California State Board of Pharmacy
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ENFORCEMENT AND COMPOUNDING COMMITTEE REPORT

Amy Gutierrez, PharmD, Licensee Member, Chair
Allen Schaad, Licensee Member, Vice Chair
Greg Lippe, Public Member
Stan Weisser, Licensee Member
Valerie Muñoz, Public Member
Ricardo Sanchez, Public Member

Report of the Enforcement and Compounding Committee Meeting held on January 4, 2017. A copy of the January 4, 2017, Enforcement and Compounding Committee Meeting minutes is provided in **Attachment 1.**

Enforcement and Compounding Committee Related Items

Part 1: Enforcement Matters

a. CURES 2.0 Prescription Monitoring Program: Presentation by California Department of Justice and Discussion of CURES System Components

Attachment 2

Background
The Controlled Substance Utilization Review and Evaluation System (CURES) / Prescription Drug Monitoring Program (PDMP) is a computer system that stores and reports Schedule II, III and IV prescription data dispensed by dispensers to the California Department of Justice (DOJ). The current CURES 1.0 system is in the process of being converted to CURES 2.0, which contains enhanced features.

All California licensed pharmacists and California licensed prescribers who are authorized to prescribe scheduled drugs were required to register for CURES by July 1, 2016 or upon licensure. Senate Bill 482 (Lara, Chapter 708, Statutes of 2016) added H&S section 11165.4 requiring prescribers to consult with the CURES database prior to first-time prescribing of a Schedule II, III, or IV controlled substance unless specific conditions are met and at least every four months thereafter if the substance remains part of the treatment of the patient.

Mike Small from the California DOJ provided a presentation on the expanded features of CURES 2.0. These features include:

- Improved business analytics
- A fully automated registration process
- The ability to assign delegates who can initiate CURES 2.0 inquiries
- Daily alerts with information on patients who reach prescribing thresholds
- Flagging to allow prescribers to notate patients with treatment contracts

Mr. Small stated that the analytics engine identifies the person's current prescriptions based on date

filled and number of days' supply. These levels are calculated and compared against pre-established thresholds. Therapy levels exceeding those thresholds trigger patient safety alerts to current prescribers.

Committee Discussion

The committee discussed pharmacist feedback that the PAR report does not indicate the days' supply of medication. Mr. Small explained that this information may be available to be downloaded via Excel but is not on the current reports.

The committee also noted that providers want to know what has been dispensed under their DEA numbers and that other states' PDMP programs do offer this in their reports. Prescribers do not have a method to reconcile their prescription pads and should have a right to this information as it is under the prescriber's DEA number. Mr. Small advised the committee that one prescription pad can be worth up to $1.5 million to a drug diverter.

The committee also considered the current timeframe for reporting dispensing records to CURES and if schedule V drugs should also be reported to CURES as currently only schedule II-IV drugs are required.

Committee Recommendation: Include the days' supply of medication in the PAR as well as the ability for prescribers to have access to the prescriptions written by them. Recommend to the board that it promote a change to report dispensing data within 48 hours and that Schedule V prescriptions be reported to the CURES system.

Attachment 2 includes a copy of the presentation provided by Mike Small as well as the proposed statutory amendment.

b. Discussion and Consideration of the University of California, San Diego's Pilot Program to Permit Patients to Access Medications From an Automated Drug Delivery System Not Immediately Adjacent to the Pharmacy

Attachment 3

Background

At the April 2015 Board Meeting, the board approved an 18-month pilot study under the auspices of the University of California, San Diego (UCSD) School of Pharmacy involving use of an automated drug delivery system (ADDS) for prescription medication from which staff of Sharp Hospital in San Diego and their families, who opted in, could pick up their outpatient medications. Consultation would be provided via telephone before medication could be dispensed to a patient for first time fills.

The committee has received quarterly updates on the study, including usage of the system.

Committee Discussion

At this meeting, via telephone, Dr. Hirsch delivered a presentation on the progress of the study and reported that the ADDS was implemented on January 20, 2016 and that data collection continued

through December 2016. Data analysis will be completed during the first quarter of 2017 and a report will be made to the board at the May 2017 board meeting. A copy of Dr. Hirsch's presentation is provided in Attachment 3.

Dr. Hirsch reported the following activity from January 20, 2016 through November 30, 2016: 7% of campus employees (338 users) utilized the ADDS kiosk. There was an average of 88 prescriptions per month. Sharp Memorial Hospital did not receive any complaints and received testimonials about the convenience of the ADDS.

The committee did not take action on this item.

c. Disposal of Sharps in Pharmacy-Operated Drug Take Back Programs: Discussion and Consideration of Statutory Framework and Possible Changes

Background

Since late 2014, the board has been working on drug take-back regulations for pharmacies. The rulemaking file to implement the board's regulation requirements was submitted to the Department of Consumer Affairs (DCA) in December 2016. Hopes are for the regulation to go into effect toward the end of the first quarter of 2017.

The committee has been in discussion about how to address the return of sharps by the public to pharmacy collection of household pharmaceutical waste. Of particular concern is the increasing widespread distribution and availability of EpiPens to respond to various emergencies in locations such as schools and restaurants.

The board's pending drug take-back regulation provides requirements that signage for collection receptacles contain the following prohibition: "Medical sharps and needles (e.g., insulin syringes) shall not be deposited." This is consistent with pharmacy law. In order to proceed with rulemaking, the board decided to consider the issue of sharps, which includes such items as needles, syringes, lancets and EpiPens as a separate piece.

Committee Discussion

Sharps are handled separately from pharmaceutical waste for a number of reasons including the Department of Transportation's (DOT) transport requirements.

The board heard comments from several community members, including the:

- Environmental Branch of the California Department of Public Health (CDPH) that regulates the generation, transport and disposal of medical waste in clinical facilities
- Sacramento County's Program Manager for Business Development and Special Waste, that runs a landfill and a transfer station, and collects household hazardous waste
- Californians Against Medical Waste
- California Product Stewardship Council

Several government entities have regulations concerning the disposal of sharps waste, which at times, conflict with each other. For example, DEA regulations require that pharmaceutical waste be disposed of in a liner. However, the DOT requires that sharps be disposed of in rigid containers. The situation is further complicated because there is the federal overlay, transportation across state lines,

and people who have been doing something for years that may not be flexible in moving forward with a different solution.

Committee Recommendation: The committee agreed that the sharps issue should remain with the Enforcement Committee until a solution is identified. The committee will work with other agencies to find a solution.

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d. Automated Drug Delivery Systems (ADDS) Including:

1. Presentations Regarding Options and Features Currently Available

Background
The board's staff continues to be contacted with questions from entities seeking to use automated drug delivery systems (ADDS) in California. Some of these ADDS offer new features not addressed in pharmacy law.

At the January 2017 Enforcement and Compounding Committee Meeting the board heard abbreviated presentations from ADDS vendors and agreed that there needs to be more discussion as to how to embrace new technology when it conflicts with existing laws.

2. Discussion and Consideration of Refilling of ADDS in Skilled Nursing Facilities

Background
In skilled nursing facilities, ADDS are sometimes installed to permit furnishing of emergency medications or to start initial doses to patients receiving care in the facilities.

The board's staff believes that California law directs that drugs in the ADDS are stock of the pharmacy and that the pharmacy is responsible for restocking the device (pharmacist, pharmacist intern, or pharmacy technician under pharmacist supervision). However, board staff is aware that some skilled nursing facilities have begun using nursing staff or perhaps other employees to refill the ADDS. Consultants from the California Department of Public Health and board inspectors note that the refilling of an ADDS is similar to the restocking of the emergency kits in SNFs, which after medication is removed from a kit, the kit is returned to the pharmacy for inventory, restocking and recordkeeping functions.

3. Next Steps

Committee Discussion
The committee directed board staff to host a one day forum with the full board within the next 60 days to hear presentations on ADDS, particularly for ADDS intended to be located away from the pharmacy, and then discuss relevant laws that permit or impede their use. The discussions will be framed around a series of questions, such as how ADDS will be controlled, how vendors ensure that drugs are matched with the correct patient, security features, and who can stock the ADDS. The board will send a subscriber alert with details about the forum once a meeting date is set.
Recent Update:
Board staff are working to identify a meeting date and location. An update will be provided during

the meeting.

e. Discussion and Consideration of Possible Regulations Regarding Patient Enrollment in Automated Refill Programs for Prescription Medications

Background

Traditionally, pharmacies have refilled prescriptions only upon the request of the patient or the patient's prescriber. However, in recent years computer programs have been developed which allow pharmacies to enroll patients in automatic refill programs ("auto-refill"). These programs automatically refill prescriptions before the patient runs out of medication. In most cases, these auto-refill programs are limited to drugs identified as maintenance medications. The argued benefit of auto-refill programs is that they increase patient compliance with drug therapy by automatically refilling maintenance medications and sending reminders to patients to pick up their prescriptions.

From late 2012 through 2013, the board received over 100 complaints directly related to auto-refill programs due to the media attention. Many of the complaints were from patients who received prescriptions they did not request and who had difficulty returning the prescriptions for a refund. Other patients inadvertently ingested medication they had not requested or ingested medication that was previously discontinued by their prescriber. Some of these events resulted in patient harm.

In response to the large number of complaints, Executive Officer Herold and other staff worked with the various agencies to address these concerns and explore possible violations of pharmacy laws and regulations.

At the October 2016 Board Meeting, staff was asked to develop an analysis and presentation for the next committee meeting to evaluate options for authorization and maintenance of auto-refill documentation in community and mail order pharmacies.

Committee Discussion

The committee discussed the draft policy developed by staff on automated refill programs and heard public comments about how other states including Oregon and Texas are regulated such programs.

As part of its discussion the committee made revisions to the draft policy. Provided below is the policy approved by the committee. (The draft policy is provided below as approved by the committee).

California State Board of Pharmacy
DRAFT Policy on Automated Refill Programs:

A retail or mail order pharmacy may use a program that automatically refills prescriptions that have existing refills available, in order to improve patient compliance and are consistent with the patient's current medication therapy when all of the following conditions are met:

(1) Written notice or disclaimer of the availability of an auto-refill program shall be given to the patient or patient's agent. The patient or patient's agent must affirmatively indicate they wish to enroll in such a program and the pharmacy shall maintain documentation of such indication. Notice shall have language that references instructions on how a patient can discontinue participation in the auto-refill program.

(a) A pharmacy patient or the patient's agent shall consent to participation in an auto-refill program with a "wet" signature or an e-signature. If the pharmacy has an online consent option, the patient may enroll in the auto-refill program through that method. The pharmacy shall keep this acknowledgement on file. If the retail pharmacy has an online consent option, the patient or patient's agent can register in that manner and the pharmacy shall keep said acknowledgment on file for one year from date of dispensing.

(b) A mail order pharmacy patient or the patient's agent shall consent to participation auto-refill program through the mail order pharmacy's website. The pharmacy shall keep this acknowledgment on file. If the mail order pharmacy does not have an online consent option, the pharmacy shall obtain a signature or email confirmation from the patient or patient's agent consenting to the auto-refill program. Acknowledgement of consent to participate in the auto-refill program shall be kept on file by the mail order pharmacy for one year from date of dispensing.

(2) The Pharmacy shall have written policies and procedures in place that ensure only medications that are for the auto-refill program are enrolled in the program.

(3) The pharmacy must discontinue auto-refill program enrollment at the request of the patient or patient's agent in a timely manner.

(4) As is required for all prescriptions, a drug regimen review shall be completed on all prescriptions filled as a result of the auto-refill program. Special attention shall be noted for drug regimen review warnings of duplication of therapy and all such conflicts shall be resolved with the prescribing practitioner prior to refilling the prescription.

(5) The retail or mail order pharmacy must reaffirm annually each prescription to be enrolled in the auto-refill program.

(6) Upon a receipt of a new prescription from a provider, the patient or patient's agent shall identify if the prescription is to be included in the auto-refill program, even if the new prescription is a continuation of existing therapy.

(7) Each time a prescription is refilled a reminder notification will be provided to the patient or patient's agent, affirming that the prescription is enrolled in the auto-refill program.

(8) Pharmacies that use an auto refill program will have policies and procedures in place that address the auto-fill program. These policies and procedures will be available for inspection upon request of the board.

(9) The pharmacy shall provide a full refund to the patient or the patient's agent and the payer for an auto-refill prescription that is reported as unneeded or unnecessary if the patient or patient's agent can provide evidence or documentation that they did not register for the auto-refill program or the patient notified the pharmacy of disenrollment.

Committee Recommendation: The committee recommends that the board approve the proposed policy as amended by the committee and direct staff to draft a regulation.

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f. Discussion and Consideration of the National Council of State Boards of Nursing (NCSBN) Nursys® e-Notify system

Attachment 4

Background

The Enforcement and Compounding Committee expressed interest in learning about this system. The National Council of State Boards of Nursing (NCSBN)® e-Notify system is a nurse licensure notification system that provides employers of registered nurses and licensed practical/vocational with real-time email notifications about nurses they employ. This e-Notify system alerts subscribers when changes are made to a nurse's record, including changes to: license status, license expiration, pending license renewal, and public disciplinary action, resolution and alerts. Their website states:

> The Nursys nurse licensure and disciplinary database is the repository of the license and disciplinary data of the NCSBN member boards of nursing. Through a written agreement, participating individual boards of nursing designate Nursys as a primary source equivalent database. NCSBN posts the information in Nursys when, and as, submitted by the individual boards of nursing.

Committee Discussion

Ms. Herold commented that the board tries to obtain National Healthcare Integrity and Protection Data Bank Reports on all licensees; however, at a cost of $2.00 per licensee and 140,000 licensees, it is cost prohibitive. The board relies on arrest reports for licensees that are arrested. Additionally, at each renewal, licensees must certify under penalty of perjury that they have no arrests or convictions since the last license renewal. The board also receives periodic information when a board takes action in another state and reports to the Healthcare Integrity and Protection Data Bank (HIPDB).

g. Discussion and Consideration of Possible Revision to Title 16 California Code of Regulations Section 1707, Off-Site Storage Waivers, to Address Licensees With Previous Records Violations

Attachment 5

Background

Existing board regulations require that pharmacies retain records of all acquisitions and dispositions of drugs for at least three years. Some pharmacies lack sufficient space within the licensed premises to store these records. Board regulations authorize the off-site storage of pharmacy acquisition and disposition records for records older than one year for dangerous drugs and two years for controlled drugs if a board-issued waiver is secured for off-site storage. These requirements are specified in CCR section 1707.

When the regulation permitting off-site storage of records was promulgated only licensees that had no records violations were eligible for an off-site storage waiver. In 2015/16, the board issued 178 off-site records storage waivers and denied approximately 10.

In recent months, the board has identified several pharmacies that requested off-site storage waivers but were ineligible for waivers because they had been cited for storing records off-site without an

approved waiver. Their attempt to get a waiver was generated by the citation, and a desire to come into compliance, however, the regulation's provisions provide no option for the board to grant such a request for five years after the violation is identified.

Committee Discussion
The committee considered staff's request that the board reconsider the full prohibition and authorize discretion in the granting of off-site waivers.

Ms. Herold clarified that a waiver request could still be denied if records had been falsified as that is a serious violation.

The committee heard public comment suggesting replacing the term "off-site" to language that more clearly defined the requirement. After discussion, the committee revised the original draft proposal in response to this comment.

Included in **Attachment 5** is the proposed language approved by the Enforcement Committee.

Committee Recommendation: The committee recommends that the board approve the proposed changes to CCR section 1707.

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h. Discussion and Consideration of a Possible Amendment to New Business and Professions Code 4316 Regarding Cease and Desist Orders

Attachment 6

Background
Last year, one provision contained in the board's sunset bill, SB 1193 (Hill), provided the board with the ability to issue a cease and desist order to an unlicensed entity operating within the board's regulatory jurisdiction without a license where one is required. However, following enactment of SB 1193, staff identified items in this provision needing clarification.

Committee Discussion
The committee considered the proposed changes and received input from counsel on additional modification. After discussion, the committee agreed with the recommendation from DCA's staff counsel.

Committee Recommendation: Recommend to the board approval of the proposed amendments to Business and Professions Code section 4316.

Included in **Attachment 6** is the proposed language approved by the Enforcement Committee.

i. Discussion and Consideration of the FDA's Article, *Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification Guidance for Industry*

Attachment 7

Background

On November 27, 2013, the Federal Drug Supply Chain Security Act was signed into law. Among other things law requires the FDA to issue guidance to aid trading partners in identifying a suspect product in the supply chain. A suspect product is defined as product for which there is reason to believe it is potentially counterfeit, diverted, or stolen; is potentially intentionally adulterated, such that the product would result in serious adverse health consequences or death to humans; is potentially the subject of a fraudulent transaction; or appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

In December 2016, the FDA published a guidance document titled *Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification Guidance for Industry* to clarify when manufacturers and other trading partners should notify the FDA if there is a high risk that a product is illegitimate. The FDA is seeking comments and suggestions regarding this document.

Committee Discussion

Supervising Inspector Michael Ignacio provided a presentation on components in this guidance document.

Included in **Attachment 7** is a copy of Dr. Ignacio's presentation and the FDA's guidance.

The committee did not recommend submission comments. The board will include an article on this guidance in a future issue of *The Script* and provide a copy of the article to other healing arts boards.

j. Discussion and Consideration of Beyond Use Labels in Institutional Settings

Background

Title 16 California Code of Regulations section 1735.1(b) effective 1/1/17 provides that:

(c) "Beyond use date" means the date, or date and time, after which administration of a compounded drug preparation shall not begin, the preparation shall not be dispensed, and the preparation shall not be stored (other than for quarantine purposes).

The board received a request from Providence Hospital for a modification of the expiration date used on prescription labels from "exp" to "do not start after." The request was made, in part, to make the terminology easier for the nursing staff to easily comply with without questions (vs. using the term BUD). Providence feels that using language that nurses can articulate will help with compliance. As the behind-the-scenes EMR work is extensive, they asked for board feedback prior to making changes to their medication labels.

Committee Discussion

The committee agreed that as long as the licensee meets the minimum label requirements, they can add additional information. The additional information provides clearer direction as to what is appropriate for this medication. The committee members agreed that additional information on the label that is intended to clarify the directions is beneficial to the patient. This issue may be addressed

in a future news article letter of *The Script*.

The committee did not take action on this item.

Part 2: Compounding Matters

a. Discussion and Consideration of Statistics for Board-issued Citations and Fines for Compounding Violations

Committee Discussion

Board Member Schaad reviewed the compounding citations and fines issued by the board. Most compounding institutions cited had both sterile and non-sterile compounding citations: 75 pharmacies had non-sterile compounding infractions and 38 had sterile compounding infractions. Out of the 1,100 sterile compounding pharmacies inspected by the board, 38 pharmacies received citations.

During the meeting it was clarified that violations are cited against the pharmacist-in-charge (PIC) at the time that the violation occurred; this may not necessarily be the same PIC at the time of the inspection.

It was noted that there were two cases where pharmacies compounded commercially available products.

The committee did not take action on this item.

b. Update and Discussion of Compounding Construction Waivers for New Requirements in Title 16 California Code of Regulations, Sections 1735 et seq., and 1751 et seq.

Committee Discussion
Supervising inspector Christina Acosta provided an update on compounding construction waivers. Board member Schaad, Chairperson Gutierrez, Executive Officer Herold, Chief Enforcement Officer Julie Ansel, and Supervising Inspector Acosta have been reviewing these waivers. Dr. Acosta provided an overview of the waivers received and the number of requests pending.

As of January 2, 2017, the board received 493 waiver requests and processed 214 requests (43%). Of the 214 requests processed, about 50 (23%) did not have a licensed sterile compounding license, so the waiver was not related to sterile compounding. Of those processed, 70 had been approved and 2 were denied. Of the 214 processed requests, 112 (52%) were for a pharmacy and 102 (48%) were for a hospital. Dr. Acosta is working with several waiver applicants to obtain additional information so that their request can be brought forward to the committee. Dr. Acosta had 280 sterile compounding waiver requests in her inbox, 70 of which were received on December 29, 2016.

The applicant needs to provide the specific section of 1735.6 and 1751.4 to be waived along with the subsection and provide information detailing their attempts to comply with the regulation and when they expect to be compliant. Waivers for non-construction requirements, such as not cleaning the facility or complying with policies and procedures, cannot be granted. A sample waiver package was provided at the October 26-27, 2016 Board Meeting and can be found on the board's website.

The committee received public comment that two challenges are section 1735.6(e)1, which is related to having a physically separate room, and 1735.6(e)2, which is related to having appropriate negative pressure. In discussing some of the challenges with modifications needed in some older facilities noting that space is a concern for adding a negative pressure room. The committee was also advised that renovation in an operating hospital takes care and time as it involves disrupting water, power, medical gasses, and air supply.

Ms. Herold reiterated that the board's goal right now is educational compliance, but noted that if an egregious situation is identified; action will be taken as the board's underlying core is public protection. Mr. Herold also noted there are some options for pharmacies to include purchasing product from somewhere else and shortening the beyond use date (administering the product before it has a chance to grow anything and injure the patient). The goal is to get licensees in compliance as quickly as possible.

The committee recommended that pharmacies seeking waivers keep a copy of the waiver request at their pharmacy to show the inspector in the event of a pharmacy inspection.

The committee did not take action on this item.

c. Discussion and Consideration of the United States Government Accountability Office Report to Congressional Committees, *Drug Compounding, FDA Has Taken Steps to Implement Compounding Law, but Some States and Stakeholders Reported Challenges*

Attachment 8

Background
In mid-November 2016, the GAO released a report on the regulation of compounding by states following the 2012 New England Compounding Center public health emergency.

Discussion and Comment
Chairperson Gutierrez remarked that she noticed that other boards of pharmacy are now looking at sterile compounding in non-pharmacy areas, such as physicians' offices noting that they are looking at areas where sterile compounding is performed; however, the board does not have regulatory oversight.

The committee did not take action on this item.

d. Review and Discussion of California Law Governing Compounding and Conflicts with USP Section 800

Attachment 9

Background
Staff has been made aware of possible conflicts between our new compounding regulation, and USP 800 and other regulatory requirements. .

Moreover, additional discussion is needed regarding California Business and Professions Code section 4127.7 as it relates to USP 800 and our new regulation requirements for hazardous drugs.

Committee Discussion
The committee discussed conflicts between the boards newly revised compounding regulations and USP 800 including a provision in USP 800 for use of a double filtration system for certain classifications of compounding. The committee also discussed conflicts with the board's new regulation and statutory requirements in Business and Professions Code section 4127.7 as well as conflicts with the board's definition of "biological safety cabinet" versus how others define them.

Committee Recommendation: Recommend that the board modify its requirements to allow the use of a double filtration system in lieu of external venting and amend CCR section 1735.1 (c) to remove the word "sterile" from the definition of a biological safety cabinet

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Committee Recommendation: Recommend to the board repeal of BPC section 4127.7.

A copy of the proposed changes is included in **Attachment 9.**

e. Presentation on Requirements for Sterile Compounding Master Formulas

Dr. Acosta provided a presentation on compounding master formula. A copy of this presentation is attached at the end of the meeting minutes under **Attachment 10.**

The committee did not take action on this item.

f. Discussion and Consideration of the Proposed Food and Drug Administration Rule, "List of Bulk Drug Substances That Can Be Used to Compound Drug Products in Accordance with Section 503A of the Federal Food, Drug, and Cosmetic Act"

Background
On December 16, 2016, the FDA proposed rule, *List of Bulk Drug Substances that can be used to Compound Drug Products*, addressing six bulk drug substances the agency has evaluated and is proposing for inclusion on a list of bulk drug substances that can be used in compounding under section 503A of the Food, Drug, and Cosmetic Act. The proposed rule also proposes that four other bulk drug substances that FDA evaluated not be included on the 503A bulks list.

If the proposed rule is finalized, the six bulk drug substances proposed for inclusion will be the first ones included on the 503A bulks list.

Discussion and Comment
Dr. Acosta and Chairperson Gutierrez agreed that this topic warrants further discussion at the next Committee Meeting.

Part 3: General Committee Matters

V. Enforcement Statistics

a. Enforcement statistics

A copy of these statistics is provided under **Attachment 11**

b. Future Committee Meeting Dates for 2017

- April 18, 2017
- July 12, 2017
- October 17, 2017

Attachment 1

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STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
ENFORCEMENT AND COMPOUNDING COMMITTEE
MEETING MINUTES

DATE: January 4, 2017

LOCATION: Department of Consumer Affairs
First Floor Hearing Room
1625 North Market Blvd.
Sacramento, CA 95834

COMMITTEE MEMBERS PRESENT: Amy Gutierrez, PharmD, Licensee Member, Chair
Allen Schaad, Licensee Member, Vice Chair
Greg Lippe, Public Member
Stan Weisser, Licensee Member
Valerie Muñoz, Public Member
Ricardo Sanchez, Public Member

STAFF MEMBERS PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Julia Ansel, Chief of Enforcement
Laura Freedman, DCA Staff Counsel
Christine Acosta, PharmD, Supervising Inspector
Kelli Williams, Complaint Unit Manager

Note: The webcast of this meeting can be found on the board's website.

I. Call to Order, Establishment of Quorum, and General Announcements

Chairperson Gutierrez called the meeting to order at 9:00 a.m. Roll call was taken and the following members were present: Amy Gutierrez, Greg Lippe, Stan Weiser, Allen Schaad, and Ricardo Sanchez.

II. Public Comments on Items Not on the Agenda/Proposed Agenda Items for Future Meetings

Jeremy Schmidt from Roadrunner Pharmacy in Arizona read the following prepared statement concerning non-sterile compounding:

"With the passage by the board of new restrictive Testing/Beyond Use Dating requirements that became effective two days ago, the compounding pharmacy and veterinary community has been negatively impacted for patient care.
The primary reason that veterinarians require longer BUD dating is because they practice differently. The board responded appropriately earlier when new office use and dispensing regulations were adopted to accommodate veterinary practice. We all know that when you take

your pet in to see the veterinarian, one expects to leave with the appropriate medication. This happens from compounded office stock on an on-going basis.

The new testing requirements for additional stability for products that have been sold for years will result in an added financial burden to every pet owner in California. Many pharmacies, like our own, have up to 300 lines of non-sterile medications that practices need daily to treat these pets when they walk in. The newly required testing can add as much as $30,000 annually per medication to meet the new board requirements. The veterinary medication market is so small that these added costs over so few products will drive pet owners away from the veterinarians. The other option of 14 days dating does not work. Many medications made in our pharmacy are routinely tested before release, leaving only a few days for the veterinary practice to use the product. They also will only purchase a tiny amount, yet shipping and testing must be spread over the company's costs inflating the price of these medications substantially.

We ask that veterinary medications be exempted from these added testing requirements. Pets are not people and our pharmacy has demonstrated over a 20 year period that our potency/stability testing has been effective and adequate for a national pet population. Reducing medications to treat your pet in California by reducing availability and/or driving up price 2 to 4 times for pet owners is not the answer.

At a minimum, we request that the board place this item of concern on the agenda for your next meeting so that we can address these challenges with the veterinary community input. Given the "service-on-demand" nature of veterinary medicine, the office use requirements are unable to give an accurate assessment of realistic office use needs. Again, we ask for your consideration of an exemption for veterinary practices."

The committee agreed to add this item to the next Enforcement and Compounding Committee Meeting agenda.

III. Enforcement Matters

a. CURES 2.0 Prescription Drug Monitoring Program

Background

The Controlled Substances Utilization Review and Evaluation System (CURES) / Prescription Drug Monitoring Program (PDMP) is a computer system that stores Schedule II, III and IV prescription data reported by dispensers.

1. Presentation by the California Department of Justice, including Features for Pharmacists

Discussion and Comment

The committee heard a presentation from Mike Small from the California DOJ. As part of the presentation Mr. Small announced that the decommission date for CURES 1.0 is March 5, 2017. He noted that fewer than 10% of users (roughly 13,000) have not migrated to new CURES 2.0. Mr. Small advised that committee that when users sign in to CURES 1.0, they receive instructions to sign on to CURES 2.0 using an appropriate browser.

As part of his presentation, Mr. Small noted that that by law

Pharmacies and direct dispensers are required to report at least weekly into CURES all Scheduled II-IV drugs they dispense and advised the committee that CURES typically receives about one million prescription reports per week, and, data in the system reflects dispensing information exactly as it is reported.

Mr. Small indicated that one of the benefits of CURES is that it registered prescribers and dispensers can access patient activity reports (PARs) that have up to one year of patient-specific prescription history. He noted that this information assists health practitioners in safely prescribing medications and in identifying patients at risk for addiction.

Mr. Small highlighted changes the law relating to the CURES system including that that all active California licensed pharmacists and California licensed prescribers who are authorized to prescribe scheduled drugs were required to register to access CURES by July 1, 2016 or upon licensure. Mr. Small noted that last year, Senate Bill 482 (Lara, Chapter 708, Statutes of 2016) added H&S section 11165.4 requiring prescribers under specified conditions to consult with the CURES database prior to first-time prescribing a Schedule II, III, or IV controlled substance and at least every four months thereafter if the medication remains part of the treatment of the patient.

Mr. Small provided an overview of some of the benefits of the expanded CURES 2.0 system including a more robust system that allows for better identification of potential doctor shoppers, better monitoring of at-risk prescribing threshold, and better peer to peer communication through features like the ability to denote if a treatment contract is in place between a prescriber and patient or if a prescriber has placed a limitation on a patient seeking controlled substance prescriptions from other prescribers

Mr. Small advised the committee that CURES 2.0 features a fully automated registration process, provides the ability to a used to assign a delegate the authority to initiation PAR requests (the delegate cannot receive the report), and provides daily alerts to prescribers on patient who reach system identified prescribing thresholds

Mr. Small discussed the improvements in the system that ensure a more comprehensive patient history and the ability to provide de-identified data to researched and public health officials as allowed under the law.

2. Discussion and Consideration of CURES System Components

The committee discussed the reporting time period for dispensers which is currently seven days and the resulting lag in information sharing. The committee discussed if it would appropriate to reduce the reporting period to allow for closer to real time information. Mr. Small advised the committee that he believes the system would be capable of accepting data on a real-time basis and could turn the data around in 24 hours making accessible to registered users.

The committee discussed some of the concerns heard from pharmacists using the system including a limitation with the patient activity report which does not currently reflect the days' supply of the medication. The committee discussed that this information is very important for a dispenser. The committee was advised by Mr. Small that sometimes pharmacists just receive a list of NDC numbers which results from the incorrect NDC being entered at a pharmacy and noted such an error can make the NDC number difficult to match.

The committee discussed the alert features of the system. Executive Officer Herold commented that 250,000 alerts a day are difficult to manage and suggested a higher, more meaningful threshold may be appropriate. Mr. Small agreed to work with Ms. Herold and board inspectors to determine if the system can be modified to provide more meaningful alert information, particularly to pharmacists.

Board member Muñoz arrived at 9:26 a.m.

As part of its discussion, the committee considered if schedule V prescriptions should be reported to CURES. Mr. Small confirmed that the CURES system can support reports of Schedule V drugs; however, the statute does not currently require that these drugs be reported to CURES.

Chairperson Gutierrez reported that she has received feedback that providers want to know what has been dispensed under their DEA numbers. The committee noted that other states' PDMP programs offer this information to prescribers. Mr. Small stated that some states that have provided this information in the past and have found that some prescribers illicitly modify their records based on this information; however, he is open to further discussion. Dr. Gutierrez commented that there are diversion cases where providers are unaware that their prescription pads have been stolen and have no idea that unauthorized prescriptions are being written under their DEA number. Dr. Gutierrez commented that prescribers do not have a method to reconcile their prescription pads and should have a right to this information as it is under the prescriber's DEA number. Mr. Small commented that the current statute does not require prescription pads to have a uniform look and feel; it only requires a list of features. Mr. Small noted that this makes it difficult for investigators to determine if a prescription is legitimate. He also stated that one prescription pad can be worth up to $1.5 million to a drug diverter. Ms. Herold suggested that the committee consider following New York's lead where, with the exception of emergency room prescribing, most controlled substances are e-prescribed.

Public Comments

The board heard public comment on the CURES system and then discussed shortening the time that dispensers have to report to CURES. Ms. Herold remarked that reporting requirements used to be once a month and were reduced to once a week as Schedule III and IV drugs were added to the CURES. Mr. Small stated that changing the reporting requirement to 24 hours would seem possible.

Public comment was provided that 24 hour reporting may be difficult to meet due to workflow and technological issues and asked that the board consider 72 hours.

MOTION: Recommend to the board changes to the CURES system to include the days' supply of medication in the PAR as well as the ability for prescribers to have access to the prescriptions written by them. Recommend to the board that it pursue a statutory change to change the reporting requirement for dispensing information to include schedule V prescriptions and require reporting within 48 hours of dispensing.

M/S: Lippe / Weisser
Support: 6 Oppose: 0 Abstain: 0

b. Discussion and Consideration of the University of California, San Diego's Pilot Program to Permit Patients to Access Medications From an Automated Drug Delivery System Not Immediately Adjacent to the Pharmacy

Background

At the April 2015 Board Meeting, the board approved an 18-month pilot study under the auspices of the University of California, San Diego (UCSD) School of Pharmacy involving use of an automated drug delivery systems (ADDS) for prescription medication from which staff of Sharp Hospital in San Diego and their families, who opted in, could pick up their outpatient medications. Consultation would be provided via telephone before medication could be dispensed to a patient for first time fills.

The committee has received quarterly updates on the study, including usage of the system.

Discussion and Comment

Dr. Hirsch delivered a presentation via telephone on the progress of the study. She reported that the ADDS was implemented on January 20, 2016 and that data collection continued through December 2016. Data analysis will be completed during the first quarter of 2017 and a report will be made to the board at the May 2017 Board Meeting.

Dr. Hirsch reported the following activity from January 20, 2016 through November 30, 2016 7% of campus employees (338 users) utilized the ADDS and that an average of 88 prescriptions were dispensed per month. Dr. Hirsch noted that in the beginning months, the data reflects that there were a higher number of new prescriptions which is due to a higher number of prescription transfers. Dr. Hirsch continued to state that many of these prescriptions turned into refills during the course of the study and noted that the majority of new and refill prescription pickups and over-the-counter medication pickups occurred during normal pharmacy hours. As part of the presentation Dr. Hirsch indicated that Sharp Memorial Hospital has not receive any complaints from user of the ADDS and has received testimonials about the convenience.

Kim Allen from Sharp Memorial Hospital was present at the committee meeting and reported that employees of Sharp do not have a closed health benefit system noting that employees have multiple health plans to choose from.

Ms. Allen also indicated that the original research proposal was to conduct the study at the corporate office where usage may have been higher based on the population. Ms. Allen reported that it was a challenge to inform employees about the ADDS and that the availability of the ADDS was communicated during rounds with different nursing units, informational tables in the cafeteria, electronic publications, and discussed during meetings. Ms. Allen noted that because Sharp employees may work at five different locations she could not conclude that most Sharp employees are aware of the ADDS and indicated that enrollment was not as high as desired.

Ms. Allen remarked that a lot of employees were using the ADDS after a change in work shifts and that offering over-the-counter medication in the ADDS has been beneficial in helping people get familiar with how to use the ADDS.

As part of its discussion, the committee reviewed a prior study that was completed on patient consultation. Board Member Weisser discussed the value of in-person consultation for patients and provided examples of new mothers with sick children and the elderly. Mr. Weisser cautioned against drawing conclusions based on a small sample size of the patient consultation study.

The committee did not take action on this item.

c. Disposal of Sharps in Pharmacy-Operated Drug Take Back Programs: Discussion and Consideration of Statutory and Regulatory Framework and Possible Changes

Background

Since late 2014, the board has been working on drug take-back regulations for pharmacies. The rulemaking file to implement the board's regulation requirements was submitted to the Department of Consumer Affairs (DCA) in December 2016. Hopes are for the regulation to go into effect toward the end of the first quarter of 2017.

The committee has previously discussed how to address the return of sharps by the public to a pharmacy collection of household pharmaceutical waste at a pharmacy. Of particular concern is the increasing widespread distribution and availability of EpiPens to respond to various emergencies in locations such as schools and restaurants.

The board's pending drug take-back regulation provides requirements that signage for collection receptacles contain the following prohibition: "Medical sharps and needles (e.g., insulin syringes) shall not be deposited." This is consistent with pharmacy law. Towards the end of the board's efforts to develop the take-back regulations, there were requests that collection receptacles also accept the return of sharps. In order to proceed with the rulemaking, the board decided to consider the issue of sharps, which includes such items as needles, syringes, lancets and EpiPens as a separate piece.

Discussion and Comment

As part of the committee's discussion, Executive Officer Herold explained that sharps are handled separately from pharmaceutical waste for a number of reasons including the Department of Transportation's (DOT) transport requirements. Ms. Herold explained that under the board's drug take back regulations pharmaceutical waste is placed in a liner that is similar to a trash bag. Ms. Herold continued that once full, the liner is removed from the holder and then placed in a rigid, impenetrable container for transport. Ms. Herold noted that as the liner is removed from the holder, the contents settle, similar to removing a trash bag at home and indicated that since the liner is not rigid, there is the possibility that sharps can poke through. She reported that California has a mandatory requirement for separate sharps take-back for any entity that provides a needle exchange program. According to Ms. Herold, in Sacramento County, any pharmacy that sells sharps must also provide a means for the public to dispose of used sharps.

Public Comments

Kelvin Yamada, Chief of the Environmental Branch of the California Department of Public Health (CDPH), commented that his agency regulates the generation, transport and disposal of medical waste from clinical facilities. Mr. Yamada commented that disposing of sharps in a liner creates a very hazardous situation for a pharmacist or staff member who may be removing the liner and then transporting it to a receptacle. Mr. Yamada noted that once sharps reach the landfill, they are run over by trucks and other heavy equipment and indicated that just because the sharps were originally in a rigid container does not mean that they will stay in one. He noted that CDPH considers an EpiPen that is encapsulated to be a sharp.

Chairperson Gutierrez commented that DEA regulations permit drug waste to be collected in a pharmacy; however, sharps can be collected in many authorized locations. Mr. Yamada pointed out that it is helpful to separate sharps waste from pharmaceutical waste because they are both disposed of differently: sharps are disposed of in an autoclave and pharmaceuticals are incinerated.

Ms. Herold pointed out that the DEA regulations require that pharmaceutical waste be disposed of in a lined container. However, the DOT requires that such waste be transported in rigid containers.

Chairperson Gutierrez commented that broader regulations that allow disposal of sharps in multiple public areas, such as airports, seem to be the best protection for the community.

Staff Counsel Laura Freedman commented that traditionally the sharps container only contained the sharp itself and not the drug. Even though regulations address the ability to have a separate container, to meet both the conditions for pharmaceutical waste and sharps waste a "super container" that meets all of the requirements of the sharps container and the medical waste container may be necessary which would require a statutory change. Ms. Herold pointed out that the situation is complicated because there is the federal overlay as well as transportation across state lines. Ms. Herold noted that people have been doing something for years and may not be flexible in moving forward with a different solution. Ms. Freedman stated that Business and Professions Code section 4145.5 does not clarify how sharps that contain medication should be disposed of.

A representative of Californians Against Medical Waste asked that the committee to consider a separate statewide policy for the disposal of sharps stating that when sharps are disposed of improperly, waste workers at landfills and recycling lines are endangered and that the public is being endangered because hypodermic needles are washing up on beaches.

Doug Kobold, Program Manager for Business Development and Special Waste, stated that his agency runs a landfill, a transfer station, and collects household hazardous waste. He commented that the rigid mail back sharps containers are a great savings to the local government and indicated that it costs $0.40 per pound to get rid of sharps in a rigid container while the cost to get rid of sharps that are not in an approved container is $8.00 per pound.

Mr. Kobold noted that while they take measures to protect staff, waste management maintenance and mechanical staff are at risk of sharp punctures when they clean out and repair equipment, such as compactors and bulldozers as the workers are not able to see sharps that have been pulled into the equipment. He continued stating that if an employee is poked, they do not know if the needle has been autoclaved. Mr. Kobold indicated that they would like to see a mandatory approved container requirement for every sharps sold.

Jorden Wells with the California Product Stewardship Council (CPSC) commented that they appreciate the board taking up this discussion as the safe disposal of sharps is critically important for Californians. Ms. Wells noted that needles are found at beaches, parks, and even public offices. Ms. Wells commented that as the primary distributor of sharps, pharmacies should take an active role in the safe and separate collection of sharps and noted that consumer convenience is the key to safe disposal. CPSC recommends that the board sponsor workshops to educate the public on the safe disposal of sharps.

Chairperson Gutierrez commented that the board has moved forward with the drug take back regulations. Ms. Herold stated that the existing regulation does not need modification right now because it does not allow for sharps to be comingled with pharmaceutical waste.

The committee agreed to keep this issue with the Enforcement Committee until a solution is identified and that the Enforcement Committee will work with other agencies, such as CalRecycle and Sacramento County to find a solution.

Motion: Recommend to the board that the committee continue to work with stakeholders to find a solution for the disposal of sharps.

M/S: Lippe / Weisser
Support: 6 Oppose: 0 Abstain: 0

A break was taken from 9:45 a.m. to 10:55 a.m.

d. Automated Drug Delivery Systems (ADDS)

1. Presentation(s) Regarding Options and Features Currently Available

Discussion and Comment
The board heard brief presentations from ADDS vendors and agreed that there needs to be more discussion as to how to embrace new technology when it conflicts with existing laws. The committee received a request to install ADDS in satellite clinics to be remotely operated by a pharmacist. Chairperson Gutierrez and Laura Freedman both commented that the committee does not have delegated authority to authorize this and that the issue has not been agendized for this meeting. Ms. Herold reported that the committee is not in a position to waive an existing law.

2. Discussion and Consideration of Refilling of ADDS in Skilled Nursing Facilities

Background
In skilled nursing facilities, ADDS are sometimes installed to permit furnishing of emergency medications or to start initial doses of medications to patients receiving care in the facilities. The board's staff believes that California law directs that drug stock maintained in the ADDS are stock of the pharmacy and that the pharmacy is responsible for restocking the device). However, board staff has been advised that some skilled nursing facilities have begun using nursing staff or perhaps other employees to refill the ADDS.

The California Department of Public Health's consultants and board inspectors note that the refilling of an ADDS is similar to the restocking of the emergency kits in SNFs, which after medication is removed from a kit, the kit is returned to the pharmacy for inventory, restocking and recordkeeping functions.

Discussion and Comment
The committee heard public comment from Robert Menet from the California Department of Public Health, Licensing and Certification Program. His program oversees licensing and certification of facilities such as acute care facilities, intermediate care facilities, skilled nursing facilities, and general acute care hospitals. Mr. Menet remarked that his organization is not aware of any regulation that allows anyone other than pharmacy personnel to restock ADDS.

He commented that Health and Safety Code section 1261.6 was enacted in 2009 and that technology has evolved significantly since the statute was put into place. Mr. Menet noted that the section is confusing, awkwardly worded, and subject to interpretation, however in the opinion of CDPH, any

medication that is not patient specific— that has not been dispensed by the pharmacy-- remains the pharmacy's inventory and should be under control of the pharmacy. Mr. Menet continued to state that he believes that section (g) is referring to the integrity of the drug distribution system and that CDPH would defer to the board's interpretation of this statute and will enforce accordingly.

3. Discussion and Consideration of Next Steps by the Committee or Board

The committee directed board staff to establish a one-day board meeting within the next 60 days to hear presentations on ADDS, particularly for ADDS intended for locations away from the pharmacy, and discussion of relevant laws relevant laws. The board's discussion will be framed around a series of questions, such as how ADDS will be controlled, how vendors ensure that drugs are matched with the correct patient, security features, and who can stock the ADDS. The board will send a subscriber alert with details about the forum.

Steve Gray, Kaiser Permanente, requested that as part of the meeting the board make a clear distinction between ADDS type devices that are used in conjunction with a skilled nursing or long-term care facility vs. a clinic where the patient takes the medication home. Dr. Gray noted that the law was recently changed to allow a registered nurse, who is working in a licensed clinic, to do the dispensing instead of a physician or pharmacist. He recommends that the board consider determining when a pharmacist will be involved and suggested reaching out to Washington State to discuss their recent changes.

e. Discussion and Consideration of Possible Regulations Regarding Patient Enrollment in Automated Refill Programs for Prescription Medications

Background

Traditionally, pharmacies have refilled prescriptions only upon the request of the patient or the patient's prescriber. However, in recent years computer programs have been developed which allow pharmacies to enroll patients in automatic refill programs ("auto-refill"). These programs automatically refill prescriptions before the patient runs out of medication. In most cases, these auto-refill programs are limited to drugs identified as maintenance medications. The argued benefit of auto-refill programs is that they increase patient compliance with drug therapy by automatically refilling maintenance medications and sending reminders to patients to pick up their prescriptions.

From late 2012 through 2013, the board received over 100 complaints directly related to auto-refill programs due to the media attention. Many of the complaints were from patients who received prescriptions they did not request and who had difficulty returning the prescriptions for a refund. Other patients inadvertently ingested medication they had not requested or ingested medication that was previously discontinued by their prescriber. Some of these events resulted in patient harm.

In response to the large number of complaints, Executive Officer Herold and other staff worked with the various agencies to address these concerns and explore possible violations of pharmacy laws and regulations.

At the October 2016 Board Meeting, staff was asked to develop an analysis and presentation for the next committee meeting to evaluate options for authorization and maintenance of auto-refill documentation in community and mail order pharmacies.

Discussion and Comment
The committee discussed the draft policy on automated refill programs:

Public Comment
The committee received public comments about Texas' auto-refill rules. The presenter stated that the auto refill program has provided pharmacists with more time to spend on consultations and that these programs have evolved significantly over the last six years. As part of Mr. McAllister's comments he noted that Texas recognizes that some Schedule IV and V medications are maintenance medications and have included them in the rule. He noted that Texas feels that the annual review is unnecessary because the patient is in charge of enrolling or disenrolling and that requiring patient approval of auto-refill medications for maintenance medications may result in a delay in therapy and inconvenience to the patient.

Ms. Herold commented that part of the purpose of the annual review is to make sure that the therapy has not changed and noted that absent a trigger to re-review medication, especially if the patient is seeing multiple prescribers, something that either duplicates the therapy or contraindicates the therapy could occur. Ms. Herold noted that some of the complaints that the board received in the past were about duplicate therapy from different pharmacies.

Mark Johnson from CVS Health offered to provide studies that show the benefit of auto-refill programs and recommended that the board review Oregon's progress in this area.

Julie Ansel, Chief of Enforcement for the board, advised the committee that regulations for Oregon and Texas and comments from CMS were taken into consideration when developing the draft policy. Ms. Herold confirmed that this document is intended to be a guideline, and from the guidelines, a regulation would be drafted and brought before the board.

Motion: Recommend to the board to approve the draft policy as amended by the committee of automated refill programs, and direct staff to use the policy to draft regulations. (The draft policy is provided below as approved by the committee)

California State Board of Pharmacy
DRAFT Policy on Automated Refill Programs:

A retail or mail order pharmacy may use a program that automatically refills prescriptions that have existing refills available, in order to improve patient compliance and are consistent with the patient's current medication therapy when all of the following conditions are met:

(1) Written notice or disclaimer of the availability of an auto-refill program shall be given to the patient or patient's agent. The patient or patient's agent must affirmatively indicate they wish to enroll in such a program and the pharmacy shall maintain documentation of such indication. Notice shall have language that references instructions on how a patient can discontinue participation in the auto-refill program.

(a) A pharmacy patient or the patient's agent shall consent to participation in an auto-refill program with a "wet" signature or an e-signature. If the pharmacy has an online consent option, the patient may enroll in the auto-refill program through that method. The pharmacy shall keep this acknowledgement on file. If the retail pharmacy has an online consent option, the patient or patient's agent can register in that manner

and the pharmacy shall keep said acknowledgment on file for one year from date of dispensing.

(b) A mail order pharmacy patient or the patient's agent shall consent to participation auto-refill program through the mail order pharmacy's website. The pharmacy shall keep this acknowledgment on file. If the mail order pharmacy does not have an online consent option, the pharmacy shall obtain a signature or email confirmation from the patient or patient's agent consenting to the auto- refill program. Acknowledgement of consent to participate in the auto-refill program shall be kept on file by the mail order pharmacy for one year from date of dispensing.

(2) The Pharmacy shall have written policies and procedures in place that ensure only medications that are eligible for the auto-refill program are enrolled in the program.

(3) The pharmacy must discontinue auto-refill program enrollment at the request of the patient or patient's agent in a timely manner.

(4) As is required for all prescriptions, a drug regimen review shall be completed on all prescriptions filled as a result of the auto-refill program. Special attention shall be noted for drug regimen review warnings of duplication of therapy and all such conflicts shall be resolved with the prescribing practitioner prior to refilling the prescription.

(5) The retail or mail order pharmacy must reaffirm annually each prescription to be enrolled in the auto-refill program.

(6) Upon a receipt of a new prescription from a provider, the patient or patient's agent shall identify if the prescription is to be included in the auto-refill program, even if the new prescription is a continuation of existing therapy.

(7) Each time a prescription is refilled a reminder notification will be provided to the patient or patient's agent, affirming that the prescription is enrolled in the auto-refill program.

(8) Pharmacies that use an auto refill program will have policies and procedures in place that address the auto-fill program. These policies and procedures will be available for inspection upon request of the board.

(9) The pharmacy shall provide a full refund to the patient or the patient's agent and the payer for an auto-refill prescription that is reported as unneeded or unnecessary if the patient or patient's agent can provide evidence or documentation that they did not register for the auto-refill program or the patient notified the pharmacy of disenrollment.

M/S: Weisser/Lippe Approve: 6 Oppose: 0 Abstain: 0

f. Discussion and Consideration of the National Council of State Boards of Nursing (NCSBN) Nursys® e-Notify system

Background

The Enforcement and Compounding Committee expressed interest during a prior meeting about

learning about the e-Notify system.

The National Council of State Boards of Nursing (NCSBN)® e-Notify system is a nurse licensure notification system that provides employers of registered nurses, and licensed practical/vocational nurses, with real-time email notifications about nurses they employ. The e-Notify system alerts subscribers when changes are made to a nurse's record, including changes to: license status, license expiration, pending license renewal, and public disciplinary action, resolution and alerts.

Discussion and Comment
As part of the discussion, Ms. Herold advised members that the National Practitioner Data Bank (Data Bank) is a central national repository for disciplinary actions taken against licensees. Ms. Herold noted that while the board would like to obtain reports from the Data Bank on all licensees; it is cost prohibitive. Ms. Herold indicated that board relies on reports for licensees that are arrested or convicted in California from the Department of Justice and reminded members that as part of an individual's license renewal licensees certify under penalty of perjury that they have no arrests or convictions since the last license renewal.

There were no public comments.

g. Discussion and Consideration of Possible Revision to Title 16 California Code of Regulations Section 1707, Off-Site Storage Waivers, to Address Licensees With Previous Records Violations

Background
Existing board regulations require that pharmacies retain records of all acquisitions and dispositions of drugs for at least three years. Some pharmacies lack sufficient space within the licensed premises to store these records. Board regulations also authorize the off-site storage of pharmacy acquisition and disposition records for records older than one year for dangerous drugs and two years for controlled drugs if a board-issued waiver is secured for off-site storage. These requirements are specified in CCR section 1707.

When the regulation permitting off-site storage of records was promulgated, only licensees that had no records violations were eligible for an off-site storage waiver. In 2015/16, the board issued 178 off-site records storage waivers and denied approximately 10.

In recent months, the board has identified several pharmacies that requested off-site storage waivers but were ineligible for waivers because they had been cited for storing records off-site without an approved waiver. Their attempt to get a waiver was generated by the citation, and a desire to come into compliance, however, the regulation's provisions provide no option for the board to grant such a request for five years after the violation occurred.

Staff requested that the committee reconsider the full prohibition and authorize discretion in the award of off-site waivers.

Discussion and Comment
As part of the discussion Ms. Herold clarified a waiver would be denied if records had been falsified. Ms. Herold advised the committee of inspections conducted by staff where, as part of the inspection it was determined that the pharmacy had moved the records off site. Ms. Herold noted that the end result was that records had to be moved back into the pharmacy because a waiver could not be

granted.

Public Comments
Steve Gray, Kaiser Permanente, suggested that the board also clarify the term "off-site" used in the regulation versus premises. Ms. Herold clarified "premises" means licensed area

Based on public comment the committee changed the language to "outside of the licensed area of the pharmacy" instead of "off-site."

The committee also heard public comment from Tony Park about independent pharmacies that close their doors for good and don't know what to do with their records. The committee discussed that waivers can only be obtained by a licensed business. Ms. Herold commented that part of the board's discontinuance of business requirement records have to be stored at a licensed location for a period of three years following the pharmacy's closure and noted that a business owner will have to find another licensee to store the records for them. Ms. Herold noted that records should not be sent to a records storage facility or stored in someone's garage where these confidential health records may not be protected. Ms. Herold indicated that records sent to a storage vault may not be appropriately protected because if the person leasing the storage vault dies or stops paying the rent, the confidential health records can be sold at public auction.

Board Member Lippe pointed out that Business and Professions Code section 4333 details records retention requirements.

Motion Recommend to the board approval of recommended changes in CCR section 1707 as discussed and amended by the committee.

(a) Pursuant to subdivision (e) of Section 4105 of the Business and Professions Code and subdivision (c) of Section 4333 of the Business and Professions Code, a waiver ~~shall~~ may be granted to any entity licensed by the board for ~~off-site~~ storage of the records outside of the licensed pharmacy described in subdivisions (a), (b) and (c) of Section 4105 of the Business and Professions Code ~~unless the applicant has, within the preceding five years, failed to produce records pursuant to Section 4081 of the Business and Professions Code or has falsified records covered by Section 4081 of the Business and Professions Code~~.

M/S: Weisser/Lippe Approve: 6 Oppose: 0 Abstain: 0

h. Discussion and Consideration of a Possible Amendment to New Business and Professions Code 4316 Regarding Cease and Desist Orders

Background
Last year, one provision contained in the board's sunset bill, SB 1193 (Hill), provided the board with the ability to issue a cease and desist order to an unlicensed entity operating within the board's regulatory jurisdiction without a license where one is required. However, following enactment of SB 1193, staff identified items in this provision needing clarification.

Discussion and Comment
As part of its discussion, counsel recommended that the committee consider replacing the words "obtaining such" in paragraph (a) with "appropriate licensure" to clarify that the licensee must have a license versus being in the process of obtaining a license.

Motion: Recommend that the board seek legislation to correct Business and Professions Code section 4316 as proposed including incorporating the revisions suggested by Ms. Freedman.

Amend Business and Professions Code Section 4316

(a) The board, through its executive officer, is authorized to issue a cease and desist order for operating any facility under this chapter that requires licensure or for practicing any activity under this chapter that requires licensure without appropriate licensure.

(b) Whenever the board issues a cease and desist order pursuant to subdivision (a), the board shall immediately issue the facility a notice setting forth the acts or omissions with which it is charged, specifying the pertinent code section or sections and any regulations.

(c) The order shall provide that the facility, within 15 days of receipt of the notice, may request a hearing before the president of the board to contest the cease and desist order. Consideration of the facility's contest of the cease and desist order shall comply with the requirements of Section 11425.10 of the Government Code. The hearing shall be held no later than five days from the date the request of the owner is received by the board. The president shall render a written decision within five days of the hearing. In the absence of the president of the board, the vice president of the board may conduct the hearing permitted by this subdivision. Review of the decision of the president of the board may be sought by the owner or person in possession or control of the ~~pharmacy~~ facility pursuant to Section 1094.5 of the Code of Civil Procedure.

M/S: Lippe/Weisser Approve: 6 Oppose: 0 Abstain: 0

i. Discussion and Consideration of U.S. Department of Health and Human Services Food and Drug Administration's Article, Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification Guidance for Industry

Board of Pharmacy Supervising Inspector Michael Ignacio provided a presentation to the committee on components provided in this guidance document concerning suspect product found in the pharmaceutical supply chain and addressed by the Drug Supply Chain Security Act.

Dr. Ignacio reminded members that on November 27, 2013, the Drug Supply Chain Security Act (Title II of Public Law 113-54) was signed into law and as part of the law the Food and Drug Administration (FDA) was required to issue guidance to aid trading partners in identifying a suspect product and terminating notifications. Dr. Ignacio reviewed the definition of a suspect product is defined as product for which there is reason to believe it is potentially counterfeit, diverted, or stolen; is potentially intentionally adulterated, such that the product would result in serious adverse health consequences or death to humans; is potentially the subject of a fraudulent transaction; or appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

Dr. Ignacio indicated that in December 2016, the FDA published a guidance document titled *Drug*

Supply Chain Security Act Implementation: Identification of Suspect Product and Notification Guidance for Industry to clarify when manufacturers and other trading partners should notify the FDA if there is a high risk that a product is illegitimate. He noted that the FDA is seeking comments and suggestions regarding this document and that the comment period ends February 7, 2017.

Dr. Ignacio stated that the guidance identifies specific scenarios that could significantly increase the risk of a suspect product entering the pharmaceutical distribution supply chain; provides recommendations on how trading partners can identify a product and determine whether a product is a suspect product as soon as practicable; and sets forth the process by which trading partners should notify FDA of illegitimate product or products with a high risk of illegitimacy, and how they must terminate the notifications, in consultation with FDA.

After discussion the committee determined that the board does not need to provide comments on the draft guidance. The committee was advised that the board's next *The Script* will include information on this guidance.

Public comment received suggested that the information should also be shared with the Medical Board and Dental Board.

j. Discussion and Consideration of Beyond Use Labels in Institutional Settings

Background

At the board's December 14 meeting in Glendale, the board received a request for a modification of the expiration date used on prescription labels from "exp" to "do not start after." The request came from Providence Hospital and stated the following:

> "Providence Health & Services in Southern California shares the same inpatient medication label template in our EMR system.
>
> The DOPs (covering 6 inpatient, acute-care facilities) met and discussed replacing the current "**Exp:**" field on the med label with "**Do Not Start after:**".
>
> Part of that decision had to do with using terminology that nursing staff can easily speak to (vs. using the term BUD). The group felt that using language that nurses can articulate will help with compliance.
>
> The behind-the-scenes EMR work is extensive and we wanted to solicit feedback from the Board of Pharmacy before making any changes to our medication labels. I have attached the image of the mock-up. Would you mind giving us some feedback as to the acceptability of using this language on our med labels? If you have any other suggestions, we would appreciate your guidance.
>
> With respect to existing law, Title 16 California Code of Regulations section 1735.1(b) effective 1/1/17 provides that:
>
> (c) "Beyond use date" means the date, or date and time, after which administration of a compounded drug preparation shall not begin, the preparation shall not be dispensed, and the preparation shall not be stored (other than for quarantine purposes)."

Discussion and Comment
Ms. Herold commented that as long as the licensee meets the minimum label requirements, they can add additional information. The additional information in this case provides clearer direction as to what is appropriate for this medication. The committee members agreed that additional information on the label that is intended to clarify the directions is beneficial to the patient. This issue may be addressed in a future news article letter of *The Script*.

IV. Compounding Matters

a. Discussion and Consideration of Statistics for Board-issued Citations and Fines for Compounding Violations

Discussion and Comment
Board Member Schaad reviewed the compounding citations and fines issued by the board between January 1, 2016 and December 16, 2016. Mr. Schaad noted that most compounding institutions cited had both sterile and non-sterile compounding citations and that 75 pharmacies had non-sterile compounding infractions and 38 had sterile compounding infractions. Mr. Schaad indicated that out of the 1,100 sterile compounding pharmacies that were inspected during the year, only 38 received citations.

The committee discussed which license(s) may be issued a citation for a violation. Ms. Herold commented that the violations are cited against the pharmacist-in-charge (PIC) at the time that the violation occurred; this may not necessarily be the PIC at the time of the inspection. She also clarified that five months can lapse between the investigation and the issuance of the citation and fine. Ms. Herold provided the committee with a brief overview of the process noting that after an inspection is completed and violations identified, a report has to be written which is then reviewed by a supervising inspector and one senior staff before the citation and fine will be issued.

Mr. Schaad also noted that there were two cases where pharmacies compounded commercially available products and were cited for this, as well as citations issued for lack of a master formula.

The committee discussed the appeal process that a licensee may request in response to a citation and heard public comment about some variances in inspector findings that are noted during an inspection.

Board member Ricardo Sanchez returned from break at 1:41.

b. Update and Discussion of Compounding Construction Waivers for New Requirements in Title 16 California Code of Regulations, Sections 1735 et seq., and 1751 et seq.

Discussion and Comment
Supervising Inspector Christina Acosta provided an update on compounding construction waivers. Dr. Acosta reminded the committee that she and Board Member Schaad, Chairperson Gutierrez, Executive Officer Herold, Chief Enforcement Officer Julie Ansel have been reviewing these construction waivers requests consistent with the board's direction. Dr. Acosta provided an overview of the waivers received and the number of requests pending. Specifically, Dr. Acosta advised the committee that as of January 2, 2017, the board has received 493 waiver requests and processed 214 requests (43%). Of the 214 requests processed, about 50 (23%) did not have a licensed sterile

compounding license, so the waiver was not related to sterile compounding. Ms. Acosta stated that of those processed, 70 have been approved and 2 have been denied. Ms. Acosta indicated that of 214 requests reviewed, 112 (52%) were for a pharmacy and 102 (48%) were for a hospital. Dr. Acosta indicated that she working with several waiver applicants to obtain additional information so that the request can be brought forward to the committee. Dr. Acosta has provided the committee with information on the additional waiver requests that 280 waivers have not been processed noting that, including 70 which were received on December 29, 2016.

Dr. Acosta advised the committee that many of the waivers are not complete and that some waiver requests are asking that all construction requirements be waived instead of a waiver only for specific items to be updated. She noted that the applicant needs to provide the specific section of 1735.6 and 1751.4 to be waived along with the subsection and provide information detailing their attempts to comply with the regulation and when they expect to be compliant. She noted that waivers for non-construction requirements, such as not cleaning the facility or complying with policies and procedures, cannot be granted. The committee was advised that waiver requests and email communication should be sent to Compounding.waivers@dca.ca.gov.

Ms. Herold stated that board inspectors focused on doing educational compliance during inspections and board staff have provided education at specially convened public forums.

Public Comments

B.J. Bartelson from the California Hospital Association (CHA) suggested that the board partner with the CHA to complete educational webinars for hospitals. Chairperson Gutierrez suggested that the board consider this option for big issues.

As part of public comment, the committee heard a request for a template of what the ideal waiver package might look like. In response, Dr. Gutierrez explained that the application is designed to provide the information that the board will need to make a decision. Dr. Acosta explained that each practice is unique and as such a single one example for all applicants to use is not possible. The committee was reminded that, at a minimum, the request needs to include the specific regulation and subsection that applies, the specific construction required, the construction start and projected end date as well as the pharmacy's plan during the transition period

The committee noted that a sample waiver package was provided at the October 26-27, 2016 Board Meeting and could be found on the board's website in the meeting materials section in pages 82 - 108. The link to the meeting materials is:
http://www.pharmacy.ca.gov/meetings/agendas/2016/16_oct_bd_mat_enf.pdf

Kaiser representatives stated that they are committed to meeting the regulations and submitted 59 waivers on December 13, 2016. The representative noted that their two most frequent waiver requests are based on sections 1735.6(e)1, which is related to having a physically separate room, and 1735.6(e)2, which is related to having appropriate negative pressure noting that their main concern is space available in some of the older facilities, may not accommodate the template that they have developed for adding a negative pressure room. The committee was advised that Kaiser is exploring all options, including mobile clean rooms and modular clean rooms and heard that some of their challenges include relocating pharmacies or clean rooms. Commenters noted that renovations in an operating hospital takes care and time as it involves disrupting water, power, medical gasses, and air supply.

Ms. Herold reiterated that the board is currently focused on educational compliance, but noted that if staff encounters an egregious situation, action will be taken as the board's underlying core is public protection. Ms. Herold noted that pharmacies and hospitals have other options including purchasing product from somewhere else or using a shorter the beyond use date (administering the product before it has a chance to grow anything). Ms. Herold reiterated that the goal is to get licensees into compliance as quickly as possible.

A representative from Dignity Hospital commented that to lower the beyond use date, the hospital has to essentially compound one product at a time which has a significant impact on their workload.

The committee also received comments from a non-sterile compounding pharmacist asking about waivers that have been submitted, but not yet approved. Chairperson Gutierrez recommended that the pharmacy keep a copy of the waiver request at their pharmacy to show the inspector in the event of a pharmacy inspection. Dr. Acosta reiterated that the focus is educational compliance and that with the inspections conducted recently, with one exception, all inspections have resulted in education and correction only.

c. Discussion and Consideration of the United States Government Accountability Office (GAO) Report to Congressional Committees, *Drug Compounding, FDA Has Taken Steps to Implement Compounding Law, but Some States and Stakeholders Reported Challenges*

Background
In mid-November 2016, the GAO released a report on the regulation of compounding by states following the 2012 New England Compounding Center public health emergency.

Discussion and Comment
Chairperson Gutierrez remarked that she noticed that other boards of pharmacy are now looking at sterile compounding in non-pharmacy areas, such as physicians' offices. Dr. Gutierrez noted that the board does not have jurisdiction over these other areas where compounding occurs and that the FDA has issued draft guidance to address this gap.

As part of public comment, clarification was requested an outsourcers ability to compound patient specific products. In response, Ms. Herold advised the committee and public that California law is different and under provisions in California law, an outsourcer cannot compound patient specific medication.

d. Review and Discussion of California Law Governing Compounding and Conflicts with USP Section 800

Background
Staff has been made aware of possible conflicts between our new compounding regulation and USP 800 and other regulatory requirements. .

Additional discussion is also needed regarding California Business and Professions Code section 4127.7 as it relates to USP 800 and our new regulations requirements for hazardous drugs.

Discussion and Comment

Dr. Acosta provided a summary of the areas of conflict between board regulations and USP 800. Dr. Acosta noted that the biggest difference is the allowance by USP for the use of a double HEPA filter for the nonsterile hazardous products which is not allowed in board's newly enacted regulations. Dr. Acosta suggested that the board may want to reconsider how it defines biological safety cabinet versus how it is defined elsewhere. Dr. Acosta noted that Business and Professions Code section 4127.7 is inconsistent Title 24 building codes.

Dr. Acosta briefly discussed the factors to consider when determining if an allowance should be made for the double HEPA filter. Dr. Acosta highlighted some of the challenges with certifying the system but suggested that it may be offset by the setting in which it is used. Chairperson Gutierrez commented that concerns have been expressed about the ability to vent the hood which is what the board's regulation currently required. The committee discussed if this requirement was appropriate for compounding such as preparing a topical preparation in a hood.

Public Comments

Rick Rhoads with University Compounding Pharmacy (UCP) noted that UCP has run into issues with the HVAC requirements as the demand of the HVAC goes up exponentially when you have to vent out the hood. UCP advised the committee that to comply with the board's current requirement a significant amount of air must leave the room that must be replaced. UCP indicated that to comply with the current regulations their pharmacy would need an air conditioner the size of a parking space to accommodate this regulation in its current form.

The committee discussed the need to create an option to allow for either the venting of the hood or the use of a double HEPA filter.

A compounding pharmacist commented that the USP 800 people are experts and that they believe that double filtration is acceptable for level 2 and 3. A representative from California Pharmacist Association also stated that they agree that the double filtration system is acceptable.

Dr. Acosta also recommended that the board reconsider its definition of "biological safety cabinet" (BSC) noting that a BSC can also be used for nonsterile drug compounding and suggested that an amendment to 1735.1(c) to remove the word "sterile."

MOTION: Recommend that the board to modify its requirements to allow the use of a double filtration system in lieu of external venting and amend CCR section 1735.1 (c) to remove the word "sterile" from the definition of a BSC.

M/S: Weisser/Lipper Approve: 5 Oppose: 0 Abstain: 1

Dr. Acosta commented that USP 800 as well as the board's new regulations create a conflict with B&P 4127.7 relating to the use of ISO 5 laminar hood. Dr. Acosta noted that the board's statute also conflicts with Current Good Manufacturing Practices (cGMPs). Dr. Acosta continued to indicate that CCR section 1751 includes reference to title 24 building codes which may also require modifications.

The committee discussed the issue and decided to focus on the most urgent issues and then have a more robust discussion about additional issues with the board's regulation in the future. The committee requested that in the future draft regulation language be provided to the committee for consideration as part of the discussion.

MOTION: Recommend to the board repeal of BPC section 4127.7.
M/S: Weisser/Lipper Approve: 6 Oppose: 0 Abstain: 0

e. Presentation on Requirements for Sterile Compounding Master Formulas

Dr. Acosta provided a presentation on compounding master formula requirements.

f. Discussion and Consideration of the Proposed Food and Drug Administration Rule, "List of Bulk Drug Substances That Can Be Used to Compound Drug Products in Accordance with Section 503A of the Federal Food, Drug, and Cosmetic Act"

Background
On December 16, 2016, the Food and Drug Administration proposed rule, List of Bulk Drug Substances that can be used to Compound Drug Products, addressing six bulk drug substances the agency has evaluated and is proposing for inclusion on a list of bulk drug substances that can be used in compounding under section 503A of the Food, Drug, and Cosmetic Act. The proposed rule also proposes that four other bulk drug substances that FDA evaluated not be included on the 503A bulks list.

If the proposed rule is finalized, the six bulk drug substances proposed for inclusion will be the first ones included on the 503A bulks list.

The public comment period on the proposed rule closes on March 16, 2017.

Discussion and Comment
Dr. Acosta and Chairperson Gutierrez agreed that this topic warrants further discussion at the next committee meeting.

V. Enforcement Statistics

The committee was directed to the following statistics:

a. Citations and Fines
b. Medication Errors
c. Other Enforcement Statistics

A copy of these statistics is provided on the board's website.

There were no board member or public comments.

Meeting Dates for 2017

The committee noted meeting dates for the remainder of the year.

- April 18, 2017
- July 12, 2017
- October 17, 2017

The meeting was adjourned at 3:31 p.m.

Attachment 2

California Department of Justice

CURES 2.0

Prescription Drug Monitoring Program

May, 2016

CURES 2.0

CURES/PDMP Program

CURES stores and reports Schedule II, III and IV prescription dispensation data reported by dispensers to DOJ.

Pharmacies and Direct Dispensers are required to report dispensations at least weekly.

CURES receives about one million prescription reports per week.

CURES data reflects dispensing information exactly as it is reported to DOJ.

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CA Department of Justice

CURES 2.0

CURES/PDMP Program

DOJ does not add, modify, or delete prescription data reported to CURES.

DOJ does not validate the accuracy or truthfulness of the data.

The pharmacy or direct dispenser creates and owns the prescription record submitted to DOJ. DOJ is a custodian (and not editor) of these aggregated prescription records.

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CA Department of Justice

CURES 2.0

CURES/PDMP Program

CURES provides registered prescribers and dispensers with a Patient Activity Report (PAR) up to one year patient prescription history to assist health practitioners prescribe safely and to identify patients at risk of addiction.

All California licensed pharmacists and all California licensed prescribers who are authorized to prescribe scheduled drugs are required to register with CURES by July 1, 2016 or upon licensure, whichever occurs later.

SB482 (stats 2016, Chapter 708, Lara) adds H&S section 11165.4, requiring prescribers to consult the CURES database prior to first-time prescribing of a Shedule II, III or IV controlled substance and at least every four months thereafter if the substance remains part of the treatment of the patient.

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CURES 2.0

CURES 2.0 Business Analysis

The iatrogenically addicted patient vs. the doctor shopper

~

The clinical community requires more data presentation than CURES 1.0's simple provisioning of a basic 12-month PAR.

~

Today's technology can provide better monitoring of at-risk prescribing thresholds and is capable of reactive reporting when therapy levels become at-risk.

~

Technology affords the capability to denote treatment exclusivity compacts, and provide prescribers the ability to communicate securely across health care plans.

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CA Department of Justice

CURES 2.0

CURES 2.0 User Features

Automated Registration

California clinical users are provided a fully automated registration process.

Delegation Authority

Prescribers and dispensers can easily assign delegates who can initiate CURES 2.0 patient inquiries on their behalf.

Patient Safety Alerts/Messaging

Prescribers are alerted daily with information regarding their patients who reach various prescribing thresholds.

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CURES 2.0

CURES 2.0 User Features

Compact Flagging

Prescribers can easily notate their patients with treatment exclusivity compacts, forewarning other providers that additional prescribing to these patients can be potentially counter-productive to their existing treatment regimen.

Peer-to-Peer Communication

Prescribers and dispensers can instigate alert messages to fellow doctors and pharmacists about mutual patients of concern.

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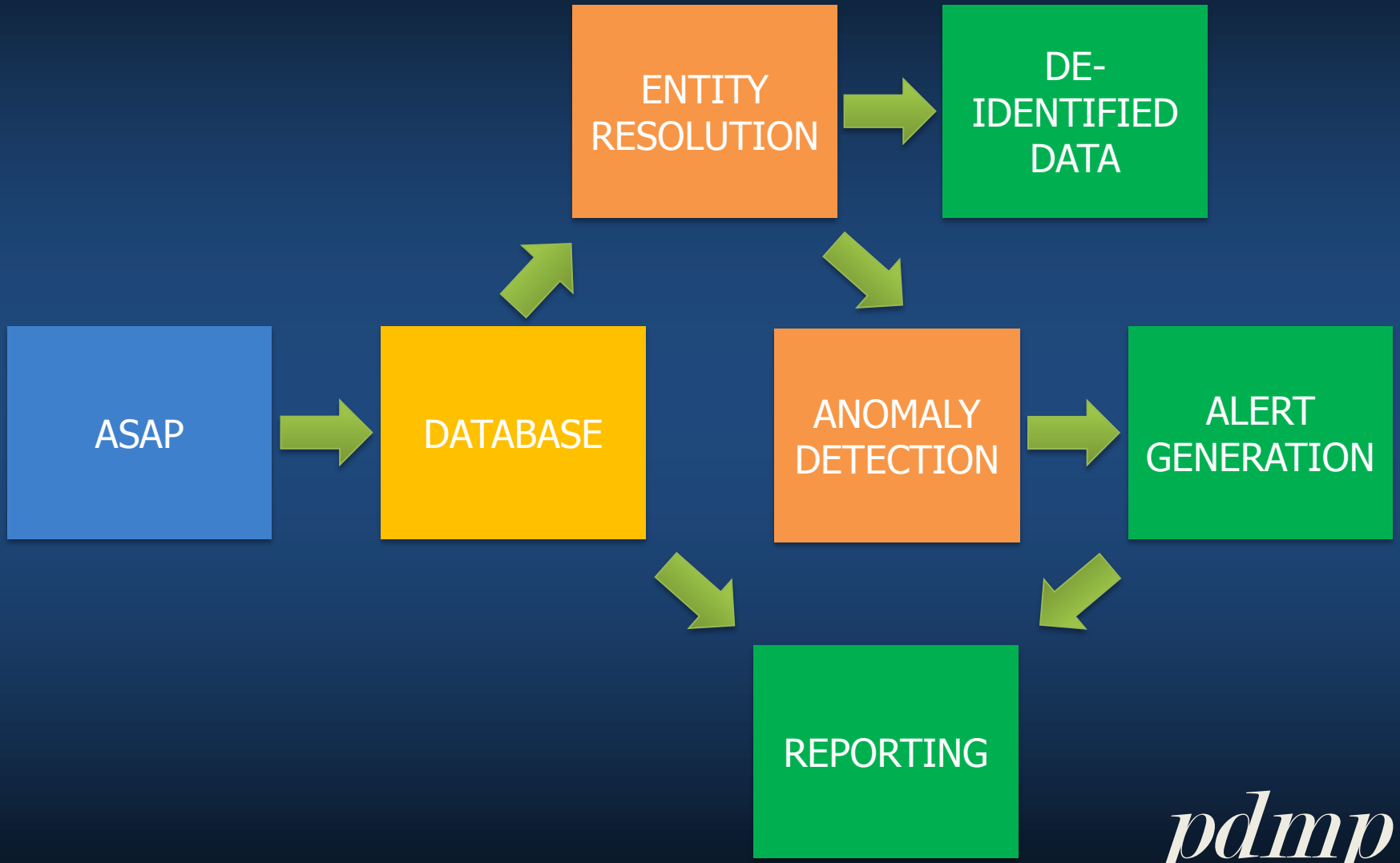
CURES 2.0



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CURES 2.0

De-Duplication

PDMP patient data lacks positive identifiers.

John Doe, Johnnie Doe, John J. Doe, Jack Doe

06/19/1953, 06/19/1935, 06/19/1963

2101 Columbus Avenue, Sacramento, CA 95814
2101 Columbus Street, Sacramento, CA 95814
1201 Columbus Boulevard, San Diego, CA 95828

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CA Department of Justice

CURES 2.0

De-Duplication

Every day approximately 145K new Rx records are added to the CURES 2.0 data base. With this new data, the analytics engine must re-resolve patient, prescriber and dispenser entities across the 1TB database every night.

Person entities are resolved by:

Name and DOB and Zip(5)

OR

Name and Street Address and City

The de-duplicated data also contributes to the quarterly and annual systematic production of 58 county and one statewide de-identified data sets for use by public health officers and researchers.

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CA Department of Justice

CURES 2.0

De-Duplication

Name *and* DOB *and* Zip(5) **OR** Name *and* Street Address *and* City

John Doe
04/19/1963
2101 Columbus Ave
Sacramento, CA 95814

John J. Doe
04/19/1963
2100 Columbia Way
Sacramento, CA 95814

John Doe
04/19/1963
1201 Columbus Boulevard
San Diego, CA 92111

One John Doe Entity

Johnnie Doe
04/19/1936
2101 Columbus Avenue
Sacramento, CA 95814

Jack Doe
04/19/1963
2101 Columbus Ave.
Sacramento, CA 95814

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CURES 2.0

Medicinal Computations

Once the data is de-duplicated nightly, the analytics engine identifies the resolved person entity's current prescriptions based on date filled and number of days supply.

The resolved person entity's current prescription medicinal therapy levels are calculated and compared against pre-established thresholds. Therapy levels exceeding those thresholds trigger Patient Safety Alerts to current prescribers.

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CURES 2.0

Patient Safety Alerts

1. Rx Recipients Who are Currently Prescribed More than 100 Morphine Milligram Equivalency Per Day
2. Rx Recipients Who Have Obtained Prescriptions from 6 or More Prescribers or 6 or More Pharmacies During Last 6 Months
3. Rx Recipients Who Are Currently Prescribed More than 40 Milligrams Methadone Daily
4. Rx Recipients Who Are Currently Prescribed Opioids More Than 90 Consecutive Days
5. Rx Recipients Who Are Currently Prescribed Both Benzodiazepines and Opioids

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CURES 2.0

De-Identified Data

CURES 2.0 systematically de-identifies county and statewide data sets for County Health Officers and researchers.

Quarterly and annual de-identified data sets are produced.

This data enables counties to calculate current rates of prescriptions, examine variations within the state, and track the impact of safe prescribing initiatives.

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CA Department of Justice

CURES 2.0

www.oag.ca.gov/cures

CURES@doj.ca.gov

(916) 227-3843

CURES Program
P.O. Box 160447
Sacramento, CA 95816

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CA Department of Justice

Proposal to Amend Health and Safety Code (HSC) section 11165.

(a) To assist health care practitioners in their efforts to ensure appropriate prescribing, ordering, administering, furnishing, and dispensing of controlled substances, law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, ~~and~~ Schedule IV, and Schedule V controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds in the CURES Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of, and Internet access to information regarding, the prescribing and dispensing of Schedule II, Schedule III, ~~and~~ Schedule IV, and Schedule V controlled substances by all practitioners authorized to prescribe, order, administer, furnish, or dispense these controlled substances.

(b) The Department of Justice may seek and use grant funds to pay the costs incurred by the operation and maintenance of CURES. The department shall annually report to the Legislature and make available to the public the amount and source of funds it receives for support of CURES.

(c) (1) The operation of CURES shall comply with all applicable federal and state privacy and security laws and regulations.

(2) (A) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party, unless authorized by, or pursuant to, state and federal privacy and security laws and regulations. The Department of Justice shall establish policies, procedures, and regulations regarding the use, access, evaluation, management, implementation, operation, storage, disclosure, and security of the information within CURES, consistent with this subdivision.

(B) Notwithstanding subparagraph (A), a regulatory board whose licensees do not prescribe, order, administer, furnish, or dispense controlled substances shall not be provided data obtained from CURES.

(3) In accordance with federal and state privacy laws and regulations, a health care practitioner may provide a patient with a copy of the patient's CURES patient activity report as long as no additional CURES data is provided and keep a copy of the report in the patient's medical record in compliance with subdivision (d) of Section 11165.1.

(d) For each prescription for a Schedule II, Schedule III, ~~or~~ Schedule IV, or Schedule V controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14,

respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the Department of Justice as soon as reasonably possible, but not more than ~~seven days~~ 48 hours after the date a controlled substance is dispensed, in a format specified by the Department of Justice:

(1) Full name, address, and, if available, telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.

(2) The prescriber's category of licensure, license number, national provider identifier (NPI) number, if applicable, the federal controlled substance registration number, and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

(3) Pharmacy prescription number, license number, NPI number, and federal controlled substance registration number.

(4) National Drug Code (NDC) number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.

(6) International Statistical Classification of Diseases, 9th revision (ICD-9) or 10th revision (ICD-10) Code, if available.

(7) Number of refills ordered.

(8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

(9) Date of origin of the prescription.

(10) Date of dispensing of the prescription.

(e) The Department of Justice may invite stakeholders to assist, advise, and make recommendations on the establishment of rules and regulations necessary to ensure the proper administration and enforcement of the CURES database. All prescriber and dispenser invitees shall be licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, in active practice in California, and a regular user of CURES.

(f) The Department of Justice shall, prior to upgrading CURES, consult with prescribers licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, one or more of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, and any other stakeholder identified by the department, for the purpose of identifying desirable capabilities and upgrades to the CURES Prescription Drug Monitoring Program (PDMP).

(g) The Department of Justice may establish a process to educate authorized subscribers of the CURES PDMP on how to access and use the CURES PDMP.

Proposed Amendment to HSC section 11165.1.

(a) (1) (A) (i) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, ~~or~~ Schedule IV, or Schedule V controlled substances pursuant to Section 11150 shall, before July 1, 2016, or upon receipt of a federal Drug Enforcement Administration (DEA) registration, whichever occurs later, submit an application developed by the Department of Justice to obtain approval to access information online regarding the controlled substance history of a patient that is stored on the Internet and maintained within the Department of Justice, and, upon approval, the department shall release to that practitioner the electronic history of controlled substances dispensed to an individual under his or her care based on data contained in the CURES Prescription Drug Monitoring Program (PDMP).

(ii) A pharmacist shall, before July 1, 2016, or upon licensure, whichever occurs later, submit an application developed by the Department of Justice to obtain approval to access information online regarding the controlled substance history of a patient that is stored on the Internet and maintained within the Department of Justice, and, upon approval, the department shall release to that pharmacist the electronic history of controlled substances dispensed to an individual under his or her care based on data contained in the CURES PDMP.

(B) An application may be denied, or a subscriber may be suspended, for reasons which include, but are not limited to, the following:

(i) Materially falsifying an application for a subscriber.

(ii) Failure to maintain effective controls for access to the patient activity report.

(iii) Suspended or revoked federal DEA registration.

(iv) Any subscriber who is arrested for a violation of law governing controlled substances or any other law for which the possession or use of a controlled substance is an element of the crime.

(v) Any subscriber accessing information for any other reason than caring for his or her patients.

(C) Any authorized subscriber shall notify the Department of Justice within 30 days of any changes to the subscriber account.

(2) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, ~~or~~ Schedule IV, or Schedule V controlled substances pursuant to Section 11150 or a pharmacist shall be deemed to have complied with paragraph (1) if the licensed health care practitioner or pharmacist has been approved to access the CURES database through the process developed pursuant to subdivision (a) of Section 209 of the Business and Professions Code.

(b) Any request for, or release of, a controlled substance history pursuant to this section shall be made in accordance with guidelines developed by the Department of Justice.

(c) In order to prevent the inappropriate, improper, or illegal use of Schedule II, Schedule III, ~~or~~ Schedule IV, or Schedule V controlled substances, the Department of Justice may initiate the referral of the history of controlled substances dispensed

to an individual based on data contained in CURES to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.

(d) The history of controlled substances dispensed to an individual based on data contained in CURES that is received by a practitioner or pharmacist from the Department of Justice pursuant to this section is medical information subject to the provisions of the Confidentiality of Medical Information Act contained in Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code.

(e) Information concerning a patient's controlled substance history provided to a prescriber or pharmacist pursuant to this section shall include prescriptions for controlled substances listed in Sections 1308.12, 1308.13, and 1308.14 of Title 21 of the Code of Federal Regulations.

(f) A health care practitioner, pharmacist, and any person acting on behalf of a health care practitioner or pharmacist, when acting with reasonable care and in good faith, is not subject to civil or administrative liability arising from any false, incomplete, inaccurate, or misattributed information submitted to, reported by, or relied upon in the CURES database or for any resulting failure of the CURES database to accurately or timely report that information.

Attachment 3

Study of Expanded Use of an Automated Delivery Device

UPDATE
January 4, 2017

Jan D. Hirsch, BPharm, PhD
UCSD Skaggs School of Pharmacy & Pharmaceutical Sciences

UC San Diego
HEALTH SCIENCES

Update

- ScriptCenter Kiosk
  - Operations Update
- Update on Study
  - Reminder: Research Design & Questions
  - IRB Amendment
  - Study Timeline Requested Revision

UC San Diego
SKAGGS SCHOOL OF PHARMACY AND PHARMACEUTICAL SCIENCES

ScriptCenter Kiosk
Sharp Memorial Hospital

Location Change June 2016

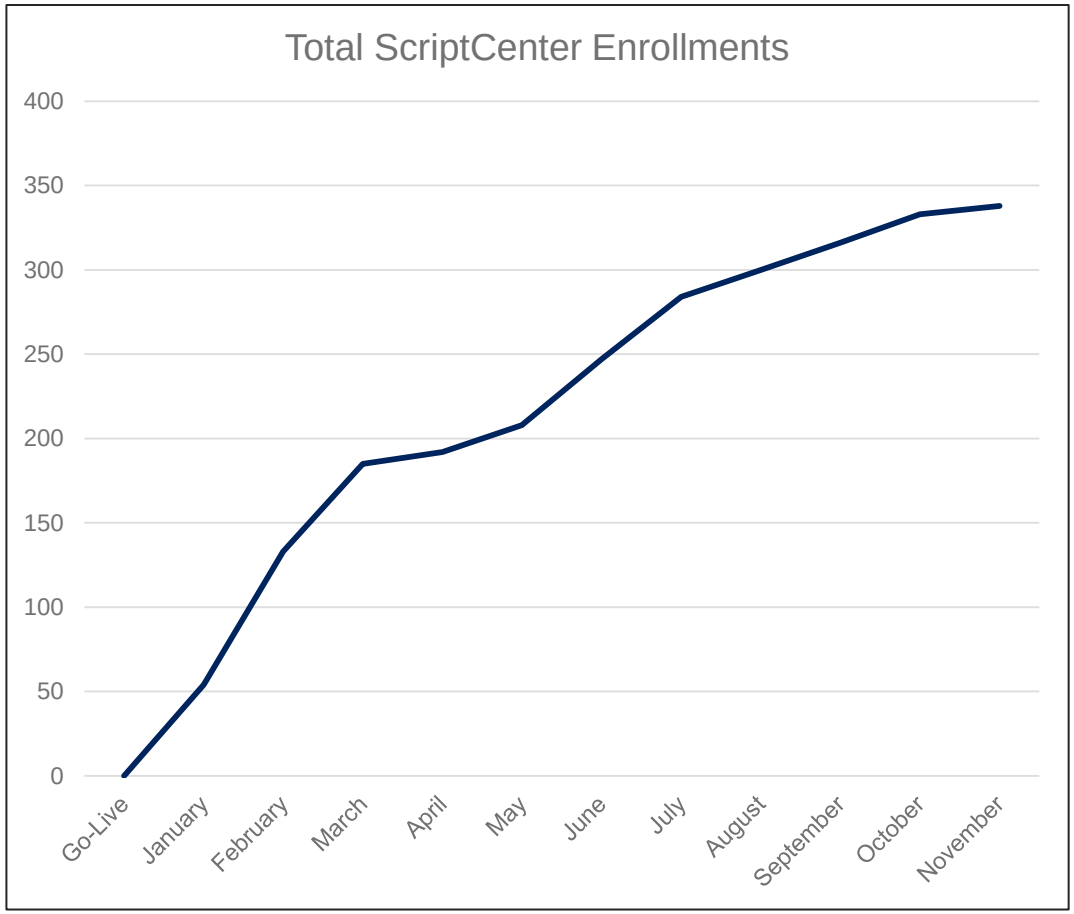
First Floor Lobby Sharp Memorial Hospital

UC San Diego
SKAGGS SCHOOL OF PHARMACY AND PHARMACEUTICAL SCIENCES

ScriptCenter Kiosk Activity 1/20/16 through 11/30/16

Kiosk Go Live Date: 1/20/16
Study Start: 3/1/16

ENROLLMENT



338 users
(*7% Campus Employees)*

Total Campus Employees
4,820
Day Shift = 2,592
PM+ Variable = 2,228

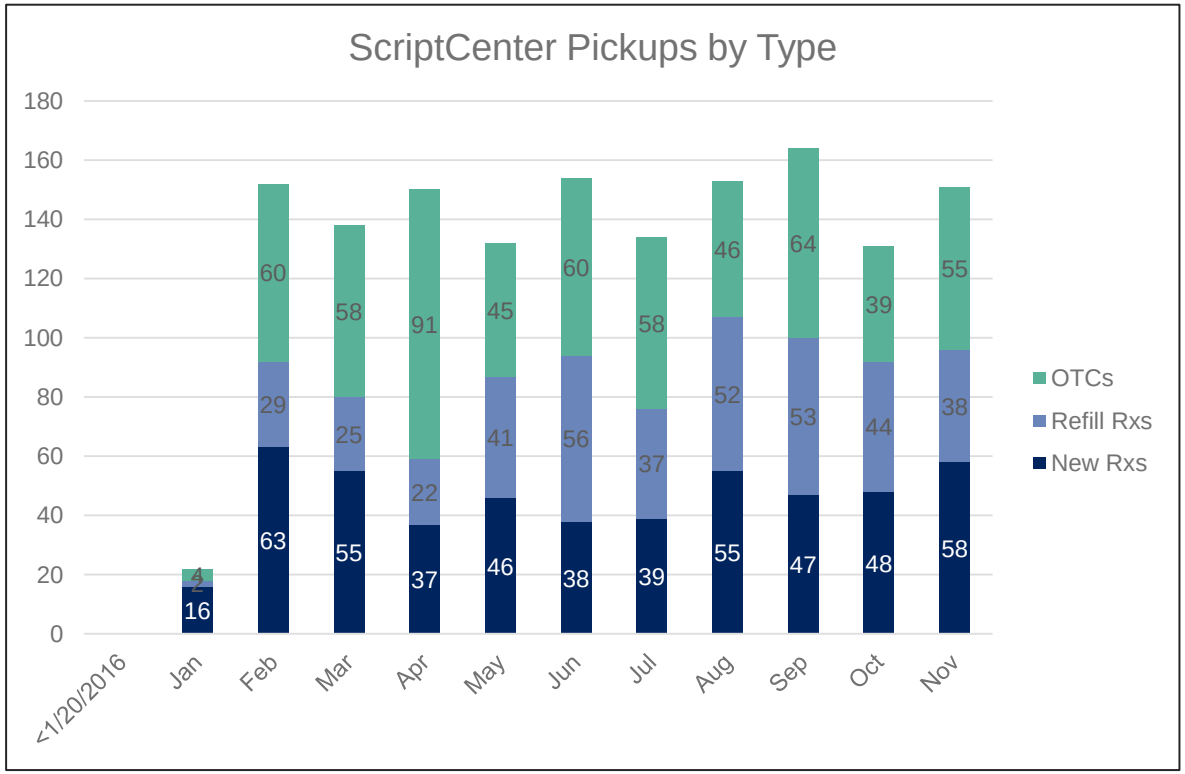
If estimate 2 per household
= 9,640

UC San Diego
Skaggs School of Pharmacy and Pharmaceutical Sciences

ScriptCenter Kiosk Activity 1/20/16 through 11/30/16

Pickups by Type

Kiosk Go Live Date: 1/20/16
Study Start: 3/1/16



- Average 88 Rxs per month
- Surpassed number needed for study on 12/7/16 (820)
- Data collection complete end of December

338 Users

Note: Higher 'new prescriptions' in the early months are due to a higher number of prescription transfers when went live. Many of these prescriptions are being turned into refills as time passes.

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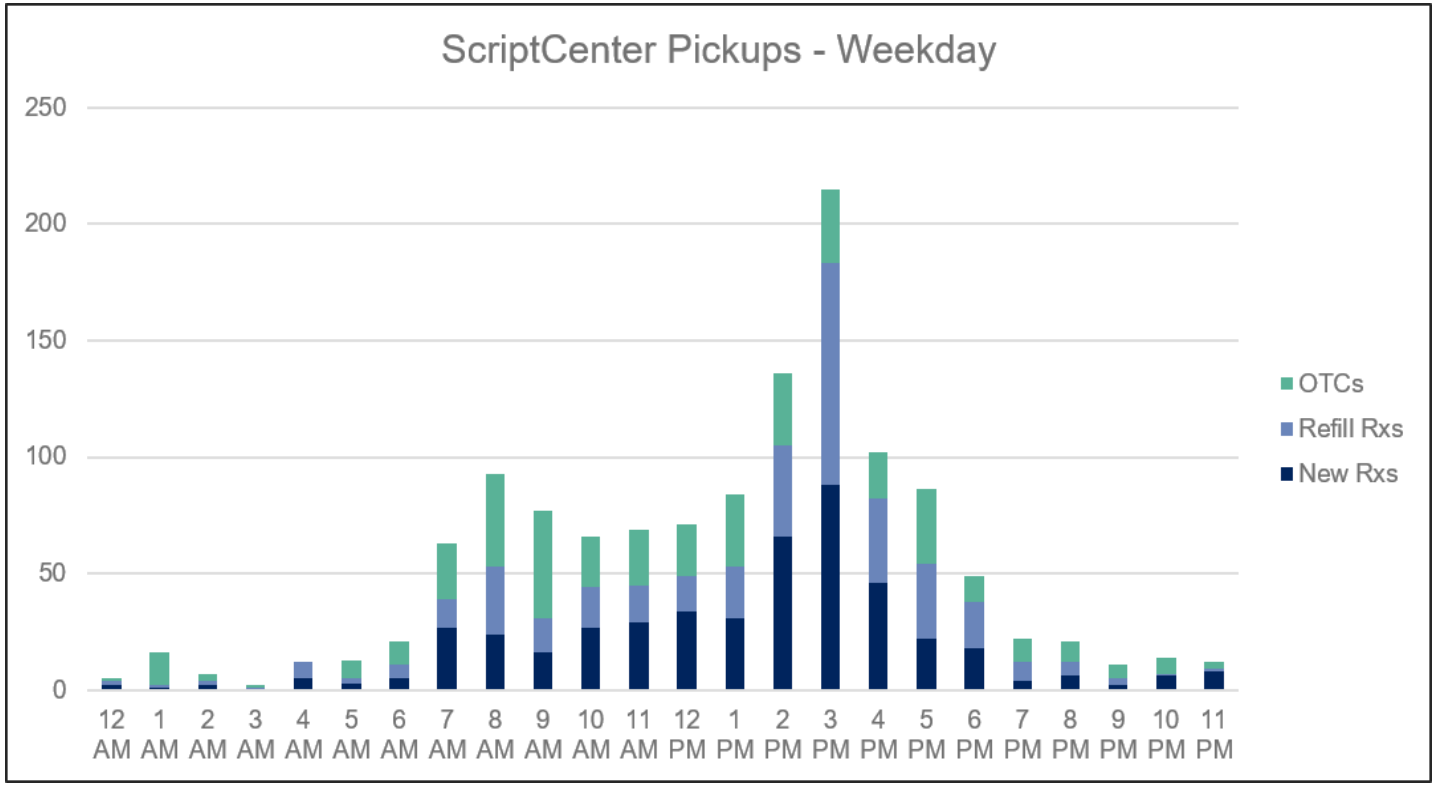
ScriptCenter Kiosk Activity 1/20/16 through 11/30/16

Pickups by Time Weekday

Kiosk Go Live Date: 1/20/16
Study Start: 3/1/16



Day Shift
2,592

PM + Variable
2,228

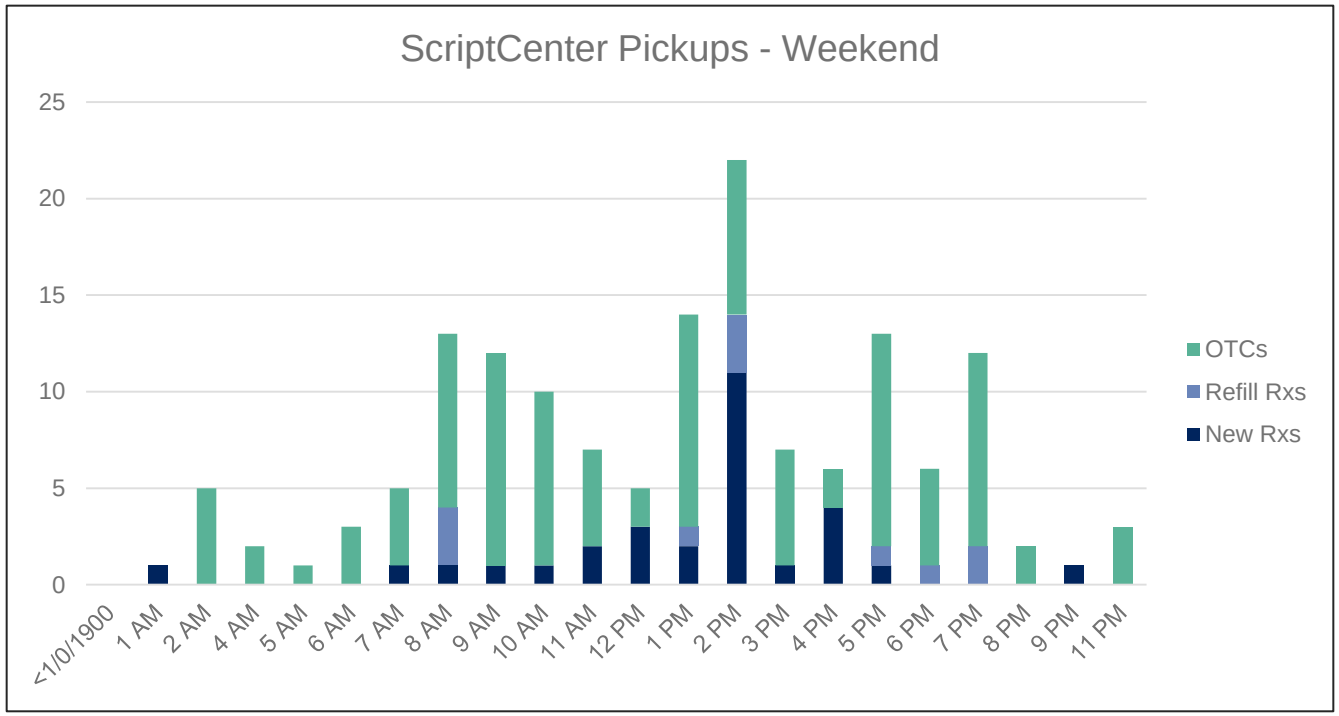
338 Users

UC San Diego
Skaggs School of Pharmacy and Pharmaceutical Sciences

ScriptCenter Kiosk Activity 1/20/16 through 11/30/16

Pickups by Time Weekend

Kiosk Go Live Date: 1/20/16
Study Start: 3/1/16



Day Shift
2,592

PM + Variable
2,228

338 Users

Pharmacy Closed

UC San Diego
Skaggs School of Pharmacy and Pharmaceutical Sciences

ScriptCenter Kiosk
During vs. After Hours Pickup

Kiosk Go Live Date: 1/20/16
Study Start: 3/1/16

1,481 Total Pickups

1,064 (72%) During pharmacy hours
417 (28%) After pharmacy hours

502 New Rx Pickups

390 (78%) During pharmacy hours
112 (22%) After pharmacy hours

399 Refill Rx Pickups

325 (81%) During pharmacy hours
74 (19%) After pharmacy hours

580 OTC Pickups

349 (60%) During pharmacy hours
231 (40%) After pharmacy hours

Day Shift 2,592

PM + Variable
2,228

338 Users

Data is 1/20/16 through 11/30/16.
After hours includes weekday & weekend times pharmacy is closed.

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ScriptCenter Kiosk Consultations Study Period (3/1/16 – 11/30/16)

Kiosk Go Live Date: 1/20/16
Study Start: 3/1/16

	Total prescriptions with a new Rx #, pharmacist released for pick up at ScriptCenter	New Rxs Requiring Counseling (including transferred) Counseling Provided	New Rxs Not Requiring Counseling (due to Sharp re write with no changes) Counseling Not Required
March	49	28	21
April	37	17	20
May	41	28	13
June	42	22	20
July	45	32	13
August	63	33	30
September	55	23	32
October	49	16	33
November	59	38	21

- New prescription # (number) is Asteres tracking method, some may not be “new” to pharmacy or patient.
- Pharmacist releases Rx after required counseling provided.
- Total Rx’s released may not match number of pick-ups per month on slide 5 due to pick-up occurring in month following release.

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ScriptCenter Kiosk
Sharp Memorial Hospital

- No complaints received at Sharp
- Sample of testimonials *(have permission to share)*

"I work weekends and can now pick up my prescriptions when the Sharp Rees-Stealy pharmacy is closed. The 24/7 kiosk is so convenient that I no longer go to anywhere else. I am more comfortable managing my family's prescriptions here at Sharp. The best part is the text notification alerting me that my medication is ready. This is one less call I have to make to the pharmacy to see if it was filled or if there were any problems. I got a co-worker to switch his pharmacy to Sharp. Very satisfied !!! "

- *Alisa Valadez – LVN, Sharp Memorial Hospital*

"I love the ScriptCenter prescription pickup kiosk because I never wait in line like I did at other pharmacies. Transferring prescriptions for my family and me to Sharp Rees-Stealy was so easy. I work the night shift so this is super convenient for me. I have told my co-workers about ScriptCenter and highly recommend it for everyone."

- *Wendell Hatten - Sharp Memorial Hospital Distribution Center*

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Study Design

Quasi-experimental with non-randomized control group

- *Pre-Kiosk Implementation Survey (Sharp Employees)*

Study Start

Month 1: *March*

Month 6: *August*

Month 10: *December*

6 months pre-kiosk
(September 2015 – February 2016)

Regular Counter

- RTS rate*

Kiosk

- RTS rate
- Consultation Log
- Time to Pickup
- Kiosk Patient Satisfaction

Regular Counter

- RTS rate*
- Consultation Log *(Sample: New Rxs weeks of 5/23&6/6 &12/5)*
- Time to Pickup*

Kiosk Go Live Date: 1/20/16
Study Start: 3/1/16

RTS = Return to Stock

* For employees and dependents

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Study Timetable

- Q4 2015 — Pre-kiosk 6-month data collection phase
- Q1 2016 — Implement Kiosk device (1/20/16)
  Refine data collection tools & process
  Deployment of program/enroll patients
- Q2-Q4 2016 — Post-kiosk implementation
  Data collection March – December
- Q1 2017 — Data analysis
- Q2 2017 — Report Results to Board
  - April 18th, 2017 Enforcement Committee
  - May 3-4th, 2017 Board

  Continue Kiosk operation until regulation 1713 revised

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Questions?

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Attachment 4

Nursy e-Notify System

The National Council of State Boards of Nursing (NCSBN) Nursys® e-Notify system is a nurse licensure notification system that provides employers with real-time e-mail notifications about nurses they employ. The system provides licensure and publicly available discipline data directly to the employer, without the employer having to seek it out.

Nursys is the only national database for verification of nurse licensure, discipline, and practice privileges for registered nurses and licensed practical/vocational nurses. It consists of data obtained directly from the licensure systems of participating national boards of nursing through frequent, secured updates. The e-Notify system alerts subscribers when changes are made to a nurse's record, including changes to:

- License status.
- License expirations.
- Pending license renewal.
- Public disciplinary action/resolutions and alerts.

There is no charge to subscribe to the service. Employers can learn more and sign up by visiting the Nursys website at **https://www.nursys.com**. An introductory video on the system is available on the website.

New Website format for the BRN

The BRN will soon implement a new look to its website! The new format is a statewide template and is being used by the BRN to make the website as helpful and user-friendly as possible by making frequently visited pages and needed information easier to locate, and overall navigation more efficient so that users can find the information they need quickly and easily. Please visit our website and take a minute or two to answer our website satisfaction survey and give us your feedback. The survey can be found at **https://www.dca.ca.gov/webapps/rn/survey.php**.

Attachment 5

Proposal to Amend 16 CCR § 1707

§ 1707. Waiver Requirements for Off-Site Storage of Records.

(a) Pursuant to subdivision (e) of Section 4105 of the Business and Professions Code and subdivision (c) of Section 4333 of the Business and Professions Code, a waiver ~~shall~~ may be granted to any entity licensed by the board for ~~off-site~~ storage of the records outside the licensed area of the pharmacy described in subdivisions (a), (b) and (c) of Section 4105 of the Business and Professions Code ~~unless the applicant has, within the preceding five years, failed to produce records pursuant to Section 4081 of the Business and Professions Code or has falsified records covered by Section 4081 of the Business and Professions Code.~~

(b) An entity that is granted a waiver pursuant to subdivision (a) shall:

(1) maintain the storage area so that the records are secure, including from unauthorized access; and

(2) be able to produce the records within two business days upon the request of the board or an authorized officer of the law.

(c) In the event that a licensee fails to comply with the conditions set forth in subdivision (b), the board may cancel the waiver without a hearing. Upon notification by the board of cancellation of the waiver, the licensee shall maintain all records at the licensed premises.

(d) A licensee whose waiver has been cancelled pursuant to the provisions set forth in subsection (c) may reapply to the board when compliance with the conditions set forth in subsection (b) can be confirmed by the board.

(e) Notwithstanding any waiver granted pursuant to subdivision (a), all prescription records for non controlled substances shall be maintained on the licensed premises for a period of one year from the date of dispensing.

(f) Notwithstanding any waiver granted pursuant to subdivision (a), all prescription records for controlled substances shall be maintained on the licensed premises for a period of two years from the date of dispensing.

(g) Notwithstanding the requirements of this section, any entity licensed by the board may store the records described in subdivisions (a), (b) and (c) of Section 4105 of the Business and Professions Code in a storage area at the same address or adjoining the licensed premises without obtaining a waiver from the board if the following conditions are met:

(1) The records are readily accessible to the pharmacist-in-charge (or other pharmacist on duty, or designated representative) and upon request to the board or any authorized officer of the law.

(2) The storage area is maintained so that the records are secure and so that the confidentiality of any patient-related information is maintained.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4105 and 4333, Business and Professions Code.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4105 and 4333, Business and Professions Code.

Attachment 6

Proposal to Amend BPC 4316.

(a) The board, through its executive offer, is authorized to issue a cease and desist order for operating any facility under this chapter that requires licensure or for practicing any activity under this chapter that requires licensure without obtaining such licensure.

(b) Whenever the board issues a cease and desist order pursuant to subdivision (a), the board shall immediately issue the facility a notice setting forth the acts or omissions with which it is charged, specifying the pertinent code section or sections and any regulations.

(c) The order shall provide that the facility, within 15 days of receipt of the notice, may request a hearing before the president of the board to contest the cease and desist order. Consideration of the facility's contest of the cease and desist order shall comply with the requirements of Section 11425.10 of the Government Code. The hearing shall be held no later than five days from the date the request of the owner is received by the board. The president shall render a written decision within five days of the hearing. In the absence of the president of the board, the vice president of the board may conduct the hearing permitted by this subdivision. Review of the decision of the president of the board may be sought by the owner or person in possession or control of the ~~pharmacy~~ facility pursuant to Section 1094.5 of the Code of Civil Procedure.

Attachment 7

Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification

Guidance for Industry

Published by the U.S. Department of Health and Human Services Food and Drug Administration

Presentation by Michael Ignacio, Supervising Inspector
California State Board of Pharmacy

Statutory Mandate

Protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

California Business and Professions Code section 4001.1

Food and Drug Administration Disclaimer

- “This guidance represents the current thinking of the Food and Drug Administration (FDA) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.”

Background

- Drug Quality and Security Act (DQSA) signed by President Obama on 11/27/2013
- Drug Supply Chain Security Act (DSCSA)-Title II of the DQSA
- *Suspect Product*[1]
  - Potentially counterfeit, diverted, or stolen
  - Potentially intentionally adulterated/ appears unfit for distribution which would result in serious adverse health consequences or death to humans
  - Potentially subject of a fraudulent transaction
- *Illegitimate Product*[2]
  - Counterfeit, diverted, or stolen
  - Intentionally adulterated/ appears unfit for distribution which would result in serious adverse health consequences or death to humans
  - Subject of a fraudulent transaction

Background

- Requirements of Section 582 of the FD&C Act
  - Notify FDA and all immediate trading partners no later than 24 hours after making a determination of an illegitimate product
  - Manufacturers additionally are required to notify FDA and immediate trading partners no later than 24 hours after the manufacturer determines or is notified by FDA or a trading partner that there is a high risk that the product is illegitimate
- The Drug Supply Chain and Security Act (DSCSA) outlines critical steps to build an electronic, interoperable system of the next 10 years that will identify and trace certain prescription drugs as they are distributed in the U.S.

Scope

- Identifies specific scenarios that could significantly increase the risk of suspect product entering the supply chain
  - Provides recommendations on how trading partners can identify such product and determine whether a product is a suspect product as soon as practicable
- Describes when manufacturers should notify FDA of a high risk that a product is illegitimate or has a high risk of illegitimacy
- Sets forth the process by which trading partners must terminate notifications in consultation with FDA regarding high risk of illegitimacy/illegitimate product
- Addresses how trading partners should notify FDA when they determine that a product in their possession or control is an illegitimate product

Identification of Suspect Product

- Trading partners must have systems in place that enable them to quarantine suspect product and promptly conduct an investigation, in coordination with other trading partners, as applicable, to determine whether a suspect product is illegitimate

Sample of Specific Scenarios that Could Increase the Risk of Suspect Products – Trading Partners and Product Sourcing

- Purchasing from a source new to the trading partner
- Receiving unsolicited sales offer from an unknown source
- Purchasing on the internet from an unknown source
- Purchasing from a source that a trading partner who has engaged in questionable or suspicious business practices

Sample of Specific Scenarios that Could Increase the Risk of Suspect Products – Supply, Demand, History, and Value of the Product

- High Demand in the U.S. market
- Higher demand because of its potential or perceived relationship to a public health or other emergency (e.g., antiviral drugs)
- High Sales volume or price in the U.S.
- Offered at a price that is “too good to be true”
- Previously or currently being counterfeited or diverted (e.g., HIV, antipsychotic, or cancer drugs)
- Subject of a drug shortage
- Been or subject of an illegitimate product notification under the DSCSA or other alert or announcement related to drug quality
- Been or subject of an FDA counterfeit or cargo theft alert

Sample of Specific Scenarios that Could Increase the Risk of Suspect Products – Appearance of the Product

- Package or container used for transport seems suspicious (e.g., label that contains misspellings or appears different from the standard label for that product in color, font, images, or otherwise)
- Exhibits unusual or excessive adhesive residue
- Contains foreign identification features
- Missing information, such as the lot number or other lot identification, or the expiration date
- Missing security or anti-counterfeiting technologies normally featured on the FDA-approved product that are easily visible to the eye (e.g., holograms, color shifting inks, neckbands, or watermarks)
- Finished dosage form that seems suspicious

Strategies for Trading Partners to Identify Suspect Products

- Be alert for offers of product for sale at a very low price or one that is “too good to be true”
- Closely examine the package and transport container
  - Look for signs that packaging may have been compromised
  - Change of packaging since last shipment of the same product type
  - Product inserts are missing, do not correspond to the product, or are suspicious in some way
  - Shipping addresses, postmarks, or other materials indicating that the product came from an unexpected foreign entity or source
- Closely examine the label on the package, and the label on the individual retail unit
  - Any missing information, such as the lot number or other lot identification, NDC, or strength of the drug
  - Any altered product information, such as smudged print or print that is very difficult to read
  - Misspelled words
  - Bubbling in the surface of a label
  - Lack of an “Rx only” symbol
  - Foreign language with little or no English provided
  - Foreign language that is used to describe the lot number
  - Product name that differs from the name that appears on the FDA-approved drug label or labeling
  - A product name that is the product name for a foreign version of the drug
  - A product that is transported in a case or tote, when not expected under the circumstances
  - Lot numbers and expiration dates on product that do not match the lot number and expiration dates of its outer container

Process to Notify FDA of Illegitimate Products

1. Trading partners should access FDA's Web page at http://www.accessdata.fda.gov/scripts/cder/email/drugnotification.cfm for notifications
2. Trading partners should follow the instructions on the web page for accessing Form FDA 3911
3. Form FDA 3911 should be submitted using the method provided in the form or on the web page
4. FDA will acknowledge receipt of the notification and assign an incident number
5. In addition to notifying the FDA, all immediate trading partners must be notified

Process for Termination of Notification in Consultation with FDA

1. The trading partner making a notification to the FDA shall be responsible for making the request for termination
2. Trading partners must access FDA's web page at http://www.accessdata.fda.gov/scripts/cder/email/drugnotification.cfm for termination of notifications
3. Trading partners must follow the instructions on the web page for accessing Form FDA 3911
4. Form FDA 3911 must be submitted by using the method provided in the form or on the web page
5. FDA will review the request and consult with the trading partner

Form FDA 3911

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Drug Notification

Form Approved: OMB No. 0910-0806
Expiration Date: December 31, 2018
See PRA Statement on page 2.

Refer to instruction sheet (Form FDA 3911 Supplement) for more information.

1. Type of Report *(Select one)*: ☐ Initial Notification ☐ Follow-Up Notification ☐ Request for Termination

2. Incident Number *(Provide this number, assigned by FDA, if you selected Follow-up Notification or Request for Termination above; see instructions.)*

3. Date of Initial Notification *(mm/dd/yyyy)*	4. Date Company Determined Product Was Illegitimate *(mm/dd/yyyy)*	5. Classification of Notification *(Select from list)*

Description of Product

6. Name of Product as It Appears on Label

7. Primary Ingredients(s) *(if known)*

8. Drug Use *(Select from list)*	9. Drug Description *(Select from list)*

10. Strength of Drug	11. Dosage Form *(Select from list)*

12. Quantity of Drug *(Number and Unit)*	13. NDC Number *(if applicable)*	14. Serial Number *(if applicable)*

References

1. Section 581(21) of the FD&C Act
2. Section 581(8) of the FD&C Act
3. www.fda.gov/downloads/aboutfda/reportsmanualsforms/forms/ucm513940
4. www.fda.gov/downloads/drugs/guidances/ucm400470.pdf

Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification

Guidance for Industry

The portion of this guidance that describes when manufacturers should notify FDA if there is a high risk that a product is illegitimate, is being distributed for comment purposes only.

Comments and suggestions regarding this document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Office of Regulatory Affairs (ORA)

December 2016
Procedural
OMB Control No. 0910-0806
Expiration Date 12/31/2018
See additional PRA statement in section V of this guidance.

Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification Guidance for Industry

Additional copies are available from:

Office of Communications, Division of Drug Information
Center for Drug Evaluation and Research
Food and Drug Administration
10001 New Hampshire Ave., Hillandale Bldg., 4th Floor
Silver Spring, MD 20993-0002
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Email: druginfo@fda.hhs.gov
http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm

and/or

Office of Communication, Outreach and Development
Center for Biologics Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 71, Room 3128
Silver Spring, MD 20993-0002
Phone: 800-835-4709 or 240-402-8010
Email: ocod@fda.hhs.gov
http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Office of Regulatory Affairs (ORA)

December 2016
Procedural

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Guidance for Industry[1]
Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public.[2] You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance is intended to aid trading partners[3,4] (manufacturers, repackagers, wholesale distributors, and dispensers) in identifying a suspect product as defined at section 581(21) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee(21)) and terminating notifications. It does not establish any rights for any person and, with the exception of section IV.B, it is not binding on FDA or the public. With respect to section IV.B, section 582 of the FD&C Act gives FDA authority to issue binding guidance on the process for terminating notifications of illegitimate product. Specifically, section 582(h)(2)(A) states that FDA "shall issue a guidance document to aid trading partners in the identification of a suspect product and notification termination. Such guidance document shall . . . set forth the process by which manufacturers, repackagers, wholesale distributors, and dispensers shall terminate notifications in consultation with the Secretary regarding illegitimate product . . . ."

As of January 1, 2015, a trading partner that determines a product in its possession or control is an illegitimate product as defined at section 581(8) of FD&C Act, must notify the Food and Drug Administration (FDA or Agency) and certain immediate trading partners under section 582 of

[1] This guidance has been prepared by the Office of Compliance in the Center for Drug Evaluation and Research in cooperation with the Center for Biologics Evaluation and Research and the Office of Regulatory Affairs at the Food and Drug Administration.

[2] Insofar as section IV.B of this guidance sets forth the process by which trading partners must terminate notifications of illegitimate product and products with a high risk of illegitimacy in consultation with FDA, it has binding effect. This is discussed further in the Introduction.

[3] For this guidance, *trading partner* is defined in section 581(23)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 30eee(23)(A)), and refers to a manufacturer, repackager, wholesale distributor, or dispenser. For purposes of this guidance, *trading partner* does not refer to a third-party logistics provider (3PL) as defined in section 581(23)(B) of the FD&C Act (21 U.S.C. 360eee(23)(B)), though FDA encourages 3PLs to follow the recommendations in this guidance to the extent relevant to the 3PL's operations.

[4] Trading partners must be authorized as defined in FD&C Act section 581(2) and required under FD&C Act section 582(b)(3), (c)(3), (d)(3) and (e)(3).

the FD&C Act (21 U.S.C. 360eee-1), as added by the Drug Supply Chain Security Act (DSCSA). Manufacturers are additionally required under section 582 to notify FDA and certain immediate trading partners after the manufacturer determines or is notified by FDA or a trading partner that there is a high risk that a product is illegitimate.[5] This guidance identifies specific scenarios that could significantly increase the risk of a suspect product entering the pharmaceutical distribution supply chain; provides recommendations on how trading partners can identify a product and determine whether a product is a suspect product as soon as practicable; and sets forth the process by which trading partners should notify FDA of illegitimate product or products with a high risk of illegitimacy, and how they must terminate the notifications, in consultation with FDA.

This guidance does not address all provisions of the DSCSA related to suspect and illegitimate products. As FDA works to implement other provisions of the DSCSA, the Agency intends to issue additional information to support efforts to develop standards, issue guidance and regulations, establish pilot programs, and conduct public meetings.

FDA's guidance documents, in general, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required. Insofar as section IV.B of this guidance sets forth the process by which trading partners must terminate notifications of illegitimate product and products with a high risk of illegitimacy in consultation with FDA, it has binding effect.[6]

II. BACKGROUND

A. Drug Supply Chain Security Act

On November 27, 2013, the DSCSA (Title II of Public Law 113-54) was signed into law. Section 203 of the DSCSA added section 582(h)(2) to the FD&C Act, which requires FDA to issue guidance to aid trading partners in identifying a suspect product and terminating notifications. *Suspect product* is defined in section 581(21) of the FD&C Act as a product for which there is reason to believe it (A) is potentially counterfeit, diverted, or stolen; (B) is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; (C) is potentially the subject of a fraudulent transaction; or (D) appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans. Section 582 of the FD&C Act requires trading partners, upon determining that a product in their possession or control is a suspect product, to quarantine the product while they promptly conduct an investigation to determine whether the product is an illegitimate product. *Illegitimate product* is defined in section 581(8) of the FD&C

[5] The portion of this guidance that describes when manufacturers should notify FDA of a high risk that a product is illegitimate is shaded in gray and is being distributed for comment purposes only.

[6] See section 582(h)(2)(A) of the FD&C Act.

Act as a product for which credible evidence shows that it is (A) counterfeit, diverted, or stolen; (B) intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; (C) is the subject of a fraudulent transaction; or (D) appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans.[7]

Section 582 of the FD&C Act requires trading partners, upon determining that a product in their possession or control is illegitimate, to notify FDA and all immediate trading partners (that they have reason to believe may have received the illegitimate product) not later than 24 hours after making the determination. Manufacturers are additionally required under section 582(b)(4)(B)(ii)(II) to notify FDA and immediate trading partners (that the manufacturer has reason to believe may possess a product manufactured by or purported to be manufactured by the manufacturer) not later than 24 hours after the manufacturer determines or is notified by FDA or a trading partner that there is a high risk that the product is illegitimate.

The DSCSA outlines critical steps to build an electronic, interoperable system over the next 10 years that will identify and trace certain prescription drugs as they are distributed within the United States. For many years, FDA has been engaged in efforts to improve the security of the drug supply chain to protect U.S. patients from unsafe, ineffective, and poor quality drugs. Since at least the formation of the first FDA Counterfeit Drug Task Force in 2003, FDA has strongly advocated for a multilayered approach to securing the supply chain. A key component of that approach has been to encourage heightened vigilance and awareness among supply chain partners. The electronic, interoperable system that will be established under the DSCSA will enhance FDA's ability to help protect U.S. consumers by improving detection and removal of potentially dangerous drugs from the drug supply chain.

B. Scope of This Guidance

Pursuant to section 582(h)(2) of the FD&C Act, this guidance identifies specific scenarios that could significantly increase the risk of a suspect product entering the pharmaceutical distribution supply chain; provides recommendations on how trading partners can identify such product and determine whether a product is a suspect product as soon as practicable; describes when manufacturers should notify FDA of a high risk that a product is illegitimate; and sets forth the process by which trading partners must terminate notifications in consultation with FDA regarding illegitimate product under section 582(b)(4)(B)(iv), (c)(4)(B)(iv), (d)(4)(B)(iv), and (e)(4)(B)(iv) of the FD&C Act and the process for terminating notifications in consultation with FDA regarding products with a high risk of illegitimacy under section 582(b)(4)(B)(iv). This guidance also addresses how trading partners should notify FDA when they determine that a product in their possession or control is an illegitimate product under section 582(b)(4)(B)(ii)(I), (c)(4)(B)(ii), (d)(4)(B)(ii), and (e)(4)(B)(ii) of the FD&C Act, and how manufacturers should notify FDA regarding products with a high risk of illegitimacy under section 582(b)(4)(B)(ii)(II).

[7] For additional definitions applicable to this guidance, please refer to section 581 of the FD&C Act.

III. IDENTIFICATION OF SUSPECT PRODUCT AND, FOR MANUFACTURERS, PRODUCT WITH A HIGH RISK OF ILLEGITIMACY

Trading partners, upon determining that a product in their possession or control is suspect or upon receiving a request for verification from the FDA (whereby FDA has made a determination that a product within the possession or control of the trading partner is a suspect product), must have systems in place that enable them to quarantine suspect product and promptly conduct an investigation, in coordination with other trading partners, as applicable, to determine whether a suspect product is illegitimate.

As trading partners conduct business on a daily basis, they should exercise vigilance, maintain awareness about suspicious activity or potential threats to their supply chain, and devote attention and effort to detecting suspect product.

The next two sections of this guidance (A.) identify some specific scenarios that could significantly increase the risk of suspect products entering the pharmaceutical distribution supply chain and (B.) make recommendations to assist trading partners in identifying suspect product and making determinations about whether a product is suspect as soon as practicable. The scenarios contained in this guidance are based on Agency experience with suspect product in the drug supply chain. These examples are illustrative and should not be viewed as an exhaustive list of all potential scenarios that increase the likelihood that a suspect product could enter the pharmaceutical distribution supply chain. Trading partners should consider the surrounding circumstances of any particular scenario they may encounter in determining whether or not a product is suspect, including whether multiple scenarios are present in any given transaction.

A. Specific Scenarios That Could Significantly Increase the Risk of a Suspect Product Entering the Pharmaceutical Distribution Supply Chain

There may be situations involving trading partners where heightened vigilance would be appropriate. In addition, there could be identifiable characteristics of products that might increase the likelihood that they are suspect products. The following are examples of some specific scenarios that could significantly increase the risk of a suspect product entering the drug supply chain. Thus, trading partners should be particularly diligent when engaging in transactions that involve:

1. Trading Partners and Product Sourcing

- Purchasing from a source new to the trading partner.

- Receiving an unsolicited sales offer from an unknown source. Trading partners might receive unsolicited offers or advertisements through an email, a fax, a telephone call, or an in-person sales call from a person or entity with whom they do not have an established business relationship.

- Purchasing on the Internet from an unknown source. Trading partners might be searching for a better price on the Internet or for a product that they cannot obtain

from their usual source, and might be tempted to turn to a person or entity with whom they do not have an established business relationship.

- Purchasing from a source that a trading partner knows or has reason to believe has engaged in questionable or suspicious business practices that could increase the risk of suspect product entering the supply chain, such as:

  - A trading partner that has been involved in business transactions where they sold or delivered illegitimate product.

  - A trading partner that has a history of problematic or potentially false transaction histories or pedigrees, such as those that contain misspelled words or incomplete information.

  - A trading partner that is reluctant to provide a transaction history associated with the product being purchased, or does not do so in a timely manner.

  - A trading partner that provides transaction information, a transaction statement, and/or transaction history that appears to be incomplete or suspicious.

2. Supply, Demand, History, and Value of the Product

- Product that is generally in high demand in the U.S. market.

- Product that is in higher demand because of its potential or perceived relationship to a public health or other emergency (e.g., antiviral drugs).

- Product that has a high sales volume or price in the United States.

- Product offered at a price that is "too good to be true."

- Product that has been previously or is currently being counterfeited or diverted (e.g., HIV, antipsychotic, or cancer drugs).

- Product that has been previously or is currently the subject of a drug shortage (see a list of current drugs in shortage at http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/Shortages/default.htm and http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm for more information).

- Product that has been or is the subject of an illegitimate product notification under the DSCSA or other alert or announcement related to drug quality.

- Product that has been or is the subject of an FDA counterfeit or cargo theft alert

(See http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/counterfeitmedicine/default.htm and http://www.fda.gov/iceci/criminalinvestigations/ucm182888.htm for more information).

3. Appearance of the Product

- Appearance of a package or a container used for transport (e.g., case or tote) that seems suspicious (e.g., it has a label that contains misspellings or appears different from the standard label for that product in color, font, images, or otherwise).

- Package that exhibits unusual or excessive adhesive residue.

- Package that contains foreign identification features (such as a different drug identification number where a National Drug Code (NDC) number would be expected).

- Package that is missing information, such as the lot number or other lot identification, or the expiration date.

- Package that is missing security or anti-counterfeiting technologies normally featured on the FDA-approved product that are easily visible to the eye, such as holograms, color shifting inks, neckbands, or watermarks.

- Finished dosage form that seems suspicious (e.g., it has a different shape or color from the FDA-approved product, a different or unusual imprint, an unusual odor, or there are signs of poor quality like chips or cracks in tablet coatings or smeared or unclear ink imprints).

B. Recommendations on How Trading Partners Might Identify Suspect Product and Determine Whether the Product Is a Suspect Product as Soon as Practicable

The following are recommendations for trading partners on ways that they can expeditiously identify suspect product and determine whether the product is suspect (and, after investigation, whether it is illegitimate). In general, trading partners should exercise due diligence when conducting business and should confirm that all trading partners are authorized. Trading partners should discuss with each other any observations, questions, or concerns they have related to the status of a drug as a suspect product to aid them in determining whether the drug should be considered a suspect product. Trading partners should also contact regulatory authorities, law enforcement, the drug's manufacturer, or other available resources to aid in that determination when additional expertise is called for to make an accurate assessment of the status of a drug as a suspect product. If a trading partner receives a product in a secured transport container or sealed homogenous case, trading partners should examine the appearance of that container as

recommended below. If trading partners observe anything suspicious, they should take steps to ascertain whether the product inside the transport container is suspect. Strategies to identify suspect product include, but are not limited to, the following recommendations:

- Be alert for offers of product for sale at a very low price or one that is "too good to be true."

- Closely examine the package and the transport container (such as the case or tote):

  - To look for signs that it has been compromised (e.g., opened, broken seal, damaged, repaired, or otherwise altered). If a trading partner receives a product in a secured transport container or sealed homogenous case, trading partners should examine the appearance of that container to see if anything about that appearance seems suspicious, such as shrink wrap that has unexpected markings, or a seal that is broken, torn, or repaired.
  - To see if the package or the transport container has changed since the last shipment of the same product type was received for an unexplained reason (e.g., a notification about the change from the manufacturer has not been received).
  - To see if product inserts are missing, do not correspond to the product, or are suspicious in some way.
  - For shipping addresses, postmarks, or other materials indicating that the product came from an unexpected foreign entity or source.

- Closely examine the label on the package, and the label on the individual retail unit, if applicable, for:

  - Any missing information, such as the lot number or other lot identification, NDC, or strength of the drug.
  - Any altered product information, such as smudged print or print that is very difficult to read.
  - Misspelled words.
  - Bubbling in the surface of a label.
  - Lack of an "Rx only" symbol.[8]
  - Foreign language with little or no English provided.[9]
  - Foreign language that is used to describe the lot number.[10]

[8] Or, for products distributed solely in the Commonwealth of Puerto Rico or any other territory where the predominant language is Spanish, "Solamente Rx" (21 CFR 201.16).

[9] Except for products distributed solely in the Commonwealth of Puerto Rico or any other territory where the predominant language is one other than English (21 CFR 201.15 (c)(1)).

[10] Except for products distributed solely in the Commonwealth of Puerto Rico or any other territory where the predominant language is one other than English (21 CFR 201.15(c)(1)).

- A product name that differs from the name that appears on the FDA-approved drug label or labeling.
- A product name that is the product name for a foreign version of the drug.
- A product that is transported in a case or tote, when not expected under the circumstances.
- Lot numbers and expiration dates on product that do not match the lot numbers and expiration dates of its outer container.

Again, under section 582 of the FD&C Act, trading partners must have systems in place that enable them, upon determining that a product in their possession or control is suspect or upon receiving a request for verification from the FDA that has made a determination that a product within the possession or control of the trading partner is a suspect product, to quarantine suspect product and promptly conduct an investigation, in coordination with other trading partners, as applicable, to determine whether a suspect product is illegitimate. In addition, trading partners must, as applicable, make the notifications described in section 582(b)(4)(B)(ii)(I), (c)(4)(B)(ii), (d)(4)(B)(ii), and (e)(4)(B) of the FD&C Act related to illegitimate product determinations, and, for manufacturers, the notification of a high risk of illegitimacy described in section 582(b)(4)(B)(ii)(II).

C. For Manufacturers: High Risk of Illegitimacy Notifications[11]

Section 582(b)(4)(B)(ii)(II) of the FD&C Act requires manufacturers to make notifications in certain circumstances for products that pose a high risk of illegitimacy. The provision states as follows:

> *(II) HIGH RISK OF ILLEGITIMACY.--A manufacturer shall notify the Secretary and immediate trading partners that the manufacturer has reason to believe may have in the trading partner's possession a product manufactured by, or purported to be a product manufactured by, the manufacturer not later than 24 hours after determining or being notified by the Secretary or a trading partner that there is a high risk that such product is an illegitimate product. For purposes of this subclause, a 'high risk' may include a specific high risk that could increase the likelihood that illegitimate product will enter the pharmaceutical distribution supply chain and other high risks as determined by the Secretary in guidance pursuant to subsection (h).*

FDA interprets this provision to require manufacturers to notify (1) FDA and (2) the manufacturer's immediate trading partners (that the manufacturer has reason to believe may have in the trading partner's possession a product manufactured by, or purported to be a product manufactured by, the manufacturer) in three general scenarios:

(1) Within 24 hours after determining or being notified by FDA or a trading partner that there is a high risk that a product that the manufacturer has reason to believe is in an immediate trading partner's possession is an illegitimate product.

[11] This section of the guidance is being distributed for comment purposes only.

(2) Within 24 hours after determining or being notified by FDA or a trading partner that there is a specific high risk that could increase the likelihood that illegitimate product will enter the U.S. pharmaceutical distribution supply chain.
(3) Within 24 hours after determining or being notified by FDA or a trading partner that there exists an "other high risk" as determined by FDA in guidance pursuant to subsection 582(h).

FDA believes that Congress intended section 582(b)(4)(B)(ii)(II) to leverage the surveillance systems that many manufacturers already have in place to detect counterfeit and otherwise violative versions of their products. Manufacturers could learn about products with a high risk of illegitimacy from a variety of sources, including from within their own company, from their trading partners, from the FDA, or from other domestic and/or foreign regulatory authorities—even when a product may not be in the manufacturer's possession or control.

Below are scenarios and examples in which a manufacturer should make a notification under section 582(b)(4)(B)(ii)(II).

1. High Risk of Illegitimacy Notification for Products That the Manufacturer Has Reason to Believe Are in an Immediate Trading Partner's Possession

The first general scenario, described above, involves notifications for products that the manufacturer has reason to believe are in an immediate trading partner's possession.

An example of this scenario might occur when the manufacturer is asked to coordinate a suspect product investigation by an immediate trading partner under section 582(c)(4)(B), 582(d)(4)(B), or 582(e)(4)(B), and the manufacturer determines that there is a high risk that the product is illegitimate. Some sample scenarios involving high risks of illegitimacy, in which a manufacturer should make a notification, include:

- A manufacturer learns from a trading partner that a suspect product purporting to be one produced by that manufacturer has been found in the U.S. pharmaceutical distribution supply chain. The manufacturer examines the suspect product and believes the product could be illegitimate but wants to take additional steps before determining that it is illegitimate. The manufacturer has reason to believe that additional illegitimate products are in the possession of immediate trading partners. For example, a wholesale distributor informs a manufacturer that it believes it has a counterfeit of that manufacturer's product. The wholesale distributor sends the product to the manufacturer. The manufacturer examines the product and believes it could be counterfeit, but wants to perform a laboratory analysis or other analysis for confirmation.

- A manufacturer learns that its product has been stolen or diverted in the United States while not in its possession or control, and the manufacturer has reason to believe that an immediate trading partner might have the stolen or diverted product in its possession.

2. Specific High Risks That Could Increase the Likelihood of an Illegitimate Product Entering the U.S. Pharmaceutical Distribution Supply Chain

Section 582(b)(4)(B)(ii)(II) states that a high risk of illegitimacy may include a "specific high risk" that could increase the likelihood that illegitimate product will enter the pharmaceutical distribution supply chain. In such cases, the product has not yet entered the pharmaceutical distribution supply chain, so no immediate trading partners would have it in their possession. Section 582(b)(4)(B)(ii)(II) thus would require the manufacturer to make a notification to FDA, but the manufacturer would not be required to notify immediate trading partners. To help ensure the integrity of the supply chain, however, FDA recommends that a manufacturer notify its immediate trading partners of such "specific high risk[s]" even if that manufacturer does not have reason to believe that its immediate trading partners may have the high risk product in their possession. Some examples involving specific high risks include:

- A manufacturer learns that a product with a high risk of illegitimacy (purporting to be one produced by that manufacturer) has been found in another country, and that such product is likely destined for a trading partner in the United States For instance, the manufacturer learns from a foreign regulatory authority that one of its products has been counterfeited in another country, and that some of that product is on a cargo ship destined for the United States for delivery to a wholesale distributor.

- A manufacturer learns that its product was stolen or diverted in another country, and that such product is destined for the United States in a manner that leads the manufacturer to believe the product will likely enter the U.S. pharmaceutical distribution supply chain. For instance, the manufacturer learns from a foreign law enforcement agency that its product was stolen during transport in another country and is on a plane destined for the United States for delivery to a dispenser.

- A manufacturer learns that there is a high risk that its product has been intentionally adulterated in another country such that the product would result in serious adverse health consequences or death to humans, and that such product is likely destined for the United States in a manner that leads the manufacturer to believe the product will enter the pharmaceutical distribution supply chain. For instance, the manufacturer learns from its own investigation that there is a high risk that a contaminant that would result in serious adverse health consequences or death to humans was added to a product in another country and sent to a repackager in the United States

As noted above, the scenarios given in sections 1 and 2 are examples, rather than an exhaustive list of circumstances in which trading partners should make notifications under section 582(b)(4)(B)(ii)(II).

3. Other High Risks as Determined by FDA: High Risk of Illegitimacy Notification Where a Manufacturer Has Reason to Believe the Product Has Entered the Pharmaceutical Distribution Supply Chain

Section 582(b)(4)(B)(ii)(II) of the FD&C Act permits FDA to determine, through guidance pursuant to section 582(h), "other high risks" that would trigger a notification under this provision. FDA believes that one "other high risk" not covered by the two general scenarios described above is when a manufacturer has reason to believe that an illegitimate product has

entered the pharmaceutical distribution supply chain, even though the manufacturer does not have reason to believe that an immediate trading partner possesses the high risk product.[12] As with the second general scenario, described above, section 582(b)(4)(B)(ii)(II) would require the manufacturer to make a notification to FDA, but the manufacturer would not be required to notify immediate trading partners. To help ensure the integrity of the supply chain, however, FDA recommends that a manufacturer notify its immediate trading partners of this "other high risk," even if that manufacturer does not have reason to believe that its immediate trading partners may have the high risk product in their possession.

A manufacturer could learn that a product with a high risk of illegitimacy that was manufactured by (or purported to be manufactured by) that manufacturer, may be in the possession of a trading partner, but that trading partner is not an immediate trading partner of the manufacturer. Some examples that involve this other high risk include:

- A manufacturer learns that a licensed health care practitioner is administering an oncology drug to patients that purports to have been manufactured by that manufacturer but the manufacturer determines that there is a high risk that the drug is a counterfeit. The licensed health care practitioner purchased the drug from a wholesale distributor, so he/she is not an immediate trading partner of the manufacturer. However, the manufacturer believes that the product has entered the pharmaceutical distribution supply chain.

- A manufacturer learns that its product has been stolen or diverted in the United States, and the manufacturer learns that a patient filled a prescription and received some of the stolen or diverted product. The patient suffers an adverse event, and FDA and the manufacturer are notified of that situation. Because the dispenser did not purchase the product from the manufacturer, it is not an immediate trading partner of the manufacturer. However, the product has entered the pharmaceutical distribution supply chain.

- A manufacturer learns that wholesale distributor B received product and transaction history going back to the manufacturer from wholesale distributor A, but the listed dosage form of the product on the transaction history is not one that has ever been used by the manufacturer. Wholesale distributor B provided a copy of the transaction history it received from wholesale distributor A to the manufacturer, and the manufacturer concluded, after reviewing the copy and receiving similar reports from other trading partners, that a fraudulent transaction had occurred. Because wholesale distributor B did not purchase the product from the manufacturer, it is not an immediate trading partner of the manufacturer. However, the product has entered the pharmaceutical distribution supply chain.

[12] FDA reserves authority to articulate additional "other high risk[s]" in subsequent guidance(s).

IV. NOTIFICATION OF ILLEGITIMATE PRODUCTS AND PRODUCTS WITH A HIGH RISK OF ILLEGITIMACY

A. Notification to FDA

As discussed above, trading partners must, as applicable, make the notifications described in section 582(b)(4)(B)(ii)(I), (c)(4)(B)(ii), (d)(4)(B)(ii), and (e)(4)(B)(ii) of the FD&C Act related to illegitimate product determinations, and, for manufacturers, the notification of a high risk of illegitimacy described in section 582(b)(4)(B)(ii)(II). This section of the guidance addresses the process by which trading partners should notify FDA and other trading partners regarding illegitimate products under section 582. After review of the circumstances surrounding the event, if FDA determines that notification is not required under section 582(b)(4)(B)(ii)(I), (c)(4)(B)(ii), (d)(4)(B)(ii), (e)(4)(B)(ii), or (b)(4)(B)(ii)(II) of the FD&C Act, FDA intends to inform the submitting entity.

1. Process to Notify FDA of Illegitimate Products

The following process should be used to notify FDA of illegitimate products:

(1) Trading partners should access FDA's Web page at http://www.accessdata.fda.gov/scripts/cder/email/drugnotification.cfm for notifications.

(2) Trading partners should follow the instructions on the Web page for accessing Form FDA 3911 (Appendix 1). Using this form, trading partners should provide information about the person or entity initiating the notification, the product determined to be illegitimate that is the subject of the notification to FDA, and a description of the circumstances surrounding the event that prompted the notification.

(3) Form FDA 3911 should be submitted using the method provided in the form or on the Web page.

(4) FDA will acknowledge receipt of the notification and assign an incident number. This number should be referenced in all future correspondence about the illegitimate product, including any request for termination.

(5) In addition to notifying FDA, the trading partner that determines it has an illegitimate product in its possession or control must notify all immediate trading partners that it has reason to believe may also possess the drug. Trading partners may notify other trading partners of an illegitimate product using existing systems and processes used for similar types of communications to those partners, which might include, but are not limited to, posting of notifications on a company Web site, telephoning, sending an email, or mailing or faxing a notification.

2. Process used by manufacturers to Notify FDA of a Product With a High Risk of Illegitimacy

The following process should be used by manufacturers to notify FDA of a product with a high risk of illegitimacy*:* under section 582(b)(4)(B)(ii)(II):

(1) Manufacturers should access FDA's Web page at: http://www.accessdata.fda.gov/scripts/cder/email/drugnotification.cfm

(2) Manufacturers should follow the instructions on the Web page for accessing Form FDA 3911 (Appendix 1). Using this form, manufacturers should provide information about the person or entity initiating the notification, the product determined to have a high risk of illegitimacy that is the subject of the notification to FDA, and a description of the circumstances surrounding the event that prompted the notification.

(3) FDA will acknowledge receipt of the notification and assign an incident number. This number should be documented in all future correspondence about the product with the high risk of illegitimacy, including any request for termination.

(4) In addition to notifying FDA, the manufacturer that determines that a product has a high risk of illegitimacy must notify all immediate trading partners that it believes may possess the drug. Manufacturers may notify other trading partners of a product with a high risk of illegitimacy using existing systems and processes used for similar types of communications to those partners, which might include, but are not limited to, posting of notifications on a company Web site, telephoning, sending an email, or mailing or faxing a notification.

(5) If a product with a high risk of illegitimacy is found to be an illegitimate product, manufacturers should submit a follow-up notification that explains the updated classification and references the incident number of the original notification of high risk of illegitimacy.

(6) If it is determined that a product that was subject to a high risk of illegitimacy notification is not an illegitimate product, manufacturers must submit a request for termination of the high risk of illegitimacy notification to the FDA according to the process in Section B below.

B. Process for Termination of Notification in Consultation With FDA[13]

Section 582(h)(2)(A) of the FD&C Act directs FDA to issue guidance setting forth the process that trading partners shall follow for terminating notifications regarding illegitimate product, or for manufacturers, terminating notification of a high risk of illegitimacy, in consultation with FDA, under section 582(b)(4)(B), (c)(4)(B), (d)(4)(B), and (e)(4)(B). Section 582(b)(4)(B), (c)(4)(B), (d)(4)(B), and (e)(4)(B) require trading partners to have in place systems to enable them to terminate notifications, in consultation with FDA. This section of the guidance addresses

[13] Insofar as section IV.B. of this guidance sets forth the process by which trading partners should terminate notifications of an illegitimate product or products with a high risk of illegitimacy in consultation with FDA, it has binding effect.

the process by which trading partners must terminate such notifications in consultation with FDA. This process must be used when trading partners believe that a notification they made to FDA regarding illegitimate product, or for a manufacturer, a notification of a high risk of illegitimacy, is no longer necessary.

The process for terminating notifications in consultation with FDA is as follows:

(1) The trading partner making a notification to the FDA shall be responsible for making the request for termination.

(2) Trading partners must access FDA's Web page at http://www.accessdata.fda.gov/scripts/cder/email/drugnotification.cfm for termination of notifications.

(3) Trading partners must follow the instructions on the Web page for accessing Form FDA 3911 (Appendix 1). Using this form, trading partners must provide to FDA information about the person or entity initiating the request for termination, the illegitimate product or the product with a high risk of illegitimacy, the notification that was issued, and an explanation about what actions have taken place or what information has become available that makes the notification no longer necessary. Trading partners should include the FDA-assigned incident number associated with the notification in the request for termination.

(4) This form must be submitted by using the method provided in the form or on the Web page. The trading partner's submission of a request for termination of a notification will be viewed as a request for consultation with FDA, as required in section 582 of the FD&C Act. FDA may request any additional information it determines necessary to complete the consultation.

(5) FDA will review the request and consult with the trading partner. The response time will depend on the number of requests for termination and the circumstances surrounding the requests for termination that are received by FDA.

FDA interprets the DSCSA's requirement for trading partners to "mak[e] a determination, in consultation with the Secretary, that a notification is no longer necessary"[14] to require that trading partners provide the Agency with an opportunity to provide its expert views and advice on proposed terminations of notifications. Therefore, a trading partner must wait until FDA responds to the termination request before the trading partner notifies other trading partners that a notification is terminated. FDA intends to respond to requests for termination within 10 business days of submission. In some cases, FDA may contact a trading partner to notify the partner that additional time is needed to respond to the request for termination. If a trading partner believes that exigent circumstances require expedited consideration of a termination request (e.g., a potential drug shortage), the trading partner must describe those circumstances to FDA in the termination request on the FDA Form 3911 when making the request for termination.

[14] Section 582(b)(4)(iv), (c)(4)(B)(iv), (d)(4)(B)(iv), and (e)(4)(B)(iv) of the FD&C Act.

Under section 582(b)(4)(B), (c)(4)(B), (d)(4)(B), and (e)(4)(B) of the FD&C Act, after FDA provides its consultation response, and the trading partner determines that the notification is no longer necessary, the trading partner that made the request for termination must promptly notify immediate trading partners that the notification has been terminated. Trading partners may notify their trading partners of a termination using existing systems and processes used for similar types of communications to those partners, which might include, but are not limited to, posting of notifications on a company Web site, telephoning, sending an email, or mailing or faxing a letter or notification.

V. PAPERWORK REDUCTION ACT OF 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

The time required to complete this information collection is estimated to average as follows.

Notify FDA of an Illegitimate Product:

- 1 hour for manufacturers and repackagers
- 1 hour for wholesale distributors
- 1 hour for dispensers

Notify Trading Partners of an Illegitimate Product or a Product With a High Risk of Illegitimacy:

- 0.20 hour (12 minutes) for manufacturers and repackagers
- 0.20 hour (12 minutes) for wholesale distributors
- 0.20 hour (12 minutes) for dispensers

Consult With FDA and Terminate Notification:

- 1 hour for manufacturers and repackagers
- 1 hour for wholesale distributors
- 1 hour for dispensers

Notify Trading Partners That a Termination Has Been Terminated:

- 0.20 hour (12 minutes) for manufacturers and repackagers
- 0.20 hour (12 minutes) for wholesale distributors
- 0.20 hour (12 minutes) for dispensers

These estimates include the time to review instructions, gather the data needed, and complete and review the information collection and transmit to FDA. It also includes the time to notify trading

partners. Send comments regarding this burden estimate or suggestions for reducing this burden to: Office of Regulatory Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0806 (expires 12/31/2018).

APPENDIX 1: FORM FDA 3911

FORM FDA 3911 and the FORM FDA 3911 Instructions Supplement are available at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/HumanDrugForms/default.htm

If you are experiencing difficulties accessing the form, please contact the FDA forms manager at FormsManager@OC.FDA.GOV for assistance.

Attachment 8

GAO Highlights

Highlights of GAO-17-64, a report to congressional committees

November 2016

DRUG COMPOUNDING

FDA Has Taken Steps to Implement Compounding Law, but Some States and Stakeholders Reported Challenges

Why GAO Did This Study

Drug compounding is the process of combining, mixing, or altering ingredients to create a drug tailored to the needs of an individual patient. An outbreak of fungal meningitis in 2012 linked to contaminated compounded drugs raised concerns about state and federal oversight of drug compounding. The Drug Quality and Security Act, enacted in 2013, helped clarify FDA's authority and included a provision for GAO to report on drug compounding.

This report examines (1) the settings in which drugs are compounded, and the extent of drug compounding; (2) state laws and policies governing drug compounding, and how they are enforced; (3) communication between states and FDA, as well as among states, regarding drug compounding, and the associated challenges; and (4) steps FDA has taken to implement its responsibilities to oversee drug compounding, and challenges that have been reported with these efforts.

GAO surveyed state pharmacy regulatory bodies in the 50 states, the District of Columbia, Guam, Puerto Rico, and the U.S. Virgin Islands (all but 4 completed the survey); reviewed documents and interviewed officials from FDA, 25 stakeholder organizations (including national pharmacy and medical associations), and agencies in 3 states selected for having differing laws and policies; reviewed relevant laws; and examined FDA data on drug compounding inspections and actions taken.

HHS provided general comments on a draft of this report, as well as technical comments, which were incorporated as appropriate.

View GAO-17-64. For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

What GAO Found

GAO's survey of state pharmacy regulatory bodies found that drugs are compounded in a variety of health care settings, and some data are collected on the number of entities that compound drugs (drug compounders), but not the volume of compounded drugs. In addition to pharmacies, drug compounding settings include physicians' offices and outsourcing facilities—a new type of facility established by law in 2013, which can compound sterile drugs without patient-specific prescriptions and register with and are inspected by the Food and Drug Administration (FDA), an agency within the Department of Health and Human Services (HHS). While FDA and some states collect data on drug compounders, only one state reported collecting data on the number of prescriptions or the volume of compounded drugs. In addition, states GAO surveyed and stakeholders GAO interviewed did not collect data specific to the extent of compounding performed by nonpharmacists, such as physicians.

Nearly all of the states GAO surveyed reported having drug compounding laws, regulations, or policies, though few apply to nonpharmacists, and states conduct inspections and can take actions to enforce them. Less than 20 percent of states reported having laws, regulations, or policies specific to compounding by nonpharmacists (e.g., physicians), and these state laws varied. To help ensure compliance, most states reported inspecting drug compounders, such as pharmacies and outsourcing facilities, and most states can take several types of actions against pharmacies, including monetary fines, and suspension and revocation of a license or registration.

Most states reported being satisfied with their communication with FDA and other states, although some reported challenges. About three quarters of the states reported participating in FDA-sponsored activities, such as intergovernmental meetings, and obtaining information from FDA's website. Some states reported challenges with this communication, such as getting FDA to respond to requests for information. In terms of communication between states, most survey respondents reported that they are satisfied with this communication, which occurs through conferences and other activities.

FDA has taken steps to implement its regulatory responsibilities to oversee drug compounding, but states and stakeholder organizations have cited challenges and concerns. FDA has issued numerous draft and final guidance documents related to drug compounding, and conducted more than 300 inspections of drug compounders, which resulted in actions such as FDA issuing warning letters and voluntary recalls of potentially contaminated compounded drugs. Some stakeholder organizations said the amount of time it takes FDA to finalize the guidance and other documents—including those required by the 2013 law—is challenging. FDA officials noted that reviewing the large number of comments received has contributed to the time the agency has taken to finalize them. States and stakeholder organizations also cited concerns related to access to compounded drugs and differences between states and FDA on the appropriate inspection protocols to use when inspecting drug compounders. In August 2016, FDA changed its procedures to address concerns about the appropriate protocols to use for these inspections.

Attachment 9

Proposal to Amend California Code of Regulations

Section **1735.1. Compounding Definitions.**

…(c) "Biological Safety Cabinet (BSC)" means a ventilated cabinet for compounding ~~sterile~~ drug preparations, having an open front with inward airflow for personnel protection, downward HEPA-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection. Where hazardous drugs are prepared, the exhaust air from the biological safety cabinet shall be appropriately removed by properly designed external building ventilation exhaust. This external venting should be dedicated to one BSC or CACI.

Section 1735.6. Compounding Facilities and Equipment.

…(e) Hazardous drug compounding shall be completed in an externally vented physically separate room with the following requirements:

(1) Minimum of 30 air changes per hour except that 12 air changes per hour are acceptable for segregated compounding areas with a BSC or CACI when products are assigned a BUD of 12 hrs or less or when non sterile products are compounded; and

(2) Maintained at a negative pressure of 0.01 to 0.03 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors); and

(3) Each ~~PEC~~ <u>BSC</u> in the room shall also be externally vented <u>except that a BSC used only for nonsterile compounding may also use a redundant-HEPA filter in series</u>; and

(4) All surfaces within the room shall be smooth, seamless, impervious, and non-shedding.

Proposal to Repeal Business and Professions Code Section 4127.7

Section 4127.7.

~~A pharmacy shall compound sterile products from one or more nonsterile ingredients in one of the following environments:~~

~~(a) An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas.~~

~~(b) An ISO class 5 cleanroom.~~

~~(c) A barrier isolator that provides an ISO class 5 environment for compounding.~~

Attachment 10

Master formula

Christine Acosta

Enforcement and Compounding Committee Meeting

1/4/17

Master Formula Requirements

CCR 1735.2(e)requires: A drug preparation shall not be compounded until the pharmacy has first prepared a written master formula document that includes at least the following elements:

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) Maximum allowable BUD, and the rationale or reference source justifying its determination.

(4) Inactive ingredients to be used.

(5) Specific and essential compounding steps used to prepare the drug.

(6) Quality reviews required at each step in preparation of the drug.

(7) Post-compounding process or procedures required, if any.

(8) Instructions for storage and handling of the compounded drug preparation.

PCA 1

Number of Unit to Compound: One (100ml) Cassette

Ingredients:	1MG/ML	2MG/ML	4MG/ML	10MG/ML
Drug 10mg/ml inj	10ml	20ml	40ml	100ml
0.9% Sodium Chloride inj	90ml	80ml	60ml	-

Equipment:

Terra Isolator
Metal Tray

Supplies:

1-100ml CADD Cassette	1-0.9% Sod Chl Inj 100ml	2-60ml syringes	2-18G Needle
2-Alcohol Prep Pads			

Clean Room Gear:

Bouffant Cap	Mask	Gown	Gloves
Shoe Covers			

Procedures:

1. Complete IV Compounding Record sheet and place all ingredients inside a basket to be checked by the Rph.
2. **RPH must perform initial quality review by verifying all calculations are correct and ingredients and supplies are free of particle and discoloration before the following procedures may be performed.**
3. If the isolator was turned OFF, must allow isolator to operate for at least 10 minutes.
4. Wipe down all materials and supplies with sterile alcohol and place them inside metal tray.
5. Place metal tray in ante-chamber and close the antechamber door.
6. Wait at least one minute to purge the antechamber before retrieving the materials.
7. Insert hands into the glove ports and retrieve the materials through the internal sliding door, closing the sliding door promptly.
8. Remove materials from metal tray and stage them inside main chamber.
9. Wait at least one minute for the main chamber to return to ISO 5 conditions before compounding.
10. **Inspect vials for particles and discoloration before removing vial caps;** wipe rubber tops with alcohol.
11. Using aseptic technique to draw up Hydromorphone with 60ml syringe and 18G needle.
12. Remove needle from syringe and white cap from un-clamped CADD cassette extension.
13. Connect CADD cassette extension and syringe and transfer Drug e solution into CADD cassette.
14. Withdraw air bubble from cassette, clamp cassette extension, and disconnect syringe.
15. Transfer 0.9% Sodium Chloride into CADD cassette by repeating procedure 7-11.
16. Clamp CADD cassette extension and secure with sterile RED cap.
17. **Inspect final CADD cassette for precipitation and air bubbles.**
18. Place final product and waste materials back in metal tray.
19. Open glass sliding door and transfer metal tray to antechamber.
20. Remove hands from glove ports and open antechamber door to retrieve metal tray.
21. Dispose waste and sharps accordingly.
22. Label CADD cassette with patient specific label with BUD and attach a refrigerate sticker
23. **RPH must perform final quality review to ensure final product is properly labeled and free of precipitations.**

Beyond Use Date:

14 Days (Under Refrigeration)

Reference:

Trissel, Lawrence A., Handbook on Injectable Drugs 16th Edition, Drug p.145.
Terra Universal Compounding Aseptic Isolator Quick-Start Operating Guide, January 2016

Logged Formula Worksheet (detailed)
1/2/2014 9:07:20 AM
Page 1

Pharmacy A
Address

Drug A

1ML 40MG/ML INJECTABLE

Tall Man:

Flavor:
Quantity made: 4500 ML

Batch yield: 4,500.000
Qty remaining: 4,500.000

Schedule:
PCCA ID:
Route of admin:

Formula ID: 371 Log ID: 79970 Active ☑

Date made: 1/2/2014
Lot number: 20140201@1
Beyond use date: 7/1/2014 8:23 AM
180 days after compounding date

Pharmacist:
Technician:
Misc. Note:
NDC1: MPF4
Description:
Packaging:
Equipment:

Pricing calculations from the log

Estimated price	$129,375.00 as of 5/8/2007	
Ingredient cost	$0.00	
Device cost	$0.00	
Time cost	$0.00	Time to make: 0
Profit	$129,375.00	

Picture

Labeling: YELLOW CAPS
Stability information: POTENCY OVER TIME STUDY CONDUCTED ON LOT 1211049

Chemicals	Schedule	Quantity used	QS (balance)	Actual Cost & date
1 Drug A	L	180 GMS	☐ 181.79 g	$855.00 12/2/2013
CAS: 53-30-1		Stock: 7,400.02		NDC: 51927-1332-00
Lot #: C159544-STERHUM	Mfg:	Exp. date: 7/31/2018		Whlsr: PCCA
Hazard code: H	Volume: Potency:	QS amount:		ChemInvID:18593
Purity: 100.60 Balance info: Percent off: 0.994% (over weight). Result: 181.79 g				AWP: 5,910.00
			Bar code checked: ☑ Each ML contains 0.04 GMS or 4%	
			NDC:	
2 BASE B, POLYETHYLENE GLYCOL 3350 NF (GRANULAF	L	130.75 GMS	☐ 130.002 g	$6.01 12/20/2013
CAS: 25322-68-3		Stock: 1,773.469		NDC: 51927-3942-00
Lot #: C159288-STERHUM	Mfg: PCCA	Exp. date: 1/8/2016		Whlsr: PCCA
Hazard code: N	Volume: Potency:	QS amount:		ChemInvID:18916
Purity: Balance info: Percent off: 0.572% (under weight). Result: 130.002 g				AWP: $19.61
			Bar code checked: ☑ Each ML contains 0.0291 GMS or 2.91%	
			NDC:	
3 SODIUM PHOSPHATE, MONOBASIC USP ANHYDROUS	L	30.6 GMS	☐ 30.606 g	$2.22 12/17/2013
CAS: 7558-80-7		Stock: 16,441.9916		NDC: 51927-3095-00
Lot #: C158936-STERHUM	Mfg: PCCA	Exp. date: 8/15/2015		Whlsr: PCCA
Hazard code: I	Volume: Potency:	QS amount:		ChemInvID:18862
Purity: 100.00 Balance info: Percent off: 0.020% (over weight). Result: 30.606 g				AWP: $7.96
			Bar code checked: ☑ Each ML contains 0.0068 GMS or 0.68%	
			NDC:	
4 SODIUM PHOSPHATE, DIBASIC USP DRIED POWDER F	L	6 GMS	☐ 6.003 g	$0.59 12/16/2013
SODIUM PHOSPHATE, DIBASIC USP DRIED POWDER				
CAS: 7558-79-4		Stock: 11,603.3615		NDC: 51927-1329-00
Lot #: C158646-STERHUM	Mfg: PCCA	Exp. date: 7/1/2015		Whlsr: PCCA
Hazard code: I	Volume: Potency:	QS amount:		ChemInvID:18819
Purity: 99.30 Balance info: Percent off: 0.050% (over weight). Result: 6.003 g				AWP: $1.62
			Bar code checked: ☑ Each ML contains 0.00133 GMS or 0.133%	
			NDC:	

Date entered: 1/2/2014 8:23:34 AM Last modified: 1/2/2014 9:07:18 AM by: RPH B
Checked by: _____ Date: ___/___/_____

Logged Formula Worksheet (detailed)
1/2/2014 9:07:20 AM
Page 2

Pharmacy A
Address

Drug A

1ML 40MG/ML INJECTABLE

Tall Man:

Flavor:
Quantity made: 4500 ML

Batch yield: 4,500.000
Qty remaining: 4,500.000

Schedule:
PCCA ID:
Route of admin:

Formula ID: 371 Log ID: 79970 Active ☑

Chemicals	Schedule	Quantity used	QS (balance)	Actual Cost & date
5 SODIUM CHLORIDE USP GRANULAR GRANULES	L	9.75 GMS	☐ 9.751 g	$0.09 9/20/2013
CAS: 7647-14-5		Stock: 3,747.0049		NDC: 62991137205
Lot #: 11210429-STERHUM	Mfg:	Exp. date: 4/13/2021		Whlsr: LETCO
Hazard code: N	Volume: Potency:	QS amount:		ChemInvID:17316
Purity: 100.10 Balance info: Percent off: 0.010% (over weight). Result: 9.751 g				AWP: $1.46
			Bar code checked: ☑ Each ML contains 0.00217 GMS or 0.217%	
			NDC:	
6 POLYSORBATE 80 NF	L	8.75 ML	☐ 8.75ML	$0.15 12/11/2012
CAS: 9005-65-6		Stock: 13,778.1997		NDC: 38779052600
Lot #: 87714/A-STERHUM	Mfg:	Exp. date: 7/30/2014		Whlsr: LETCO
Hazard code: N	Volume: Potency:	QS amount:		ChemInvID:13729
Purity: Balance info:				AWP: $3.94
			Bar code checked: ☑ Each ML contains 0.00194 ML or 0.194%	
			NDC:	
7 WATER STERILE FOR INJECTION, BAG LIQUID		4500 ML	☒ 4500ML	$0.00
CAS:		Stock: -1,189,336.4132		NDC:
Lot #: J3N568	Mfg:	Exp. date: 04/2016		Whlsr:
Hazard code:	Volume: Potency:	QS amount:		ChemInvID:
Purity: Balance info:				AWP:
			Bar code checked ☐ Each ML contains 1 ML or 100%	
			NDC:	

(Added all GM & GMS: 357.10 All ML: 4,508.75) **Total ingredient cost** $864.06

Log Instructions & Notes

Originally made as: 4500 Drug A 1ML 40MG/ML INJECTABLE
Calculated lot number: 20140201@1 Beyond use date: 7/1/2014

FORMULA INSTRUCTIONS:
1. MIX ALL POWDERS IN STERILE WATER FOR INJECTION; QS TO TOTAL VOLUME & HOMOGENIZE.
2. AUTOCLAVE @250F FOR 30 min.
3. IN CLEAN ROOM, HOMOGENIZE FOR 15 MIN WHEN COOLED .
4. PUT IN 1 ML STERILE AMBER VIALS;STOPPER; CAP WITH YELLOW CAPS.
5. STORE AT ROOM TEMP.
6. SEND SAMPLES TO ANALYTICAL FOR TESTING.

Date entered: 1/2/2014 8:23:34 AM Last modified: 1/2/2014 9:07:18 AM by: RPH B
Checked by: _____ Date: ___/___/_____

Drug A

Domperidone 10 mg Capsules Size #3

SUGGESTED FORMULA FOR
Domperidone 10 mg Capsules Size #3
100 Capsules

Drug A		
Domperidone BP	1	Gm
Microcrystalline Cellulose NF (PH-105)	11.943	Gm

SUGGESTED COMPOUNDING PROCEDURE

NOTE: It is recommended that you follow USP <795> recommendations for potency testing which states "... each preparation shall contain not less than 90.0% and not more than 110.0% of the theoretically calculated and labeled quantity of active ingredient ...". In order to provide some guidance in this area, please contact Eagle Analytical Services regarding the use of Skip Lot testing.

NOTE: This is a theoretical formula and has not been tested in the PCCA lab.

NOTE: This formula was calculated using the following capsule packing statistics:

Drug A
Domperidone BP:
Lot #C115148, 123 milligrams in a size #3 capsule
Microcrystalline Cellulose NF (PH-105):
Lot #C113154, 130 milligrams in a size #3 capsule

Pack stats will vary from lot to lot so it is recommended that you perform your own packing statistics before proceeding with this formulation. Please contact PCCA's Pharmacy Consulting Department for further assistance.

8196

SEE ATTACHED

NOTE: Lactose Monohydrate NF or Lactose Anhydrous NF may be used as an alternative to Microcrystalline Cellulose NF (PH-105). Be sure to recalculate the amount of filler needed based on the pack statistics for the filler you choose. If you have questions or need further assistance, please contact PCCA's Pharmacy Consulting Department.

1. Using the Principles of Geometric Dilution, mix Domperidone and Microcrystalline Cellulose (PH-105) together with trituration in a mortar and pestle.

2. Capsule formulations should have powders where the particle size is the same throughout. Once powders are thoroughly mixed, sieve through an 80 mesh sieve (PCCA #35-3125) to ensure even particle size. Do not force large particles through the sieve as this destroys the integrity of the sieve. Instead, any particles remaining in the sieve should be triturated in a mortar and pestle to reduce particle size, and ALL powders should be sieved again.

3. Encapsulate in size #3 capsules.

Principles of Geometric Dilution

This procedure should be followed when mixing an ingredient of a larger quantity (L) with a second ingredient of a smaller quantity (S). L is to be mixed into S in small portions.

First, add a portion of L which has the same volume of that of S followed by thorough mixing. You will get a mixture (M_1).

Then, add another portion of L which has the same volume of that of M_1 followed by thorough mixing. Do the mixing based on the above principle until L is mixed into S completely.

Under no circumstance should the entire quantity of L be added at once to S in the expectation that uniform dispersion of the latter will be more expeditiously achieved on brief trituration of the mixture.

8196

NOTE: No claims are made as to the safety or efficacy of this preparation. This formulation is provided solely at the unsolicited request of the pharmacist.

NOTE: Beyond Use Dates of preparations are conservative estimates by the formulator using reference books, peer reviewed literature, intended duration of therapy, formulation from commercially available products, organoleptic stability observations and current USP guidelines. Compounders may have stability tests performed by a reputable laboratory if they wish to extend the Beyond Use Date.

NOTE: Beyond Use Date after compounding is estimated to be 180 days.

8196
08/16/00 (o)
05/05/09 (r)
MM/mfe

Attachment 11

Board of Pharmacy Enforcement Statistics
Fiscal Year 2016/2017

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 16/17
Complaints/Investigations					
Received	792	659			1451
Closed	790	623			1413
4301 letters	4	9			13
Pending (at the end of quarter)	2441	2459			2459
Cases Assigned & Pending (by Team) at end of quarter*					
Compliance / Routine Team	1063	1158			1158
Drug Diversion/Fraud	450	429			429
RX Abuse	171	151			151
Compounding	126	114			114
Probation/PRP	75	79			79
Mediation/Enforcement **	252	228			228
Criminal Conviction	304	300			300
Application Investigations					
Received	154	159			313
Closed					
Approved	110	71			181
Denied	10	15			25
Total ***	147	109			256
Pending (at the end of quarter)	111	161			112
Letter of Admonishment (LOA) / Citation & Fine					
LOAs Issued	114	117			231
Citations Issued	589	379			968
Total Fines Collected ****	$447,974.15	$577,712.00			$1,025,686.15

* This figure includes reports submitted to the supervisor and cases with SI awaiting assignment.

** This figure include reports submitted to the citation and fine unit, AG referral, as well as cases assigned to enf. Staff

*** This figure includes withdrawn applications.

****Fines collected (through 12/31/2016 and reports in previous fiscal year.)

Board of Pharmacy Enforcement Statistics
Fiscal Year 2016/2017

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 16/17
Administrative Cases (by effective date of decision)					
Referred to AG's Office*	105	68			173
Accusations Filed	73	56			129
Statement of Issues Filed	5	7			12
Petitions to Revoke Filed	4	0			4
Pending					
Pre-accusation	255	240			255
Post Accusation	278	252			278
Total*	573	519			573
Closed					
Revocation					
Pharmacist	4	2			6
Intern Pharmacist	1	0			1
Pharmacy Technician	37	33			70
Designated Representative	0	0			0
Wholesaler	0	0			0
Sterile Compounding	0	0			0
Pharmacy	4	2			6
Revocation,stayed; suspension/probation					
Pharmacist	1	1			2
Intern Pharmacist	0	0			0
Pharmacy Technician	0	2			2
Designated Representative	0	0			0
Wholesaler	0	0			0
Sterile Compounding	0	0			0
Pharmacy	0	0			0
Revocation,stayed; probation					
Pharmacist	8	17			25
Intern Pharmacist	0	0			0
Pharmacy Technician	4	1			5
Designated Representative	0	0			0
Wholesaler	1	0			1
Sterile Compounding	0	0			0
Pharmacy	5	10			15
Surrender/Voluntary Surrender					
Pharmacist	7	8			15
Intern Pharmacist	0	1			1
Pharmacy Technician	10	10			20
Designated Representative	0	0			0
Wholesaler	0	0			0
Sterile Compounding	0	0			0
Pharmacy	3	9			12

Board of Pharmacy Enforcement Statistics
Fiscal Year 2016/2017

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 16/17
Public Reproval/Reprimand					
Pharmacist	5	2			7
Intern Pharmacist	0	0			0
Pharmacy Technician	0	1			1
Designated Representative	0	0			0
Wholesaler	0	0			0
Sterile Compounding	0	0			0
Pharmacy	0	1			1
Licenses Granted					
Pharmacist	0	1			1
Intern Pharmacist	0	2			2
Pharmacy Technician	1	2			3
Designated Representative	1	0			1
Wholesaler	0	0			0
Sterile Compounding	0	0			0
Pharmacy	0	0			0
Licenses Denied					
Pharmacist	0	0			0
Intern Pharmacist	0	0			0
Pharmacy Technician	3	4			7
Designated Representative	0	0			0
Wholesaler	0	0			0
Sterile Compounding	0	0			0
Pharmacy	0	0			0
Cost Recovery Requested**	$307,270.00	$6,201,803.11			$6,509,073.11
Cost Recovery Collected**	$132,381.11	$275,441.13			$407,822.24

* This figure includes Citation Appeals

** This figure includes administrative penalties

Immediate Public Protection Sanctions					
Interim Suspension Order	0	0			0
Automatic Suspension / Based on Conviction	0	0			0
Penal Code 23 Restriction	2	3			5
Cease & Desist - Sterile Compounding	0	0			0

Board of Pharmacy Enforcement Statistics
Fiscal Year 2016/2017

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 16/17
Probation Statistics					
Licenses on Probation					
Pharmacist	176	190			190
Intern Pharmacist	3	6			6
Pharmacy Technician	37	36			36
Designated Representative	1	1			1
Pharmacy	54	56			56
Sterile Compounding	10	10			10
Wholesaler	5	5			5
Probation Office Conferences	15	36			36
Probation Site Inspections	141	126			267
Successful Completion	5	4			9
Probationers Referred to AG for non-compliance	0	4			4

As part of probation monitoring, the board requires licensees to appear before the supervising inspector at probation office conferences. These conferences are used as 1) an orientation to probation and the specific requirements of probation at the onset, 2) to address areas of non-compliance when other efforts such as letters have failed, and 3) when a licensee is scheduled to end probation.

As of December 31, 2016.

SB 1441 – Program Statistics

Licensees with substance abuse problems who are either on board probation and/or participating in the Pharmacist Recovery Program (PRP)

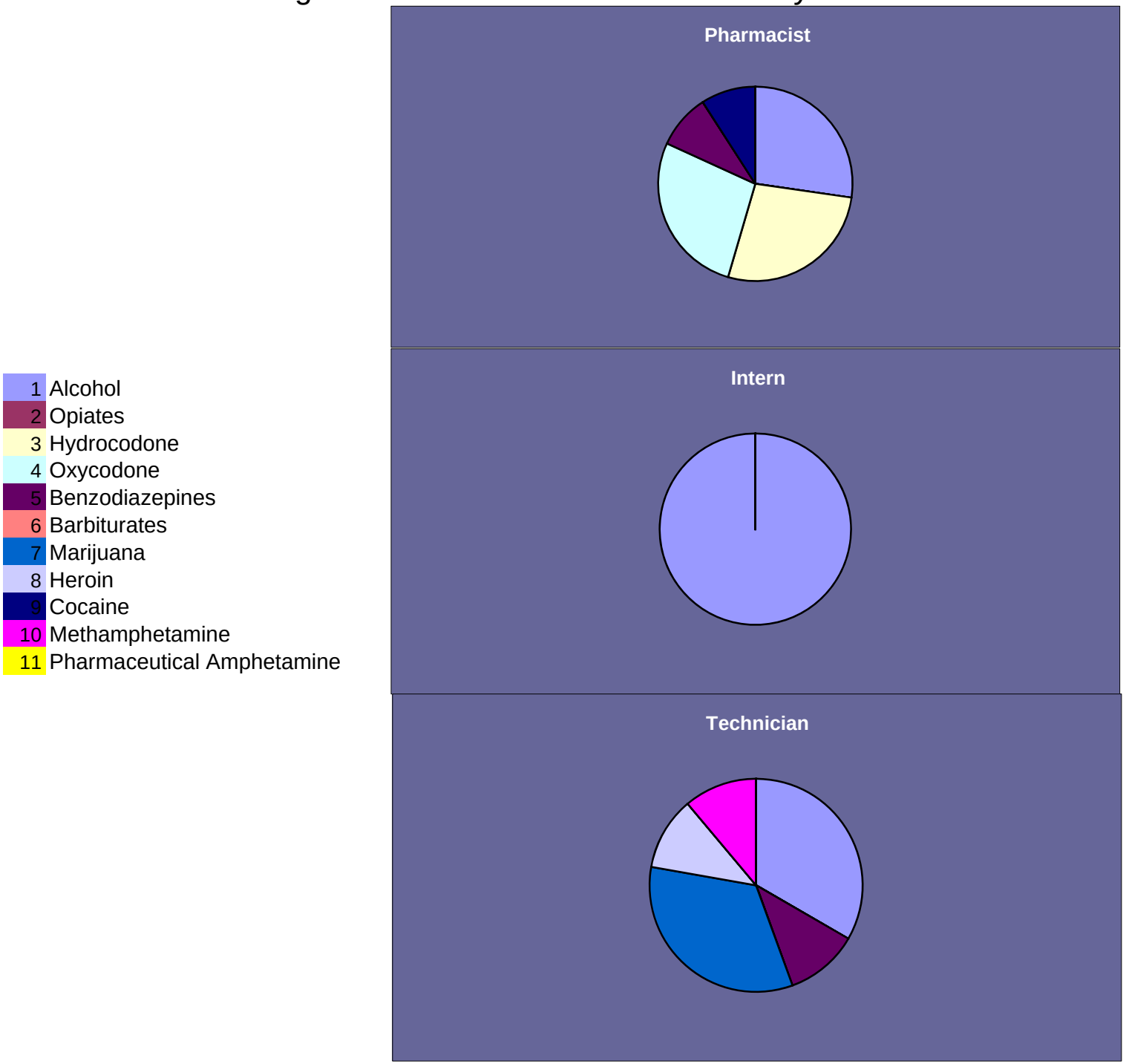
Board of Pharmacy	July -Sep	Oct – Dec	Jan-Mar	Apr-Jun	Total 16/17
PRP Intakes					
PRP Self-Referrals					
PRP Board Referrals		3			3
PRP Under Investigation	3	1			4
PRP In Lieu Of					
Total Number of PRP Intakes	3	4			7
New Probationers					
Pharmacists	2	2			4
Interns		2			2
Technicians	2	4			6
Total New Probationers	4	8			12
PRP Participants and Contracts					
Total PRP Participants	53	55			N/A
Contracts Reviewed	50	47			97
Probationers and Inspections					
Total Probationers	81	83			N/A
Inspections Completed	141	126			267
PRP Referrals to Treatment					
Referrals to Treatment	2	4			6
Drug Tests					
Drug Test Ordered	911	908			1819
Drug Tests Conducted	895	898			1793
Relapse					
Relapsed	1	3			4
Major Violation Actions					
Cease Practice/Suspension	4	8			12
Termination - PRP	2	3			5
Referral for Discipline					
Exit from PRP or Probation					
Successful Completion	4	1			5
Termination - Probation	1				1
Voluntary Surrender	3	4			7
Surrender as a result of PTR	1	1			2
Public Risk	2				2
Non-compliance	19	7			26
Other		1			1
Patients Harmed					
Number of Patients Harmed	None	None	None	None	None

SB 1441 – Program Statistics

Licensees with substance abuse problems who are either on board probation and/or participating in the Pharmacist Recovery Program (PRP)

Board of Pharmacy	July -Sep	Oct – Dec	Jan-Mar	Apr-Jun	Total 16/17
Drug of Choice at PRP Intake or Probation					
Pharmacists	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 16/17**
Alcohol	1	2			3
Ambien					
Opiates	3				3
Hydrocodone	1	2			3
Oxycodone	1				1
Morphine					
Benzodiazepines					
Barbiturates					
Marijuana		1			1
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol		1			1
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					
Intern Pharmacists	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 16/17**
Alcohol		2			2
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					
Pharmacy Technicians	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 16/17**
Alcohol	1	2			3
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines	1				1
Barbiturates					
Marijuana	2	1			3
Heroin		1			1
Cocaine					
Methamphetamine	1				1
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					

Drug Of Choice - Data entered from July 2016 to June 2017



Printed on 1/12/2017

California State Board of Pharmacy
Citation and Fine Statistics
October 1, 2016 - December 31, 2016

379 Citations were issued this fiscal year

Total dollar amount of fines issued this fiscal year $585,750.00

The average number of days from date case is opened until a citation is issued is 348.37

Average number of days from date case is routed to Citation Unit to date citation is issued 37.99

426 citations are closed. The average number of days from date citation is issued to date citation is closed is 85.97

Citation Breakdown by license type

Total issued	RPH with fine	RPH no fine	PHY with fine	PHY no fine	TCH with fine	TCH no fine
379	134	14	65	45	45	1

Citation Breakdown by Miscellaneous license type

Wholesalers	Exemptee's	Clinics	Drug Room	Exempt Hosp.	Hosp. Pharmacy	Misc.*	Unlicensed Premises	Unlicensed person
10	2	0	0	1	11	30	20	1

*Intern Pharmacist, Licensed Correctional Facilities, Exempt Pharmacies, Non-Resident Pharmacies, and Vet Retailers

Top Ten Violations by license type

Pharmacists	%	Pharmacies	%	Pharmacists In Charge	%
1716 - Variation from prescription	26%	1716 - Variation from prescription	26%	1714(d) - Operational Standards and Security; Pharmacist responsible for pharmacy security	30%
1714(d) - Operational Standards and Security; Pharmacist responsible for pharmacy security	17%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	23%	1716 - Variation from prescription	14%
4231(d)/1732.5 - Failure to provide documentation substantiating completion of continuing education/Renewal Requirements for Pharmacist	14%	4113(d) - Every pharmacy shall notify the board in writing within 30 days of the date of a change in pharmacist-in-charge	15%	1707.1(a)(1)(B)(2) - Duty to maintain medication profiles; a patient medication profile shall be maintained… for each prescription dispensed by the pharmacy-Prescribers name, license number, DEA regis	13%
4301(g) - Unprofessional Conduct - Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts	14%	4113(a) - Pharmacist-in-Charge: Notification to Board; Responsibilities; Every pharmacy shall designate a pharmacist-in-charge within 30 days in writing of the identity and license number of that phar	10%	11165(d) - For each prescription for a Schedule II or Schedule III controlled substance, the dispensing pharmacy shall report to the Department of Justice...	8%
1751.4(d) - Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly	6%	4305(b) - Disciplinary Grounds: Failure of Pharmacy or Pharmacist to Notify Board of Termination of Pharmacist-in-Charge; Continuing to Operate Without Pharmacist; Operation of a pharmacy for more tha	5%	4076(a)(4) - Prescription Container - Requirements for Labeling/The name of the prescriber…	8%
1707.2(b)(1)(A) - In addition to the obligation to consult…a pharmacist shall provide oral consultation to his or her patients…whenever the prescription drug has not previously been dispensed to a pat	5%	11165(d)(2) - Pharmacy shall provide the following information the Department of Justice: prescriber's category of licensure and license number; federal controlled substance registration number ...	4%	1714(c) - Operational Standards and Security; the pharmacy must be maintained in a sanitary condition	6%
1761 - Erroneous or uncertain prescriptions	5%	4076(a)(4) - Prescription Container - Requirements for Labeling/The name of the prescriber…	4%	1751.4(d) - Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly	6%
1714(c) - Operational Standards and Security; the pharmacy must be maintained in a sanitary condition	5%	1764/56.10(a) - Unauthorized disclosure of prescription and medical information	4%	1764/56.10(a) - Unauthorized disclosure of prescription and medical information	5%
4081(a) - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory	5%	1714(c) - Operational Standards and Security; the pharmacy must be maintained in a sanitary condition	4%	1751.4(c) - Equipment used in the designated area or cleanroom must be made of a material which can be easily cleaned and disinfected	5%
11165(d)(2) - Pharmacy shall provide the following information the Department of Justice: prescriber's category of licensure and license number; federal controlled substance registration number ...	4%	4081(a) - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory	4%	1735.4(a) - The label of a compounded drug product must contain the generic name(s) of the principal active ingredient(s) in addition to other required labeling information	5%