies were allowed to become members and were screened through NCPDP Database and background searches of pharmacies are conducted. Mr. Galloway further stated that pharmacies that are wholesalers and internet pharmacies could not become members.

Dr. Gutierrez inquired if the remaining pills of an open package and/or refrigerated items could be sold and was advised that open packages could be sold and that refrigerated items must be shipped Monday through Thursday by FedEx Priority Overnight only. Dr. Gutierrez also inquired if a pharmacy could sell or buy across state lines. Dr. Gutierrez was advised that a pharmacy could but that the buyer wouldn't know where the product is coming from until the seller indicates they have medication to sell.

Dr. Gutierrez also inquired if a patient is notified that the pharmacy is participating in MatchRx and was advised that there was no requirement to notify the patient but the patient was often notified when something wasn't available and that the pharmacy was participating in MatchRx.

Public Comment
Dr. Dang stated that if a pharmacy is shipping into California it would have to be licensed as a nonresident pharmacy pursuant to Business and Professions Code section 4112. Ms. Herold stated that this would be something the board would have to take a look at legally since it would be coming under the auspice of a third-party logistics provider.

There was no further public or committee comment.

c. PRESENTATION: Jan Hirsch, BSPharm, PhD of UCSD on a Research Proposal Pursuant to 16 California Code of Regulations Section 1706.5 to Permit Patients to Access Medications from an Automated Storage Device Not Immediately Adjacent to a Pharmacy, and an Assessment of the Research Design by Board Member Ramon Castellblanch, PhD

Background
Several years ago, the board promulgated regulations (16 California Code of Regulation section 1713) to allow for the use of automated delivery devices, which are markedly like vending machines, to permit the furnishing of refill medication in specified circumstances, to include the requirement that the patient must opt in to use the machine and that the medication to be refilled through the machine is appropriate.

In recent years, the board has received several requests to use automated delivery devices in a variety of settings including workplace clinics, hospital lobbies, other areas on a hospital campus, and in employment locations. During each of these discussions, several concerns were raised about whether the request would comply with current regulations and whether the board had the authority to approve the request without specific regulatory changes. To date the board has not approved any waivers since enactment of the regulation.

At the June 2013 committee meeting, representatives from Asteres and Sharp Healthcare requested a revision to section 1713 to allow three separate pilot studies on the campuses of Sharp, UCSD Health System and USC Hospital to expand the use of automated delivery devices. At the July 2013 board meeting, Mr. Burgess, representing Asteres reminded the board that section 1713(b) already allows the delivery of prescriptions to employees at their worksite.

Mr. Burgess proposed to revise section 1713(d)(6) to allow for the placement of automated devices in a secure building controlled by a Board licensee at an alternate location readily accessible for Board inspection, but not adjacent to a secure pharmacy area.

At the July 2013 board meeting where this proposal was discussed, the board asked that Dr. Castellblanch provide assistance in developing a more traditional research protocol. Following the meeting, Dr. Castellblanch did provide this review and his comments were sent to the lead researcher at UCSD, Charles Daniels, for incorporation into a more robust research proposal.

In November 2014, UCSD approved the Experimental Program/Research Study on Automated Delivery Systems.

At this meeting, Dr. Hirsh will provide a PowerPoint presentation that provides an overview of the research study.

Discussion and Comment

At this meeting, Dr. Hirsh of University of California, San Diego and Kim Allen of Sharp Rees-Stealy, provided a PowerPoint presentation that provided an overview of the research study and protocol.

Dr. Gutierrez inquired if refills were going to be handled separately than new prescriptions. Ms. Allen advised that the kiosk will withhold the refill prescription, if in the pharmacist's professional judgment, that a refill needs counseling.

Dr. Gutierrez introduced Dr. Castellblanch, board member, who advised the committee that he reviewed the current IRB protocol and indicated that it is a well-designed protocol for the committee to consider. Dr. Castellblanch further indicated that he was not a pharmacist and could not comment on potential risks or the need for informed consent.

Dr. Gutierrez sought clarification from Laura Freedman and Michael Santiago, DCA counsel, on whether a vote was required to bring the IRB protocol to the board. Counsel advised the committee that the two members can agree to bring the proposal to the board as a subcommittee. Dr. Gutierrez and Mr. Lippe both recommended bringing the protocol to the board for action.

Ms. Herold asked that if a participant agreed to participate in this study voluntarily, if it would be considered a form of consent. Dr. Hirsh advised that because there is no identifying information being given that no consent is needed.

Ms. Sodergren asked how a patient would be contacted when a consultation is required. Ms. Allen advised that when a participant is identified as needing a consultation, the prescription would be filled by the pharmacist and it's at that time the pharmacist would attempt to contact the participant for a consultation. The medication will still be placed in the kiosk but not be released until consultation has occurred.

There was no further public or committee comment.

The committee thanked Dr. Castellblanch for his work on reviewing the protocol.

d. DISCUSSION: <u>Drug Enforcement Administration's Regulations for the Take Back of Prescription Medication and Development of Regulations for Pharmacies and Reverse Distributors Who Take Back Prescription Medication from Patients</u>

<u>Background</u>
On September 9, 2014, the DEA released its regulations on the take back of drugs from the public – specifically the take back of controlled substances.

The final rule authorizes certain DEA registrants (manufacturers, distributors, reverse distributors, narcotic treatment programs, retail pharmacies, and hospitals/clinics with an on-site pharmacy) to modify their registration with the DEA to become authorized collectors. All collectors may operate a collection receptacle at their registered location, and collectors with an on-site means of destruction may operate a mail-back program. Retail pharmacies and hospitals/clinics with an on-site pharmacy may operate collection receptacles at long-term care facilities.

At the December 2014 committee meeting, Ms. Herold provided an overview of the DEA's new drug take-back regulations. Committee discussion included how an average person would know which drugs are acceptable for disposal. The committee heard comments from the public in which the board was asked not to place the collection burden on pharmacists.

At the January Board Meeting, the board was advised that the committee would be working on draft regulations for drug take back.

At this meeting, the committee reviewed proposed language prepared by Ms. Herold for a California regulation for drug take back from pharmacies and reverse distributors.

<u>Discussion and Comment</u>
Ms. Herold provided a brief overview of the first draft of the proposed language that would provide guidance to pharmacies that are registered with the federal Drug Enforcement Administration to assist patients seeking to destroy unwanted, dispensed prescription medication.

This language would also provide guidance to reverse distributors and those pharmacies who wish to establish a mail back service or provide a collection receptacle in the pharmacy.

Mr. Lippe inquired as to how a patient would know if their prescription was a Schedule I drug that couldn't be deposited in the receptacle. Ms. Herold stated that patients wouldn't necessarily know if their drugs couldn't be placed in the receptacle.

Dr. Gutierrez inquired if the collection receptacles had to be located inside the pharmacy. Ms. Herold suggested going with the mail back option if a pharmacy is concerned with the receptacle being placed in the pharmacy.

Dr. Gutierrez suggested obtaining some input from pharmacies with history and experience with a take back program.

Dr. Gutierrez stated that San Francisco just approved their protocol and is rolling it out. Ms. Herold stated that San Francisco will have to follow the DEA requirements because there is nothing else in place.

Steve Gray, representing Kaiser Permanente, indicated that he has been very much involved with the development of the San Francisco ordinance developing a pilot program. It was their position that the pharmacies could not be involved until the California Board of Pharmacy had given their approval, as well as DEA, if controlled substances were going to be involved. Dr. Gray also stated that the pharmaceutical producers would be paying for the envelopes as part of the process. Dr. Gray indicated that San Francisco intends to offer all types of return options, whether it is collection sites or envelopes for mail away.

Dr. Gutierrez advised that the committee will bring this item back to the next committee meeting.

There was no further public or committee comment.

Dr. Gutierrez recessed for a 45-minute lunch break at 11:58 am.

The meeting reconvened at 12:51 pm.

e. DISCUSSION: <u>Evaluation of 16 CCR Section 1744 Regarding Required Warning Labels on Prescription Container Labels</u>

<u>Background</u>

Prior to July 1, 2014, Pharmacy Law required a pharmacist to inform a patient orally or in writing of the harmful effects of a drug: (1.) if the drug posed a substantial risk to the person consuming the drug, when taken in combination with alcohol, or if the drug could impair a person's ability to drive a motor vehicle, and (2.) the drug was determined by the Board of Pharmacy to be a drug or drug type for which the warning shall be given.

Assembly Bill 1136 (Levine), signed by the Governor on September 9, 2013, amended existing law to require a pharmacist on or after July 1, 2014, to include a written label on a prescription drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel, if in the pharmacist's professional judgment, the drug may impair a

person's ability to operate a vehicle or vessel. The required label may be printed on an auxiliary label that is affixed to the prescription container.

Section 1744 of the board's regulations provides the specific classes of drugs which trigger a pharmacist's verbal or written notice to patients where a patient's ability to operate a vehicle (and now a vessel) may be impaired. This section has not been revised in a number of years, so recently the schools of pharmacy were asked to provide comments to the list of medications listed in this regulation.

A number of California's schools of pharmacy provided comments. Those comments were integrated in the first draft.

At the September 2014 committee meeting, the committee revised those comments into the version that was referred to the board for action.

However, at the October Board Meeting, the board sent the language back to the committee for further discussion and review.

At the December 2014 committee meeting the committee heard legal guidance that the board needs to update 4074(a) with the drugs or drug classes it believes should require a warning label for posing a substantial risk when taken with alcohol, or for impairing one's ability to safely operate a vehicle or vessel.

Ms. Herold proposed the following language for committee review and discussion regarding changes from the prior proposal and indicated below in double underscore and double strikeout.

1744. Drug Warnings

Pursuant to Business and Professions Code Section 4074, a pharmacist shall inform the patient or his or her representative of the harmful effects of certain drugs dispensed by prescription. Whenever ~~If~~ a pharmacist exercising his or her professional judgment determines that a drug may impair a person's ability to operate a vehicle or vessel, the pharmacist shall include a written label on the drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel.

(a) The following classes are examples of drugs that may impair a person's ability to drive a motor vehicle, vessel or operate machinery when taken alone or in combination with alcohol and that require a written warning notice on the label:

(1) Muscle relaxants.

(2) ~~Analgesics with central nervous system depressant effects.~~

~~(3)~~ Antipsychotic drugs with central nervous system depressant effects ~~including phenothiazines~~.

(~~4~~3) Antidepressants with central nervous system depressant effects.

(~~5~~4) Antihistamines, motion sickness agents, antipruritics, antinauseants, anticonvulsants and antihypertensive agents with central nervous system depressant effects.

(~~6~~5) All Schedule II, III, IV and V agents with central nervous system depressant effects. ~~or narcotic controlled substances as set forth in Health and Safety Code at Section 11055 et seq. prescribed in doses which could have an adverse effect on a person's ability to operate a motor vehicle.~~

(~~7~~6) Anticholinergic agents ~~and other drugs which may~~ that impair vision.

(b) The following are examples of drugs which may have harmful effects when taken in combination with alcohol. While these ~~These~~ may or may not affect a person's ability to operate a motor vehicle they still require a written warning notice on the label to alert the patient about possible problems:

(1) Disulfiram and other drugs (e.g., chlorpropamide, metronidazole) which may cause a disulfiram-like reaction.

(2) Mono amine oxidase inhibitors.

(3) Nitrates.

(4) Cycloserine.

(5) Insulin (hypoglycemia) antidiabetic agents including insulin and sulfonylureas (due to risk of hypoglycemia).

Discussion and Comment

Ms. Herold highlighted the current changes made to the proposed language. Dr. Gutierrez asked DCA counsel if the current proposed version would meet the law. Counsel advised that they had not had an opportunity to review the proposed language.

Comments included adding a sentence to possibly making the language more clear regarding the classes of drugs listed in subsections (a) and (b), such as, “require written warning notices on the labels,” as well as adding language to subsection (b) regarding

potential harmful effects of the drugs when taken with alcohol and removing "examples" from the proposed language.

Michael Santiago, DCA counsel, stated that the statute requires that a pharmacist shall inform a patient orally or in writing, however, the proposed language states that the warning must be in writing.

The committee requested DCA counsel to modify the language so that it could be brought to the board at its April 2015 meeting. Counsel agreed to review and amend the language.

Dr. Gray stated that subsection (a) in the statute allows for the warning to be given orally or in writing whereas subsection (b) requires it to be in writing and this may be where the confusion lies with respect to what needs to be in writing or what can be done orally.

There was no further public or committee comment.

f. DISCUSSION AND POSSIBLE ACTION: Proposed Regulation for Pharmacies Aimed at Reducing Losses of Controlled Substances

Background

At the March 2014 Enforcement and Compounding Committee Meeting, Chairperson Gutierrez led a discussion of losses of controlled substances reported to the board as required by California Pharmacy law. A pharmacy or a wholesaler must report any loss of controlled substances to the board within 14 days.

The board's staff compiled some statistics regarding drug losses reported to the board over the last few years.

In 2013, 3.06 million dosage units of controlled substances were reported to the board as lost. This includes 1.7 million units that were from a major manufacturer who had a truck stolen. These numbers are only estimates provided by the entity when they first realize there has been a loss. As such, the reported numbers are most likely significantly less than actual losses.

The committee expressed concern about the significant losses and the need for more stringent inventory controls in pharmacies to identify losses resulting from employee pilferage. Comments from the committee included developing steps for inventory controls, which could be done either by regulation, statute or policy and perhaps reconciling the top ten drugs for the pharmacy.

At the January Board Meeting, the board reviewed proposed language from the committee. The proposed language was rejected by the board and Chair Gutierrez and Ms. Herold reported that the committee would continue to revise the language.

At the January Board Meeting, after hearing comments from the board and the public, board staff has revised the proposed language into the version below.

1715.65 Monthly Inventory Counts of Controlled Substances

(a) Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall maintain a perpetual inventory for all controlled substances acquired by the licensee. A perpetual inventory as used in this article shall mean an inventory system whereby the pharmacy's or clinic's records about stock on hand for every controlled substance acquired and dispensed are continuously updated to reflect the actual quantity of stock on hand. Such an accounting will include all acquisitions and all dispositions for each controlled substance.

(b) As an alternative to the maintenance of a perpetual inventory in subdivision (a), a pharmacy or clinic must have a written policy that identifies a monthly reconciliation process for the 10 highest volume controlled substances acquired by the licensee in the last year (or as determined by the last DEA biennial inventory, or as purchased by the pharmacy if there has been no biennial inventory taken). This policy shall address reconciliation of all purchases and acquisitions, dispensings, transfers and current inventory, including the inventory in quarantine for a reverse distributor. The pharmacy or clinic shall perform a count of these 10 controlled substances pursuant to this policy every month.

(c) The pharmacist-in-charge of a hospital pharmacy or of pharmacy servicing skilled nursing homes wherever an automated drug delivery system is used shall review at least once each month all controlled substances removed from or added into each automated drug delivery machine operated by the pharmacy. Any discrepancy or unusual access identified shall be investigated. Controlled drugs inappropriately accessed or removed from the automated delivery shall be reported to the board within 14 days.

(d) Losses of controlled substances identified by pharmacies from the perpetual inventory or monthly audit shall be reported to the board as required by section 1715.6 and California Business and Profession Code section 4104.

(e) A clinic shall report to the board all losses detected from the perpetual inventory or monthly audit undertaken pursuant to this section within 14 and no later than 30 days.

(f) The pharmacist-in-charge or consultant pharmacist for the clinic shall sign and date each monthly reconciliation within 14 days of completion. These signed reconciliations shall be retained by the licensed premises for three years and be readily retrievable for review by the board.

(g) The pharmacist-in-charge or consultant pharmacist shall review all inventories and reconciliations to establish and maintain secure methods to prevent losses of dangerous drugs.

Discussion and Comment

Megan Maddox, representing CPhA, indicated that CPhA strongly supports the proposed regulation if the board narrowed the regulation to Schedule II only. Ms. Maddox indicated that some of CPhA's members' top drugs are hormones and didn't think the board was interested in hormones but rather drugs that were being diverted. Ms. Maddox suggested changing the regulation to the top 5 if the board was going to require Schedule II to IV. Ms. Maddox further stated that physical counting of the drugs would become consuming and burdensome.

Dr. Gutierrez asked Ms. Herold if the board could require that the regulation state Schedule II only and any other drug identified by the board. Ms. Herold stated that this type of language would require a different regulation and the board would need to identify what drugs it wanted tracked most likely in a regulation, to be able to enforce it.

Mr. Lippe suggested starting with Schedule II drugs. Dr. Gutierrez agreed with this suggestion and to reevaluate it in a year.

Dr. Dang stated that it would be a disservice to the board if the regulation only focused on Schedule II controlled substances. Dr. Dang stated that the reason that high quantities of hydrocodone products were being diverted was because it was easier to order Schedule III, IV, and V don't require a DEA-222 form. Dr. Dang also stated that a fair amount of the benzodiazepine's (IV) and Phenergan with codeine (V) are also being diverted and should consider these drugs.

Dr. Gray, representing Kaiser, supports this proposed regulation but would like the regulation to define the definition of reconciliation because pharmacy students are not trained on "reconciliation."

Dr. Gray also stated that the language was confusing regarding perpetual inventory and monthly reconciliation. Dr. Gutierrez stated that a perpetual inventory includes reconciliation.

Christine Versichele, representing Dynalabs, sought clarification on whether hospital pharmacies are also required to report and was advised that hospitals are required to report.

Dr. Gutierrez agreed with Dr. Dang's point regarding non-Schedule II controlled substances being more easily diverted because of higher security measure normally taken with

Schedule II medications and she recommended leaving the language as the top ten because of the ordering processing.

Mr. Lippe suggested revising the language to the top five as a compromise to keeping it to read as all controlled substances. Mr. Lippe and Dr. Gutierrez agreed to reduce the language from top ten to the top five as well as including a definition of reconciliation to the language.

The following language will be brought to the April board meeting for consideration:

1715.65 Monthly Inventory Counts of Controlled Substances

(a) Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall maintain a perpetual inventory for all Schedule II controlled substances acquired by the licensee. A perpetual inventory as used in this article shall mean an inventory system whereby the pharmacy's or clinic's records about stock on hand for every Schedule II controlled substance acquired and dispensed are continuously updated to reflect the actual quantity of stock on hand. Such an accounting will include all acquisitions and all dispositions for each Schedule II controlled substance.

(g) As an alternative to the maintenance of a perpetual inventory for Schedule II controlled substances in subdivision (a), a pharmacy or clinic must have a written policy that identifies a monthly reconciliation process for the five highest volume controlled substances acquired by the licensee in the last year (or as determined by the last DEA biennial inventory, or as purchased by the pharmacy if there has been no biennial inventory taken). This policy shall address reconciliation of all purchases and acquisitions, dispensings, transfers and current inventory, including the inventory in quarantine for a reverse distributor. The pharmacy or clinic shall perform a count of these five controlled substances pursuant to this policy at least every month.

(h) The pharmacist-in-charge of a hospital pharmacy or of pharmacy servicing skilled nursing homes wherever an automated drug delivery system is used shall review at least once each month all controlled substances removed from or added into each automated drug delivery machine operated by the pharmacy. Any discrepancy or unusual access identified shall be investigated. Controlled drugs inappropriately accessed or removed from the automated delivery shall be reported to the board within 14 days.

(d) Losses of controlled substances identified by pharmacies from the perpetual inventory or monthly audit shall be reported to the board as required by section 1715.6 and California Business and Professions Code section 4104.

(e) A clinic shall report to the board all losses detected from the perpetual inventory or monthly audit undertaken pursuant to this section within 14 and no later than 30 days.

(f) The pharmacist-in-charge or consultant pharmacist for the clinic shall sign and date each monthly reconciliation within 14 days of completion. These signed reconciliations shall be retained by the licensed premises for three years and be readily retrievable for review by the board.

(g) The pharmacist-in-charge of a pharmacy or consultant pharmacist shall review all inventories and reconciliations to establish and maintain secure methods to prevent losses of dangerous drugs.

Ms. Sodergren sought clarification on whether the committee wanted the revised language to be brought back to the committee or to bring it to the full board and was advised that the revised language should be brought to the full board at its next meeting.

There was no further public or committee comment.

g. PRESENTATION: <u>Demonstration by Carefusion on Drug Diversion Deterrent Reports Available with Their Automation Storage Containers</u>

<u>Background</u>
At this meeting, a representative from Carefusion will provide an overview of the drug diversion reports available with the use of their Pyxis automation.

<u>Discussion and Comment</u>
Representatives from Carefusion provided information regarding Pyxis technologies and its various reports used to monitor for diversion with a Pyxis machine.

Crystal Woodward, representing Carefusion, indicated that Pyxis machines are primarily used in hospitals and are tied to the pharmacy information system. Carefusion's Enterprise System (ES) has one database that can spread across several hospitals which can be controlled by the corporate office. This system can also be accessed over the web or at any hospital computer system.

One attendee asked if the Pyxis machine was connected to Omnicell and was advised that Omnicell had its own product.

Steve Gray, representing Kaiser, asked if some hospitals used the drawers for patient specific drugs and medication specific drugs and was advised that it could not be used for patient specific drugs.

Mr. Lippe asked if the BioID was more sensitive and was advised that there is a workaround should a fingerprint get rejected. An authorized user could scan a barcode to gain access. The hospital can add an additional layer of security to the device by adding a pad lock on the back of the machine.

Dr. Gutierrez asked how often it was recommended that a perpetual inventory be taken and was advised that it varied by each hospital but was taken at least once a month.

Shari Gaukroger, representing Carefusion, indicated that access to the data can go back ten years for an audit to be conducted. The hospital can pull a report to look at any user, any transaction, any medication and any patient to reconcile the machine and can be tied together between more than once hospital location. Carefusion provides suggested reports to be used for controlled substance management and reconciliation. These reports can also be programmed to run automatically.

Dr. Gray inquired if the machine had the capability to tie the loop back to compare what was taken out of the machine and administered at the bedside and was advised that this function was currently being developed. Dr. Gray also asked if the systems hardware is being used by outpatient pharmacies and was advised that the regulations are different for outpatient so the software is different.

Dr. Dang asked how many facilities are using these machines and was advised that about 1,300 have been installed throughout the Unites States. Dr. Dang also inquired how many facilities in California were using the machines and was advised that this number was unknown.

There was no further public or committee comment.

The PowerPoint slides can be found at the back of the minutes.

h. DISCUSSION: <u>Proposed Regulations for Third-Party Logistics Providers; Proposed Amendments to 16 California Code of Regulations Sections 1780 -1786</u>

<u>Background</u>
In 2014, the board sponsored legislation to enact provisions to license third-party logistic providers as a separate class and not as the board had previously done under the category of wholesaler. This legislation was enacted by AB 2605 (Bonilla, Chapter 507, Statutes of 2014). This legislation was needed because federal law enacted in 2013 prohibited licensure of third-party logistics providers as wholesalers.

The board now needs to amend its regulations to ensure that third-party logistics providers also must adhere to board regulations for all drug distributors, whether they are a wholesaler or third party-logistics provider.

At this meeting, the committee will review and discuss proposed regulation requirement for third-party logistics providers that originate from drug wholesalers. The committee will also review and discuss a proposed revised self-assessment form that will be part of the process.

Discussion and Comment

Ms. Herold stated that the regulations for wholesalers were developed over a period of time and that some of the language is now in statute and will be removed from the regulation. The revised language provides added details on how a third-party logistics provider is directed to protect the products in storage or being selected at its facility. Ms. Herold also indicated that the board's goal for requiring a self-assessment which includes the general requirements for which a board inspector will look for when inspecting a facility. Ms. Herold stated that the proposed language is still a draft and still in the process of setting up the program.

Pat O'Connor, representing International Warehouse Logistics Association (IWLA), whose members are warehouse based third-party logistics providers. The role of the provider is to receive, store, and ship product but, never own, sell, or make decisions on how to dispose of the product. Mr. O'Connor indicated that IWLA reviewed the most recent draft of the proposed rule and it felt that many of the provisions of the proposal are subject to federal preemption under the Drug and Supply Chain Security Act. Mr. O'Connor urged the committee to not move forward on the proposed rule until the FDA issued its final licensing standards due in November 2015. Mr. O'Conner invited the board and committee to visit a third-party logistics provider to see how it operates.

Dr. Gutierrez asked for an example of a third-party logistics provider in California and was advised that there were few in the pharmaceutical drug space but that the best example was Florida which is the only state requiring licensure with 160 being licensed. One of the major third-party logistics providers in California is UPS Supply Chain Systems (UPS SCS). The product is managed through Warehouse Management System that tracks inventory supply coming and going out.

John Spence, representing UPS SCS, indicated that UPS SCS is essentially a storage and management facility. Some manufacturers doing business with UPS SCS have a pallet in and pallet out model. In some instances, UPS SCS may break down a case of medication and distribute a smaller quantity to a pharmacy or distribution center.

Dr. Gutierrez asked if UPS SCS functioned as a warehouse for the manufacturer and was advised yes, that they served as a warehouse for the manufacturer but not always on a pallet in and pallet out basis.

Dr. Dang stated one of concerns of a third-party logistics provider is the storage of the medications. Dr. Dang shared a scenario from an inspection of a third-party logistics provider where the drugs were being stored next to cleaning agents and other products as

well as not being aware of storage requirements such as temperature and humidity control. There was also only one designated representative-in-charge on location during the day but the facility was open 24/7.

Mr. O'Conner stated that a manufacturer would not allow their product to be stored in these types of conditions and that the FDA had strict guidelines for storage requirements.

Dr. Gutierrez asked Mr. Spence who would be notified if there is a drug loss and was advised that a report is filed directly to the DEA and to the applicable state board of pharmacy.

Christine Versichele, representing Dynalabs, stated that third-party logistics providers are an important part of the supply chain.

i. PRESENTATION: <u>CURES Data on the Impact of the Federal Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II</u>

The board's staff has compiled the data regarding the number of oxycodone and hydrocodone prescriptions dispensed before and after hydrocodone was rescheduled to Schedule II in October.

<u>Discussion and Comment</u>
Ms. Herold provided an overview of the attached charts for hydrocodone and oxycodone prescriptions dispensed in 2014 compared to what was dispensed the prior year during the same time period.

Comments from the committee included that there didn't appear to be much of a difference between the two time periods and one member thought that some abusers may be switching over to heroin rather than hydrocodone products.

There were no comments from the public.

j. DISCUSSION: <u>Regarding the Adoption of e-Prescribing</u>

<u>Background</u>
E-prescribing had been required for all New York State prescriptions effective March 27, 2015, pursuant to regulations adopted by New York State. Recent legislation has delayed this implementation for one year, to March 27, 2016. At the last committee meeting, the committee heard a presentation by New York's Board of Pharmacy Executive Officer Larry Mokhiber.

Provided as background on this topic was a 2013 project report of two locations in California that were pilot testing e-prescribing.

Discussion and Comment

Dr. Gutierrez asked if the board would be regulating SureScripts. Ms. Herold responded that it would be up to the DEA if California would regulate. In a meeting held by the DEA, the DEA encouraged e-prescribing but was uncertain of the impact on New York prescribers.

Ms. Herold requested the DEA to post on their website a list of audited and approved software that prescribers and pharmacies can use.

There were no public comments.

k. DISCUSSION: Regarding Duty Inspector

Background

At the October 2014 Board Meeting, Ms. Herold reported that the board had reinstated the duty inspector wherein one inspector is assigned to respond to emergent inquiries. The duty inspector takes called from 9 AM to 11 AM on Monday, Wednesday and Friday.

At this meeting, Dr. Dang will provide an update regarding how the duty inspector program is progressing.

Discussion and Comment

Dr. Dang reported that an inspector spends an average of 11 hours a week responding to calls received during an assigned week. Since the inception of the duty inspector program, the board has received an average of 24 questions a week.

Dr. Gutierrez asked if the board could put together some kind of guidance document of FAQ's to post on the board's website or publish in the Script and was advised that it was the intention of the board to put something together for the Script. Dr. Gutierrez also asked about limiting this service to licensed pharmacists and was advised that it was up to the board to determine.

One comment received from the public was that this was a valuable service to the public and need to keep it going. No further comments from the public were received.

The PowerPoint slides can be found at the back of the minutes.

III. COMPOUNDING MATTERS

a. INFORMATION: Report of Sterile Compounding Pharmacy Inspections Conducted

Dr. Dang provided information about sterile compounding inspections and violations identified since December 1, 2014.

There were no public or committee comments.

IV. REMAINING MEETING DATES FOR 2015

Dr. Gutierrez stated that the committee has established the following enforcement committee dates:

June 24, 2015
September 2, 2015
December to be determined

There were no public or committee comments.

Dr. Gutierrez adjourned the meeting at 3:23 pm.

Maximize the security, availability and predictability of medications

CUBIE® system for Pyxis® technologies

Safe, effective medication administration is a multidisciplinary responsibility shared by nursing and pharmacy, with time to initial dose critically affecting patient care. The practice of getting the right medication, to the right patient, at the right time depends on numerous factors—and is often hindered by challenges in safety, workflow, availability and cost.

The CUBIE system from CareFusion helps maximize the security, availability and predictability of medications. Supporting the rapid initiation of medication orders via Pyxis MedStation® system, the modular CUBIE system helps nurses reduce the risk of medication errors, missed doses and time-consuming non-value activities.

Half-height and full-height CUBIE pockets and drawers help healthcare facilities:

- Increase medication availability and predictability
- Enhance the security of high-risk, high-alert medications
- Reduce risk of medication errors
- Maximize drawer configurability and capacity for the storage of small to large medications
- Reduce inventory shrinkage and lost charge capture

Pyxis®

CareFusion

Full-height CUBIE pockets—increasing storage capacity for larger medications

New to Pyxis MedStation 4000 system and Pyxis MedStation ES system, full-height CUBIE pockets leverage the same demonstrated benefits of half-height CUBIE pockets, while adding capacity to securely store larger medications.

Promoting efficiency to improve workflow and reduce costs, CUBIE system helps:

- Increase medication availability and predictability, reducing time to first dose
- Accommodate ever-changing inventory due to drug shortages, formulary adjustments or packaging changes by enabling pocket reconfiguration or exchange
- Reduce loss of revenue on non-controlled medications due to inventory shrinkage
- Increase Pyxis MedStation system security and capacity with more line items and doses using full-height CUBIE pockets vs. other drawer types
- Enable storage for larger medications—such as pre-filled syringes, vials and IV bags—using full-height CUBIE pockets

Facilitating medication safety, CUBIE system helps:

- Optimally secure high-risk and high-alert medications
- Reduce errors on the refill and removal of look-alike, sound-alike medications
- Decrease the risk of medication errors and diversion with single pocket access
- Ensure only authorized personnel can access medications

Increasing choice and storage capacity to optimize customization

CUBIE pocket technology is secure and flexible, enabling pharmacy to reconfigure drawers and adjust pocket sizes to accommodate an ever-changing formulary. With options in CUBIE pocket sizes, you can easily configure your Pyxis MedStation system to dynamically manage your inventory:

Half-height CUBIE pockets

Name	Height *(mm/in)*	Depth *(mm/in)*	Width *(mm/in)*
1x1	38/1.5	86/3.4	53/2.1
1x2	38/1.5	86/3.4	117/4.6
1x3	38/1.5	86/3.4	183/7.2

Available for all Pyxis MedStation systems.

Full-height CUBIE pockets

Name	Height *(mm/in)*	Depth *(mm/in)*	Width *(mm/in)*
2x1	105/4.1	76/3	55/2.1
2x2	105/4.1	69/2.7	125/4.9
2x3	105/4.1	69/2.7	194/7.6
2x5	105/4.1	69/2.7	337/13.2

Available for Pyxis MedStation 4000 system and Pyxis MedStation ES system.

CareFusion
San Diego, CA

carefusion.com

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Diversion prevention and detection

Pyxis MedStation™ system and Pyxis C^{II}Safe™ system

Patient safety is at risk when impaired healthcare professionals are undetected. Facilities must ensure that controlled substance management, security and monitoring is a priority, and that healthcare professionals only have access to controlled substances that are needed to provide high quality and safe patient care.

The purpose of this document is to:

- Define Pyxis MedStation™ system features that help deter controlled substance diversion
- Describe policies that deter diversion
- Discuss reports used to monitor diversion

Pyxis MedStation system features and functionality that help deter controlled substance diversion

- **Single-pocket (single drug) access:** CUBIE® pockets, MiniDrawer secure medication dispensing pockets (in single or multidose mode) and Carousel drawers provide secured pockets that give the user access only to the medication requested. This prevents the user from removing a medication in an adjacent pocket when the drawer is opened.
- **Single-dose access:** MiniDrawer secure medication dispensing pockets can be configured at the console to dispense a single dose of a controlled substance each time the drug is requested. This prevents the user from removing more doses than requested.
- **Blind Count:** The Blind Count setting requires the user to physically count the medications in a pocket and enter the beginning count before removing the medication. In contrast, the Verify Count setting gives the expected count and asks the user if it is correct. The Blind Count setting prevents discrepancies from going undetected by requiring a count be entered each time the pocket is accessed.
- **Limited user access:**
  - **Security Group setting:** The Security Group setting on the console can be used to limit types of users, such as respiratory therapists or emergency medical technicians, to medications that are within their scope of practice.
  - **Area Access setting:** User access to the Pyxis MedStation system(s) can be restricted to the units where the user routinely works. Users who float to another unit can be activated at that Pyxis MedStation system for a defined period of time (e.g., 14 hours). This feature prevents users from removing controlled substances from Pyxis MedStation system(s) outside of their assigned area(s).
  - **Limit activated user time:** Activated (e.g., float nurses) and temporary user access expires after a defined period of time. The defined period is usually the typical shift plus two hours. This prevents the activated or temporary user from accessing the Pyxis MedStation system after their worked shift.

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- **Pyxis Profile:** Profile limits user access to those medications that were ordered for a specific patient and were verified and entered into the pharmacy information system by the pharmacist. This prevents the user from removing a controlled substance that was not ordered by the physician. The exception would be those medications available via override that the user has the privilege to remove.
- **BioID fingerprint identification system:** Use of this system physically verifies a user's identity with a fingerprint scan prior to granting access to the station. The system enhances security by decreasing the chances of diversion due to lost, stolen or shared passwords or swipe cards. Use of the BioID system meets state regulatory requirements for physical identification of users.
- **Clinical Data Categories (CDCs):** CDCs can be used to require a reason for overriding a medication. This may help reduce chances of diversion because of the perception of increased monitoring of the user and override reason.
- **Too Close removal warning:** A Too Close removal warning can be set to appear when a user removes a medication on a patient that previously had the same medication removed within a defined time frame. The warning will appear even if the medication was removed at another Pyxis MedStation system, as long as it is the same med ID and within the defined time frame. The warning will appear at both profile and non-profile Pyxis MedStation systems. Users can override the remove warnings, but they are required to document a reason (select from predetermined list or type in) before continuing with the removal. A report of the warning overrides can be printed at the console and reviewed for appropriateness. This feature will discourage a diverter from removing multiple doses in a short period of time.
- **Override settings:** The Override settings allow a user to remove a medication from a profile Pyxis MedStation system prior to a pharmacist review and verification of the order. The ability to remove a drug via override can be limited by drug and by user. Limiting the number of controlled substances available via override (especially oral medications) can decrease the potential for diversion.
- **Witness on Override:** When the Witness on Override setting is turned on at the console, a witness is required each time a medication is removed from a profile Pyxis MedStation system via override. This feature will stop a diverter from removing controlled substances via override independently. Consider the availability of a witness to override before deciding to use this feature.
- **Return bins:** Return bins are a standard feature of the Pyxis MedStation system. Returning all controlled substances to the return bin for inspection by pharmacy personnel prevents a tampered with medication from being returned to stock.
- **Witness to Empty Return Bins:** The Witness to Empty Return Bins setting can be turned on at the console. Requiring a witness protects the pharmacy technician and the user from suspicion of diversion.
- **Menu Time Out:** The Menu Time Out is set at the console for each Pyxis MedStation system and will automatically log out the user if there is no activity during this time. Set the menu time out for 1 minute 30 seconds or less. A time out of two minutes or more gives a diverter ample time to remove a controlled substance under another user's name, if that user does not exit prior to walking away from the Pyxis MedStation system.
- **Discharge Delay:** Discharge Delay is set at the console for each Pyxis MedStation system to allow a user to return or waste a medication on a patient that was recently discharged. Set the discharge delay for two hours or less. A long discharge delay provides a diverter an opportunity to remove controlled substances on a patient that is discharged.
- **Lock Loops:** Security Lock Loops can be installed on Pyxis MedStation systems that are located in areas that are not staffed 24 hours per day.

Policies that help deter controlled substance diversion

- **Limit who can add users:** Limit the ability to add permanent users to the system to Pyxis MedStation system managers and select pharmacy personnel. Assign all users to the appropriate user template with defined privileges.
- **Implement a formal policy for adding users:** Develop a standardized process for new user access and define requirements and roles in hospital Policies and Procedures. All Pyxis MedStation system and Pyxis C^{II}Safe™ system

users should complete a standardized training program and have competency verified on the use, policies and procedures, and expectations of system use. Restrict user access to the area where they routinely work.

At a minimum, all users should complete the tutorial on the Pyxis MedStation system and sign a user confidentiality statement before being added as a user. Requiring a competency criteria checklist and documenting minimal competency using the device is strongly recommended. Once the criteria have been met, forward the appropriate documentation to the system manager who can then build the appropriate user account.

- **Implement a policy for removing users:** Define a process for communicating the routine termination of employees automatically to pharmacy (or other appropriate department) for Pyxis MedStation system user database management and include in hospital policies and procedures. Set user privileges to expire on employees' last day of employment. Delete terminated employees from the system after 30 days. Also define and implement a process for the managers to notify pharmacy either prior to or immediately after an unfriendly termination. Immediately inactivate users of unfriendly terminations ("ID Valid Until"= NOW). Run reports before deleting the user from the user database.
- **Enter all users as permanent users:** Include management of controlled substances and Pyxis® product policies and procedures in new hire and traveler/agency/float pool orientation. After completion of orientation, add new employees at the console as permanent users according to defined hospital policy. Travelers are added as permanent users with an ID valid until date matching the contract end date. Float and agency users are added as permanent users without any areas, and are activated at the Pyxis MedStation systems for the shift they work. Limit the use of the temporary user feature to emergencies. If the temporary user feature is not used by policy, do not assign any privileges to the temporary user on the Station Privileges tab of the device settings. This will prevent access if a temporary user is created.
- **Perform a routine inventory of controlled substances:** A weekly count of all controlled drugs in each Pyxis MedStation system is recommended. Consider a second inventory on the weekend if weekend-only staff are utilized.
- **Limit or avoid dose range orders:** Dose range orders are discouraged by regulatory and accrediting agencies. The use of dose range orders increases the potential for diversion and medication errors.
- **Standardize doses:** The use of standardized dosing decreases the potential of medication errors and potential diversion.
- **Require a witness for failed log in at the BioID fingerprint identification system:** Require a witness for unsuccessful BioID fingerprint identification system log-in attempts. Put a procedure in place stating that if a user is unable to access the Pyxis MedStation system with the BioID fingerprint identification system feature, a designated individual in pharmacy (system manager) is responsible for granting password access with a defined expiration date. Match the Pyxis MedStation system policy for password change to the hospital IT department password change policy.
- **Use strong passwords:** Create strong passwords that are at least six characters in length and are alpha-numeric. Password policy should match hospital IT department password policy.
- **Manage all controlled substances within the Pyxis MedStation system:** Load all controlled drugs into the Pyxis MedStation systems for consistent practice and documentation. Store controlled substances in secure drawers: CUBIE pockets, Carousel pockets or MiniDrawer secure medication dispensing pockets with a single medication per subdrawer (single dose or multidose mode). Do not store controlled medications in matrix drawers or in MiniDrawer secure medication dispensing pockets configured in the matrix mode. Limit the quantity of doses in each pocket to no more than 10-25 doses (depending on dose type) for simple, accurate counting.
- **Exit the system before stepping away from the Pyxis MedStation system:** The end user must exit the screen when leaving the Pyxis MedStation system. If the user walks away from the Pyxis MedStation system without logging off, a diverter can access controlled substances under the previous user's login. Set the menu time-out for 1 minute 30 seconds or less.
- **Empty the return bin daily:** Empty the return bin daily, using the Empty Return Bin icon at the station. The pharmacy technician must verify the expected quantity of each drug. Use of the Pyxis MedStation system functionality

to require a witness when emptying the return bin protects both the end user and technician. Return all bin contents to pharmacy for inspection for evidence of tampering. Verify that medications emptied from the Pyxis MedStation system return bin are returned to the vault.

Reports used to monitor for diversion

Pyxis MedStation system station reports

- **Activities reports:**
  - **Run reports:** Encourage staff to print an Activity report by user at the end of each shift to verify activity. This identifies problems with password security and failure to log off of the system. Users may also print an Activity report for controlled substances on their patients. This will identify another user removing controlled substances for their patients.
  - **Review reports:** Encourage nurse managers to review Activity reports for controlled substances to verify that activity is limited to nurses assigned to the unit and shift. Activity reports can also be used to conduct concurrent audits of activity by drug, user or patient. Printed activity for one of these parameters can be compared with the patient's orders to assure the removal matched the order, the removal matched the order time frame, documentation of administration matched the order and removal, waste matched the order and removal and there was a clinical indication for the ordered medication.
- **Discrepancy reports:**
  - **Run reports:** All discrepancies should be resolved according to hospital policy (usually by the end of each shift). The oncoming and offgoing charge nurses should check to make sure there are no icons on the Pyxis devices, which indicate an open discrepancy. Some hospitals have the charge nurse leave documentation that they looked for open discrepancies and that all are resolved. They run an Open Discrepancy report at the end of the shift, review and sign the report and leave it for the nurse manager to review. There should be no open discrepancies on the report.
  - **Review reports:** Encourage nurse managers to review the discrepancy report on the Pyxis MedStation system for compliance with hospital policy and to look for trends and patterns. The nurse managers need to know the number of discrepancies occurring on their units. This includes resolved and unresolved discrepancies. When reviewing each discrepancy, note the reason for the discrepancy and whether it makes sense. Look for the same user or pairs of users consistently creating/resolving discrepancies.
- **Return/Waste reports:** Recommend nurse managers routinely print the Return/Waste report by user and perform random audits of nurses for accurate documentation of controlled substances removed from and wasted at the Pyxis MedStation system. Wastage of partial controlled drugs can be performed either at the time of withdrawal or after administration. Predetermined waste locations can be added to the waste CDC to avoid having to type in the location.
- **Override report:** Removing controlled substances via override can be a source of diversion. Nurse managers can monitor the Override report at the station to assure there is an order for the medication removed on override and that the circumstances warrant an override. Also look for users that override medications even though there is a profiled order for that medication.

Pyxis MedStation system console reports

- **Daily reports:**
  - **All Station Events for Controlled Substances report:** Check with your State Board of Pharmacy to determine if controlled substance records can be stored electronically. If the records cannot be stored electronically, print CII medications separate from CIII-V. Sort by station and by medication. Print daily and save for DEA records. Review for unusual non-patient activity, cancelled transactions and removals by the same user at close intervals.
  - **Open Discrepancies report:** Print and review daily. Follow up with the nurse managers on all open discrepancies that have been open longer than the acceptable time defined by the hospital's policy.

- **All Discrepancies report:** Review discrepancy resolution reasons for appropriateness. Follow up on any variances with nurse managers. Review daily.

- **Weekly reports:**
  - **User Modification report:** Review to make certain users added/modified are legitimate. Follow up with nurse managers or pharmacy leadership for any questionable transactions.
  - **Patients Added at the Console or Station report:** Sort by User to review temporary patients added to the system. Look for trends of users adding more temporary patients than their colleagues.
  - **Profile Override Report for Controlled Substances by User report:** Review for an unusually high amount of controlled substance removals on override or users that remove via override even though a profiled order for that medication exists.
  - **Waste Activity by User report:** Review for unusually high amount of waste activity for specific user compared with other staff.
  - **Outdated Med Removal report:** Review the Outdated Med Removal report to make certain that only appropriate pharmacy personnel are removing expired medications. Look for any non-pharmacy employees who might be using this function as a source of diversion.
  - **Service Message report:** Review for log-in failures, unusually long log-in time and drawer left open messages. These could indicate attempts at diversion.
- **On-demand reports:**
  - **All Station Events by User report:** Run this report to review user-specific transactions. (Use Pyxis C^{II}Safe system Proactive Diversion Search report to identify high-access users.)
  - **All Station Events by Station/Med report:** Run this report as needed for specific medication/nursing unit to aid in discrepancy resolution.

Pyxis C^{II}Safe system reports

See Pyxis C^{II}Safe system reporting clinical white paper on the CareFusion Customer Connection website at **pyxis.com/CustomerConnection.aspx**.

- **Open Discrepancies report:** This report lists items in the Pyxis C^{II}Safe system with counts different than what's expected. Run this report at the end of each shift.
- **All Pyxis C^{II}Safe Events report:** This report shows all Pyxis C^{II}Safe system drug transactions for the prior 24-hour period. The report automatically runs at midnight.
- **Pyxis C^{II}Safe Compare report:** Run this report after all deliveries are completed to make sure all controlled substances sent from the Pyxis C^{II}Safe system were placed into the appropriate Pyxis MedStation system. It assists in detecting potential diversion as well as detecting pocket refill, unload or load errors.
- **Reconcile Physical Counts report:** Use this report to verify and document the counts of the controlled substance vault.
- **Pyxis MedStation system Transaction report:** This report provides a record of the Pyxis MedStation system transactions that happened prior to the last 31 days. It can be used to research outliers found on the Proactive Diversion Search report and to review Pyxis MedStation system cancelled transactions.
- **Review Transaction Corrections report:** This report provides a list of the corrections that have been made to certain transactions (i.e., compound, prescription, receive, return, sale, send or waste). It provides specific details for the transaction such as who corrected it, why and witness if applicable. This report allows management to monitor any transaction corrections.
- **Review Resolve Discrepancies report:** This report prints all discrepancies that have been documented using the discrepancy resolution feature on the Pyxis C^{II}Safe system. The Resolve Discrepancy function should be reserved to those circumstances when the controlled substance transaction cannot be fixed (with a second transaction) or corrected (via the Transaction Correction routine), and is therefore irresolvable.

- **Proactive Diversion Search report:** This report will identify individuals who have removed significantly more controlled substances than their peers. The Pyxis C-Safe system calculates the average number of controlled substances removed per user per day for a defined period, and then lists any users that fall above the user-defined standard deviation from norm (usually 2 standard deviations). Run this report by specific unit to compare like patient types. Run this report by all units to compare users such as float nurses who have access to multiple units.
- **Migration Summary report:** This report summarizes all controlled substance debit and credit activity. It is useful for DEA audits or situations requiring total calculation of drug received and dispensed by pharmacy over a period of time.
- **Outstanding Transactions/Sheets report:** Use this report for non-ADM monthly unit inspections to ensure all sign-out sheets and controlled substances are accounted for on these units.
- **Send Transactions report:** Review this report for multiple send transactions to non-ADM by the same pharmacist or technician.
- **Prescription Transactions report:** This report lists controlled substances issued to fill outpatient prescriptions. Audit to ensure there is a prescription on file for each Pyxis C-Safe system prescription transaction.

Integrated Analytics Solutions

With the CareFusion Knowledge Portal and Performance Analytics Services, you can quickly access much needed information, so you can take action and monitor performance over time. These programs offer the insight you need to make timely decisions and identify improvement opportunities previously hidden from view.

The Knowledge Portal is an intuitive, web-based application for hospitals seeking flexibility in their analytical processes and easy access to all their transaction data. Our Performance Analytics Services answer your critical questions without adding complexity or increasing your workload. Both solutions will help you with continuous performance improvement, while providing you the ability to efficiently measure key processes across disparate medical devices. You will benefit from actionable measures and easy access to relevant information without incurring the burden and expense of daily data management.

For detailed information on these offerings, contact your Pyxis Account Executive or Clinical Consultant.

CareFusion
San Diego, CA

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Phone Duty
10/18/14 to 3/20/15

California State Board of Pharmacy

Phone Duty

est: 10/13/2014

questions

Implemented: 10/18/2014

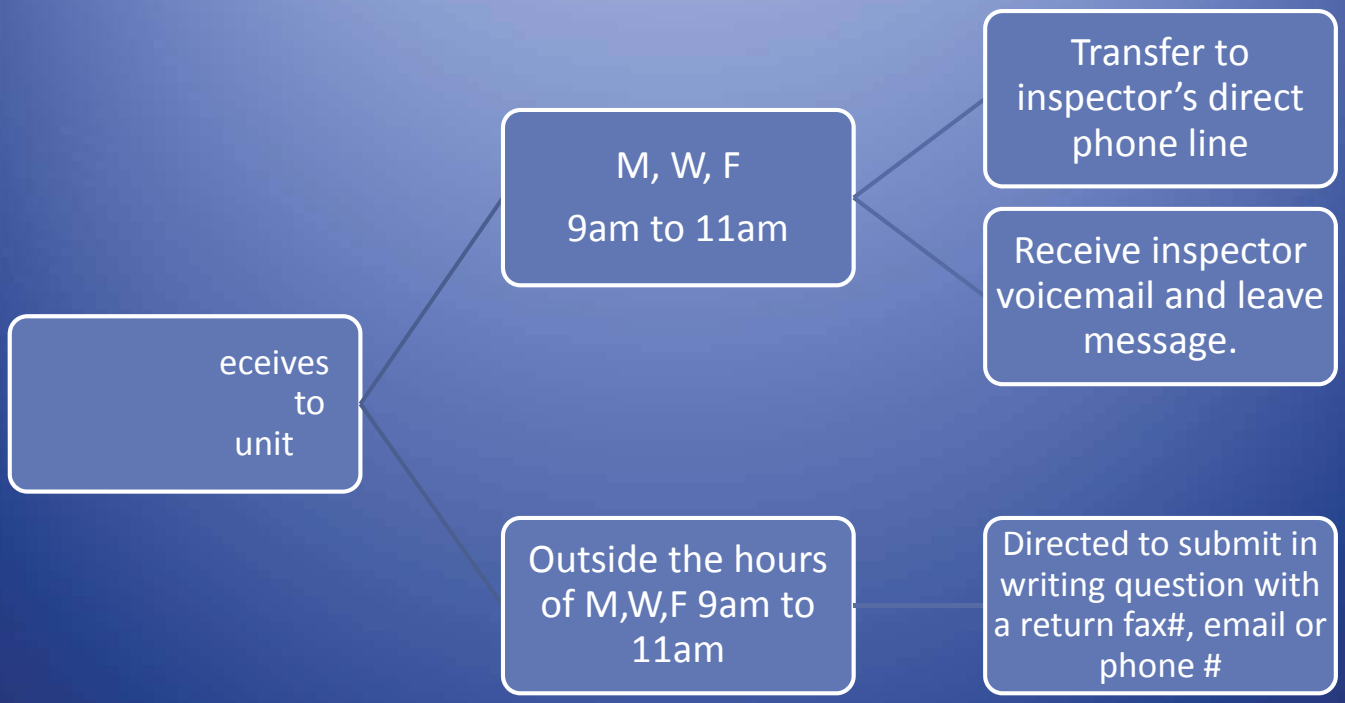
Assigned inspector rotation

inspector is assigned to cover 1-week

F from 9am to 11am to answer phone

sponsible for all questions for the week

Phone Duty


eceives
to
unit
M, W, F
9am to 11am
Transfer to inspector's direct phone line
Receive inspector voicemail and leave message.
Outside the hours of M,W,F 9am to 11am
Directed to submit in writing question with a return fax#, email or phone #

Phone Duty

of questions: 531 questions

age # per week: 24

Highest # per week: 55 (week of 3/7-3/13)

est # per week: 1 (week of 1/3-1/9)

ime spent: 245 hours (22 weeks)

age time spent per question: 27 minutes

age inspector time per week: 648 minutes (10.75 hours/week)

Phone Duty

(Number of Calls Per Week)

Week 12:	**1**	**(lowest) 1/3/15/to 1/9/15**
Week 13:	5	
Week 14:	45	
Week 15:	27	
Week 16:	12	
Week 17:	28	
Week 18:	28	
Week 19:	31	
Week 20:	46	
Week 21:	55	(highest) 3/7/15 to 3/13/15
Week 22:	26	

Phone Duty – Question Type

ount:	%:	Time (hrs)	Question Type:	Count:	%:	Time (hrs)
142	26.74%	61 hrs	Clinic	8	1.51%	3.5 hrs
84	15.8%	36.5 hrs	PHY Construction	7	1.32%	3 hrs
46	8.66%	19 hrs	TCH Duties	7	1.32%	2.25 hrs
42	7.91%	20 hrs	Ownership	6	1.13%	2 hrs
34	6.40%	15.75 hrs	Complaint	4	0.75%	2 hrs
33	6.21%	16.75 hrs	Manufacturing	4	0.75%	3.75 hrs
20	3.77%	14.5 hrs	Shipping	4	0.75%	3.25 hrs
18	3.39%	9.75 hrs	HIPPA	3	0.56%	1 hr
10	1.88%	4.25 hrs	Medical Device	3	0.56%	1.25 hrs
10	1.88%	4.75 hrs	Out-of-State CS	3	0.56%	1.25 hrs
10	1.88%	5.75 hrs	Intern	2	0.38%	0.75 hrs
e 9	1.69%	3.25 hrs	Waste Disposal	2	0.38%	1.5 hrs
9	1.69%	3.5 hrs	DQSA	1	0.19%	0.25 hrs
8	1.51%	4 hrs	Physician Assistant	1	0.19%	0.25 hrs

Phone Duty – Question Type: Other

collabrative agreements between phy and physicians.

laws regarding the use of sporicidal agents.

pharmacy share space with a licensed laboratory?

own a pharmacy?

open a wholesaler and a pharmacy, what are the requirements?

state pharmacist work under a licensed pharmacist under CA law?

ind details about protocols, credentialing and other requirements of SB 493?

or a client to determine what licensing, if any, is needed to open an ambulatory

ontainers are required to store expired/discarded/discontinued medications

t an unlicensed facility? The facility is an apartment complex and holds no

business need a license from the BOP to arrange a contract for emergency use

an industrial setting?

nic fruit and vegetables wants to name their business “farmacy”. Does this

gulations?

rohibit an LVN from writing a note on a bubble-packed medicine for a SNF or

facility for a medication already dispensed to the patient without the direction

the prescriber?

Phone Duty – Question Type: Other

(continued)

authorize a pharmacy to contract or sub-contract dispensing activities? \

HIPPA to place a flyer at a pharmacy looking for research subjects?

ve a CA licensed RPH do consulting and rx verification for the NRP? ylvania.

quired from the BOP for a courier company to ship to contact lens scriber to a patient?

holesaler license required to sell acupuncture needles? (question asked times)

ny created a new medical device to assist pharmacies when meds. What type of license would be required in order to purchase olled and non-controlled drugs to test their devices during the acturing process to insure accuracy?

resident pharmacy license be approved for mailing non-prescription products?

lab that completes process validation testing for sterile mpounding pharmacies, is asking if they need to be licensed by the BOP.

restrooms do we need to have, a unisex or separate male and female

Phone Duty – Caller Type

%:	Time (hrs)
37.66%	83 hrs
15.44%	37.5 hrs
10.92%	27.3 hrs
6.21%	15 hrs
6.03%	21 hrs
4.52%	12.3 hrs
2.64%	5.25 hrs
2.07%	8.75 hrs
2.07%	4.5 hrs
1.88%	5.5 hrs
1.88%	5.25 hrs
1.88%	3 hrs
1.32%	3 hrs
0.94%	2.75 hrs

Question Type:	Count:	%:	Time (hrs)
DDS	4	0.75%	2.25 hrs
Insurance Co.	3	0.56%	1 hr
Law Enforcement	3	0.56%	1.5 hrs
Pharmacy Owner	3	0.56%	1.5 hrs
DHCS	2	0.38%	0.75 hrs
Medical Board	2	0.38%	1 hr
NP	2	0.38%	0.75 hrs
PA	2	0.38%	0.5 hrs
TCH applicant	2	0.38%	1 hr
DCHS	1	0.19%	1.25 hrs
DOI	1	0.19%	0.25 hrs

Phone Duty – Caller Type: Other

ccount managers.
software vendors.
oftware vendors.
tional therapist.
ood company.
company.
living facility.

Acupuncturist.
company.
ects.

Questions