



ENFORCEMENT AND COMPOUNDING COMMITTEE REPORT

Amy Gutierrez, PharmD, Chair, Professional Member

Allen Schaad, RPh, Professional Member

Rosalyn Hackworth, Public Member

Greg Murphy, Public Member

Greg Lippe, Public Member

Report of the Enforcement and Compounding Committee Meeting held on March 26, 2015.

I. ENFORCEMENT MATTERS

a. SUMMARY OF PRESENTATION: EMD Serono's Program to Permit Patients to Authenticate Medication via Checking a Serial Number on a Medication Container Against a Manufacturer's Data Base

Ms. Fleming provided a brief explanation of EMD Serono's background and its affiliation with Merck KGaA in Germany. A copy of EMD Serono's brochure is provided in **Attachment 1**.

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

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

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

b. SUMMARY OF PRESENTATION: MatchRx's Model to Enable the Transfer of Prescription Medication in Short Supply Between Two Pharmacies

MatchRx is a private web-based inter-pharmacy marketplace for non-controlled, non-expired overstocked prescription drugs and drugs in short supply. MatchRx maintains safe,

secure and detailed electronic transaction records, providing track and trace compliance for dispenser-to-dispenser transactions. A copy of the PowerPoint is provided in **Attachment 2**.

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

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

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

Questions included whether a pharmacy could sell across state lines, to whom MatchRx would report a drug loss, and licensing requirements for shipping into California.

c. **SUMMARY OF PRESENTATION: University of California, San Diego's Request for Waiver of title 16, California Code of Regulations, Section 1706.5, to Permit a Pilot Program to Allow Patients to Access Medications from an Automated Storage Device Not Immediately Adjacent to a Pharmacy**

Several years ago, the board promulgated regulations (16 California Code of Regulation section 1713) to allow for the use of automated delivery devices, which are markedly like vending machines, to permit the furnishing of refill medication in specified circumstances, to include the requirement that the patient must opt in to use the machine and that the medication to be refilled through the machine is appropriate. [A copy of the regulation is included in **Attachment 3**. The relevant section of the regulation is in bold.]

In recent years, the board has received several requests to use automated delivery devices in a variety of settings including workplace clinics, hospital lobbies, other areas on a hospital campus, and in employment locations. During each of these discussions, several concerns were raised about whether the request would comply with current regulations and whether

the board had the authority to approve the request without specific regulatory changes. To date the board has not approved any waivers since enactment of the regulation.

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

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

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

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

The committee recommended bringing the protocol to the board for action.

Committee Recommendation:

Recommend the board review and approve the protocol for UCSD Automated Delivery Systems.

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

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

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

pharmacies and hospitals/clinics with an on-site pharmacy may operate collection receptacles at long-term care facilities. A copy of the final rule is provided in **Attachment 4**.

Also in **Attachment 4** is a newspaper article providing information about one of the country's largest reverse distributors and criminal arrests.

At the December 2014 committee meeting, Ms. Herold provided an overview of the DEA's new drug take-back regulations. Committee discussion included how an average person would know which drugs are acceptable for disposal. The committee heard comments from the public in which the board was asked not to place the collection burden on pharmacists. A copy of Ms. Herold's PowerPoint presentation is also provided in **Attachment 4**.

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

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

Dr. Gutierrez stated that the committee would bring this item back to the June 2015 committee meeting.

e. **SUMMARY OF DISCUSSION: Evaluation of title 16 California Code of Regulations, section 1744 Regarding Required Warning Labels on Prescription Container Labels**

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

Assembly Bill 1136 (Levine), signed by the Governor on September 9, 2013, amended existing law to require a pharmacist on or after July 1, 2014, to include a written label on a prescription drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel, if in the pharmacist's professional judgment, the drug may impair a person's ability to operate a vehicle or vessel. The required label may be printed on an auxiliary label that is affixed to the prescription container. The revised version of Business and Professions Code section 4074, which AB 1136 amended, is provided in **Attachment 5**.

Section 1744 of the board's regulations provides the specific classes of drugs which trigger a pharmacist's verbal or written notice to patients where a patient's ability to operate a vehicle (and now a vessel) may be impaired. This section has not been revised in a number

of years, so recently the schools of pharmacy were asked to provide comments to the list of medications listed in this regulation.

A number of California's schools of pharmacy provided comments. Those comments were integrated in the first draft. This draft can be found in **Attachment 5**.

At the September 2014 committee meeting, the committee revised those comments into the version that was referred to the board for action. This proposed version can be found in **Attachment 5**.

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

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

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

1744. Drug Warnings

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

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

(1) Muscle relaxants.

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

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

- (~~43~~) Antidepressants with central nervous system depressant effects.
- (~~54~~) Antihistamines, motion sickness agents, antipruritics, antinauseants, anticonvulsants and antihypertensive agents with central nervous system depressant effects.
- (~~65~~) All Schedule II, III, IV and V agents with central nervous system depressant effects. ~~or narcotic controlled substances as set forth in Health and Safety Code at Section 11055 et seq. prescribed in doses which could have an adverse effect on a person's ability to operate a motor vehicle.~~
- (~~76~~) Anticholinergic agents ~~and other drugs which may~~ that impair vision.
- (b) The following are examples of drugs which may have harmful effects when taken in combination with alcohol. ~~While these~~ These may or may not affect a person's ability to operate a motor vehicle they still require a written warning notice on the label to alert the patient about possible problems:
- (1) Disulfiram and other drugs (e.g., chlorpropamide, metronidazole) which may cause a disulfiram-like reaction.
 - (2) Mono amine oxidase inhibitors.
 - (3) Nitrates.
 - (4) Cycloserine.
 - (5) Insulin (hypoglycemia) antidiabetic agents including insulin and sulfonylureas (due to risk of hypoglycemia).

At this meeting, Ms. Herold highlighted the current changes made to the proposed language and sought legal guidance from DCA counsel. The committee requested counsel to modify the language so that it could be brought to the board at its April 2015 meeting.

Board staff worked with counsel and the following language has been proposed:

1744. Drug Warnings.

Pursuant to Business and Professions Code Section 4074, a pharmacist shall inform the patient or his or her representative of the harmful effects of certain drugs dispensed by prescription.

(a) Because the following classes of drugs may impair a person's ability to operate a vehicle or vessel, a pharmacist shall include a written label on the drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel.

- (1) Muscle relaxants.
- (2) Antipsychotic drugs with central nervous system depressant effects
- (3) Antidepressants with central nervous system depressant effects.
- (4) Antihistamines, motion sickness agents, antipruritics, anti-nauseants, anticonvulsants and antihypertensive agents with central nervous system depressant effects.
- (5) All Schedule II, III, IV and V agents with central nervous system depressant effects.
- (6) Anticholinergic agents that impair vision.
- (7) Any other drug based upon a pharmacist profession judgment that may impair a patient's ability to operate a vehicle or vessel.

(b) Because the following classes of drugs pose a substantial risk to the person consuming the drug when taken in combination with alcohol, a pharmacist shall provide a written warning notice on the label to alert the patient about possible potentiating effects:

- (1) Disulfiram and other drugs (e.g., chlorpropamide, metronidazole) which may cause a disulfiram-like reaction.
- (2) Mono amine oxidase inhibitors.
- (3) Nitrates.
- (4) Cycloserine.
- (5) Insulin (hypoglycemia) antidiabetic agents including insulin and sulfonylureas (due to risk of hypoglycemia).
- (6) Any other drug based upon a pharmacist profession judgment that may pose a substantial risk to the person consuming the drug when taken in combination with alcohol.

Committee Recommendation:

Recommend the board review and approve the proposed language for title 16 California Code of Regulations section 1744.

f. **SUMMARY OF DISCUSSION: Proposed Regulation for Pharmacies Aimed at Reducing Losses of Controlled Substances**

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

The board's staff compiled some statistics regarding drug losses reported to the board over the last few years. **Attachment 6** includes tables displaying the losses of controlled substances reported to the board.

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

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

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

Attachment 6 also includes the prior proposed language from the September and December 2014 Enforcement and Compounding Committee meetings.

At this meeting, after hearing comments from the committee and the public, board staff has revised the proposed language into the version below for consideration:

1715.65 Monthly Inventory Counts of Controlled Substances

- (a) Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall maintain a perpetual inventory for all Schedule II controlled substances acquired by the licensee. A perpetual inventory as used in this article shall mean an inventory system whereby the pharmacy's or clinic's records about stock on hand for every Schedule II controlled substance acquired and dispensed are continuously updated to reflect the actual quantity of stock on hand. Such an accounting will include all acquisitions and all dispositions for each Schedule II controlled substance.
- (a) As an alternative to the maintenance of a perpetual inventory for Schedule II controlled substances in subdivision (a), a pharmacy or clinic must have a written policy that identifies a monthly reconciliation process for the five highest volume controlled substances acquired by the licensee in the last year (or as determined by the last DEA biennial inventory, or as purchased by the pharmacy if there has been no biennial inventory taken). This policy shall address reconciliation of all purchases and acquisitions, dispensings, transfers and current inventory, including the inventory in quarantine for a reverse distributor. The pharmacy or clinic shall perform a count of these five controlled substances pursuant to this policy at least every month.
- (b) The pharmacist-in-charge of a hospital pharmacy or of pharmacy servicing skilled nursing homes wherever an automated drug delivery system is used shall review at least once each month all controlled substances removed from or added into each automated drug delivery machine operated by the pharmacy. Any discrepancy or unusual access identified shall be investigated. Controlled drugs inappropriately accessed or removed from the automated delivery shall be reported to the board within 14 days.
- (d) Losses of controlled substances identified by pharmacies from the perpetual inventory or monthly audit shall be reported to the board as required by section 1715.6 and California Business and Professions Code section 4104.
- (e) A clinic shall report to the board all losses detected from the perpetual inventory or monthly audit undertaken pursuant to this section within 14 and no later than 30 days.
- (f) The pharmacist-in-charge or consultant pharmacist for the clinic shall sign and date each monthly reconciliation within 14 days of completion. These signed

reconciliations shall be retained by the licensed premises for three years and be readily retrievable for review by the board.

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

Committee Recommendation:

Recommend the board review and approve the proposed language for title 16 California Code of Regulations section 1715.65.

g. SUMMARY OF PRESENTATION: Carefusion’s Drug Diversion Deterrent Reports Available with Its Automation Storage Cabinets

At this meeting, representatives from Carefusion appeared before the committee to provide information on the features of the Pyxis system that help deter controlled substance diversion and the available drug diversion reports available within the system. Copies of their background information and PowerPoint presentation are included in **Attachment 7.**

h. SUMMARY OF DISCUSSION: Discussion of Proposed Regulations for Third-Party Logistics Providers; Proposed Amendments to title 16 California Code of Regulations Sections 1780-1786

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

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

At this meeting, Ms. Herold stated that the regulations for wholesalers were developed over a period of time and that some of the language is now in statute and will be removed from the regulation. The revised language provides added details on how a third-party logistics provider is directed to protect the products in storage or being selected at its

facility. Ms. Herold also indicated that the board's goal for requiring a self-assessment which includes the general requirements for which a board inspector will look for when inspecting a facility. Ms. Herold stated that the proposed language is still a draft and still in the process of setting up the program. **Attachment 8** contains a copy of the proposed regulation and self-assessment for third-party logistics providers.

i. **SUMMARY OF DISCUSSION: CURES Data on the Impact of the Federal Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II**

The board's staff compiled data regarding the number of oxycodone and hydrocodone prescriptions dispensed before and after hydrocodone was rescheduled to Schedule II in October. **Attachment 9** includes the compiled data and data regarding losses reported for hydrocodone and oxycodone products during 2014.

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

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

j. **SUMMARY OF DISCUSSION: Discussion Regarding the Adoption of e-Prescribing**

E-prescribing had been required for all New York State prescriptions effective March 27, 2015, pursuant to regulations adopted by New York State. Recent legislation has delayed this implementation for one year, to March 27, 2016. At the last committee meeting, the committee heard a presentation by New York's Board of Pharmacy Executive Officer Larry Mokhiber. A copy of the regulation is provided in **Attachment 10**.

Provided as background on this topic was a 2013 project report of two locations in California that were pilot testing e-prescribing. This report is provided in **Attachment 10**.

Attachment 10 also includes a copy of SureScripts, "*Second Update Regarding Industry Progress in Implementing Electronic Prescribing for Controlled Substances (EPCS)*."

At this meeting, Dr. Gutierrez asked if the board would be regulating SureScripts. Ms. Herold stated that it would be up to the DEA if California would regulate. Ms. Herold stated that she requested DEA to post on their website a list of audited and approved software that prescribers and pharmacies can use. There were no public comments.

k. **DISCUSSION AND POSSIBLE ACTION: Opportunity to Provide Comments on U.S. Food and Drug Administration Draft Guidance Documents**

The FDA recently released five guidance documents on various aspects of sterile compounding by pharmacies and the production of medication by outsourcing facilities. At the March Board Meeting and again at this meeting, each of these guidance documents has been agendaized so the board may discuss and take action on any of them. The comments are due on May 20, 2015, except for the proposed MOU.

If comments are desired, the board may direct staff to develop comments based on board discussion and have the board president approve and sign them. Providing no comments may be the board's decision as well.

In mid-March, the board's executive officer attended and was an invited speaker at a 50-state meeting convened by the FDA to discuss these guidance documents, and the continued development of the federal outsourcing facility licensing provisions and sterile compounding by pharmacies. At the bottom of this section (immediately before agenda item K) is a list of all outsourcing facilities licensed by the FDA.

1. Draft Guidance: For Entities Considering Whether to Register As Outsourcing Facilities under Section 503B of the Federal Food, Drug, and Cosmetic Act

Attachment 11

This guidance states that entities registered with the FDA as outsourcing facilities will be regulated as outsourcing facilities according to current good manufacturing practice requirements (CGMP) for all products they produce or compound. (Federal law allows outsourcing facilities to be sterile compounding pharmacies as well.) These facilities will be inspected by the FDA on a risk-based schedule. There are approximately 50 FDA registered outsourcing facilities, including one in Switzerland.

The outsourcing guidance states (page 4) that if a facility does not intend to compound all drugs under CGMPs, then the facility should not be registered as an outsourcing facility. Additionally,

The facility:

- Must be engaged in the production of compounding sterile human drugs.
- Does Not repackage drugs (except as discussed in other guidance documents)
- Does Not produce biologic drugs
- Does Not produce animal drugs

The guidance concludes that a facility should not register as an outsourcing facility if the only activities it performs are repackaging, compounding non-sterile or animal drugs, or mixing, diluting or repackaging biological products.

Regardless of whether the board submits comments on this guidance document, these guidance statements may be of value to the board in developing parameters for its legislation to regulate outsourcing facilities.

2. Draft Guidance for Industry: Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities

Attachment 12

From Page 3 of this guidance:

“When a drug product is prepackaged, its characteristics may change in ways that have not been evaluated during the FDA approval process and that could affect the safety and efficacy of the drug product. Improper repackaging of drug products can cause serious adverse events. Of particular concern is repackaging of sterile drug products which are susceptible to contamination and degradation. For example, failure to properly manipulate sterile drug products under appropriate aseptic conditions could introduce contaminants that could cause serious patient injury or death. Repackaging practices that conflict with approved product labeling could result in drug product degradation and adverse events associated with impurities in the product or lack of efficacy because the active ingredient has deteriorated.”

Drugs that are repackaged are not regulated by the FDA under provisions dealing with pharmacy or outsourcing facilities. The guidance states that the FDA does not intend to take action for certain violations of federal requirements for entities that repackage drugs, provided:

1. The facility is licensed by a state as a pharmacy or holds an outsourcing facility license
2. If the repackaging occurs in a pharmacy or federal institution only: 1. after receipt of a patient-specific prescription or written chart order, or 2. Repackaged in advance of receipt of a patient-specific order based on prior demand for a previous, consecutive 14-day period AND history for prior 14-day periods.
3. The repackaging is done by or under the supervision of a licensed pharmacist
4. For single dose vials, the repackaging does not conflict with drug product labeling
5. For single dose vials repackaged into multiple units, the product is repackaged in a way that does not conflict with drug product labeling
6. The repackaged drug product conforms to specific beyond use dating (BUD)
7. Provides different requirements for BUD for an outsourcing facility, and requires CGPMs for the repackaging processes. Additionally the guidance provides labeling requirements for the repackaged product.

8. The repackaged product is not sold or transferred by an entity other than the one that repackaged the product.
 9. The repackaged drug product is distributed only in states in which the facility repackaging the product meets all applicable state requirements.
 10. Addresses guidance for repacking drugs on the FDA's drug shortage list.
3. Draft Guidance for Industry: Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application (BLA)

Attachment 13

The background section of this guidance document provides an overview of biological products, their characteristics and their regulation by the FDA. The guidance generally excludes compounding or outsourcing preparation of biologic products. Instead, such a company must possess an approved biologics license application (BLA) for the biologic.

However, the guidance notes that biologics sometimes must be mixed, diluted or repackaged in ways not addressed by the BLA and the guidance notes that the FDA will not take action against a state-licensed pharmacy, federal institution or outsourcing facility that conforms to mix, dilute or repackage a biologic under the conditions specific in the guidance. This includes:

- A biological product that is mixed, diluted or repackaged in a pharmacy or federal facility (but NOT an outsourcing facility) 1. after receipt of a patient-specific prescription or written chart order, or 2. is mixed, diluted or repackaged in anticipation of need based on prior demand, but not dispensed until ordered for a patient.
- The biologic must be mixed, diluted or repackaged by or under the direct supervision of a pharmacist.'
- Specifics about beyond use dating (BUD) for the mixed, diluted or repackaged biologic.

The guidance also specifies a BUD for an outsourcing facility that mixes or dilutes a biologic, and a separate process for a BUD for an outsourcing facility that repackages a biologic.

The guidance provides labeling instructions for biologic products mixed, diluted or repackaged by a pharmacy, federal institution or outsourcing facility.

The guidance also establishes criteria for the creation of prescription sets of allergic extracts under which the FDA will not take action against a pharmacy, federal institution, outsourcing facility or physician.

4. Draft Guidance for Industry: Adverse Event Reporting for Outsourcing Facilities under Section 503B of the Federal Food, Drug, and Cosmetic Act

Attachment 14

This guidance provides that outsourcing facilities are required to report adverse drug events to the FDA within 15 days. Specifically, all serious, unexpected adverse drug experiences associated with the use of their compounded prescription drug products, and “strongly recommends” that outsourcing facilities report all serious adverse drug experiences generally.

The guidance lists four elements for the investigation to include: the patient, the reporter, the suspect drug, the serious adverse event. It then describes the specific details about each element to include in the report.

Regarding the board’s outsourcing facility legislative proposal: the 15-day reporting report for adverse events is longer than the 12-hour requirement in existing California law for compounding pharmacies to report to the board any drug recalled.

5. Draft Memorandum of Understanding Between A State and the U.S. Food and Drug Administration Addressing Certain Distributions of Compounded Human Drug Products

Attachment 15

From Page 1:

“This Memorandum of Understanding (MOU) establishes an agreement between the State of [insert State] and the U.S. Food and Drug Administration (FDA) regarding the distribution of inordinate amounts of compounded human drug products interstate and the appropriate investigation by the State of [insert State] of complaints relating to compounded human drug products distributed outside the state. This is the MOU provided for by section 503A(b)(3)(B)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C 353a), and does not apply to drugs that are compounded by registered outsourcing facilities.”

The MOU exempts the compounded products of pharmacies under specific circumstances from:

- Complying with CGMPs
 - Labeling with adequate directions for use
 - Possessing FDA prior approval of the drug product
- provided the state has entered into the MOU.

If the state has entered into the MOU, then the MOU:

- Requires the home state to investigate issues arising from the interstate

distribution of compounded drugs by a pharmacy and to identify the root cause of the problem, and take response to the action

- Requires the state to review compounding records during the inspections of compounding pharmacies to ensure the compounding pharmacy has not distributed an inordinate amount of compounded drug product interstate.
- Defines an inordinate amount as not more than 30 percent of the total number of compounded and non-compounded drug products distributed or dispensed (both in-state and interstate).

At some point in the future, once finalized, the board will need to determine whether it wishes to enter into such an agreement with the FDA.

FDA Registered Outsourcing Facilities

Facility Name	Initial Date of Registration as an Outsourcing Facility ¹	Date of Most Recent Registration as an Outsourcing Facility ¹	End Date of Last FDA Inspection Related to Compounding ²	Was a Form FDA-483 issued? ³	Other FDA Action, if Any, Based on Last Inspection ^{4,5}	Intends to Compounds Sterile Drugs From Bulk Drug Substances ⁶
Absolute Pharmacy, Lutz, FL	9/3/2014	12/30/2014	11/19/2014	Yes	Open	Yes
ACS Dobfar Info S.A., Campascio, Switzerland	1/9/2015	1/9/2015	Not yet inspected	N/A	N/A	Yes
Advanced Pharma, Inc., Houston, TX	1/22/2014	11/26/2014	3/17/2014	Yes	Open	No
Alexander Infusion LLC dba Avanti Health Care, New Hyde Park, NY	4/21/2014	1/7/2015	7/9/2014	Yes	Warning Letter - 3/27/2015	Yes

AnazaoHealth Corporation, Las Vegas, NV	9/23/2014	12/29/2014	1/30/2015	Yes	Open	Yes
Avella Specialty Pharmacy, Phoenix, AZ	2/24/2014	1/20/2015	2/25/2013	Yes	Warning Letter - 1/17/2014	No
Banner Health, Chandler, AZ	12/26/2013	1/27/2015	3/20/2015	Yes	Open	No
Brookfield Medical/Surgical Supply, Inc., Brookfield, CT	1/12/2015	1/12/2015	Not yet inspected	N/A	N/A	Yes
Brown's Compounding Center, Inc., Englewood, CO	12/22/2014	12/22/2014	8/11/2014	Yes	Open	Yes
California Pharmacy and Compounding Center, Newport Beach, CA	4/30/2014	11/24/2014	8/25/2014; 10/17/2014	Yes (8/25/2014 and (10/17/2014))	Open	Yes
Cantrell Drug Company, Little Rock, AR	12/16/2013	12/30/2014	11/4/2013	Yes	Warning Letter - 1/21/2015	Yes
Central Admixture Pharmacy Services, Inc., Allentown, PA	2/28/2014	12/15/2014	2/11/2015	Yes	Open	Yes
Central Admixture Pharmacy Services, Inc., San Diego, CA	6/4/2014	12/15/2014	8/8/2014	Yes	Open	No
Coastal Meds LLC, Biloxi, MS	12/23/2014	12/23/2014	11/10/2014	Yes	Open	Yes
Complete Pharmacy and	6/6/2014	1/13/2015	8/12/2014	Yes	Open	Yes

Medical Systems, Miami Lakes, FL						
Delta Pharma, Inc., Ripley, MS	8/6/2014	3/10/2015	10/2/2013	Yes	Warning Letter - 12/9/2014	Yes
Edge Pharmacy Services, LLC, Colchester, VT	1/21/2014	1/15/2015	8/20/2014	Yes	Open	Yes
Exela Pharma Sciences, LLC, Lenoir, NC	6/6/2014	1/5/2015	11/21/2014	Yes	Open	Yes
Greer Laboratories, Inc., Lenoir, NC	2/24/2014	2/11/2015	11/15/2013	Yes	Warning Letter - 4/21/2014	Yes
Healix Infusion Therapy, Inc., Sugar Land, TX	2/12/2014	11/25/2014	5/16/2014	Yes	Open	Yes
Hybrid Pharma, LLC, Deerfield Beach, FL	1/14/2015	1/14/2015	Not yet inspected	N/A	N/A	Yes
Infusion Options Inc., Brooklyn, NY	1/24/2014	12/23/2014	4/23/2014	Yes	Open	No
JCB Laboratories, North Wichita, KS	1/21/2014	11/25/2014	2/27/2013	Yes	Warning Letter - 7/7/2014	Yes
Jubilant HollisterStier LLC, Spokane, WA	6/3/2014	2/13/2015	12/02/2014	Yes	Open	Yes
Kings Park Slope, Inc., Brooklyn, NY	12/23/2013	1/5/2015	3/14/2014	Yes	Warning Letter - 3/27/2015	Yes
KRS Global Biotechnology, Inc., Boca Raton, FL	12/15/2013	1/7/2015	3/17/2014	Yes	Open	Yes
LeeSar, Inc., Fort Myers, FL	4/30/2014	1/30/2015	8/8/2014	Yes	Open	No
Leiter's Compounding, 17 Great Oaks Blvd., San Jose, CA	1/31/2014	1/26/2015	10/7/2014	Yes	Open	Yes
Medi-Fare Drug, Blacksburg, SC	12/17/2013	12/31/2014	9/12/2014	Yes	Open	Yes
Medistat RX, LLC, Foley, AL	11/21/2014	11/21/2014	9/18/2014	Yes	Open	Yes
Nephron Sterile Compounding Center, LLC (NSCC), West Columbia, SC	7/15/2014	12/29/2014	Not yet inspected	N/A	N/A	Yes
OPS International	3/10/2014	1/27/2015	12/4/2014	Yes	Open	Yes

Inc., Olympia Pharmacy, Orlando, FL						
PHARMACEUTIC LABS, LLC, Albany, NY	3/10/2014	1/28/2015	Not yet inspected	N/A	N/A	Yes
Pharmakon Pharmaceuticals, Noblesville, IN	1/23/2014	12/2/2014	3/13/2014; 4/8/2014	Yes (3/13/2014) and (4/8/2014)	Open	No
Pharmalogic CSP, Bridgeport, WV	7/1/2014	1/5/2015	12/12/2014	Yes	Open	Yes
Pharm D Solutions, LLC, Houston, TX	8/6/2014	3/24/2015	Not yet inspected	N/A	N/A	Yes
PharMedium Services, LLC, Cleveland, MS	12/11/2013	11/24/2014	2/22/2013	Yes	Warning letter - 7/18/2014	No
PharMedium Services, LLC, Edison, NJ	12/11/2013	11/24/2014	2/28/2013	Yes	Warning letter - 7/18/2014	No
PharMedium Services, LLC, Memphis, TN	12/11/2013	11/24/2014	3/22/2013	Yes	Warning letter - 7/18/2014	No
PharMedium Services, LLC, Sugar Land, TX	12/11/2013	11/24/2014	2/27/2013	Yes	Warning letter - 7/18/2014	No
Pine Pharmaceuticals, LLC, Tonawanda, NY	6/17/2014	12/29/2014	10/16/2014	No	No	Yes
Premier Pharmacy Labs Inc., Weeki Wachee, FL	4/16/2014	12/18/2014	5/9/2014	Yes	Open	Yes
RC Compounding Services, LLC, Poland, OH	2/12/2014	1/5/2015	2/7/2013	Yes	Warning letter - 7/14/2014	Yes
Region Care, Inc., Great Neck, NY	12/24/2013	1/7/2015	3/20/2014	Yes	Open	Yes
RXQ Compounding LLC, Athens, OH	1/2/2015	1/2/2015	Not yet inspected	N/A	N/A	Yes
SCA Pharmaceuticals, Little Rock, AR	12/13/2013	12/22/2014	4/1/2014	Yes	Open	Yes
SSM St. Clare Health Center, Fenton, MO	2/18/2014	1/5/2015	8/14/2014	Yes	Open	No

Triangle Compounding Pharmacy Inc., Cary, NC	1/24/2014	12/15/2014	9/22/2014; 1/16/2015	Yes (9/22/2014 and 1/16/2015)	Open	Yes
Unique Pharmaceuticals, Ltd., Temple TX	1/17/2014	11/25/2014	1/23/2015	Yes	Open	Yes
US Compounding, Inc., Conway, AR	12/20/2013	12/24/2014	3/27/2014	Yes	Open	Yes
US Specialty Formulations LLC, Bethlehem, PA	1/31/2014	11/28/2014	Not yet inspected	N/A	N/A	Yes

I. INFORMATION: Enforcement Statistics

Attachment 16 includes the first and second quarterly report of the enforcement workload statistics and SB 1441 Program Statistics for the fiscal year.

m. Remaining Meeting Dates for 2015

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

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

II. COMPOUNDING MATTERS

a. INFORMATION: Summary of the Report of Sterile Compounding Pharmacy Inspections Conducted

Dr. Dang, supervising inspector, provided information about sterile compounding inspections and violations identified from December 1, 2014 through March 18, 2015.

Attachment 17 contains the data found as a result of sterile compounding inspections.

The minutes from the March 26, 2015 enforcement and compounding committee meeting are provided in **Attachment 18**.

Attachment 1

At EMD Serono, your safety is our first priority. That's why we created Check My Meds™ — a smartphone application to help you and your healthcare professional verify the integrity of EMD Serono prescriptions.

Safeguarding against counterfeit drugs

In an effort to verify the authenticity of all drugs dispensed to patients, the U.S. Food and Drug Administration (FDA) will require that drug companies include a unique serial number on each package of drugs dispensed by 2017. As part of a commitment to product integrity, EMD Serono is implementing this program well ahead of the FDA's requirement.

EMD Serono has been a long-standing leader in product integrity and patient safety, and the Check My Meds™ app is just the latest example of that. We are committed to doing our part to safeguard patients and physicians against counterfeiting.

About EMD Serono

EMD Serono, a subsidiary of Merck KGaA, Darmstadt, Germany, is a leading US biopharmaceutical company focused exclusively on specialty care. For more than 40 years, EMD Serono has integrated cutting-edge science, innovative products and devices, and industry-leading patient support and access programs. EMD Serono has deep expertise in neurology, fertility and endocrinology, as well as a robust pipeline of potential therapies in neurology, oncology, immunology and immuno-oncology. Today, EMD Serono has more than 1,100 employees around the country with commercial, clinical and research operations based in the company's home state of Massachusetts.

For more information, please visit www.emdserono.com



EMD Serono
Check My Meds™ App

Authenticate your EMD Serono prescriptions with your smartphone

Now available for download on iOS and Android products

Using the Check My Meds™ App

How can I Check My Meds™?

All major* EMD Serono brands have a two dimensional barcode that is generated and printed on each package during the packaging process.



Serialized brands include Rebif® (interferon beta-1a), Gonal-® (follitropin alfa for injection), Saizen® [somatropin (rDNA origin) for injection], Serostim® [somatropin (rDNA origin) for injection], Ovidrel® Pre-Filled Syringe (choriogonadotropin alfa injection) and Zorbtive® [somatropin (rDNA origin) for injection].

The Check My Meds™ app allows you to scan the two dimensional barcode to verify the authenticity of your prescription. From the app, you can also link to EMD Serono's patient support information.



1

Download the free Check My Meds™ app from your smartphone's app store and register for a user name and password in order to log in.



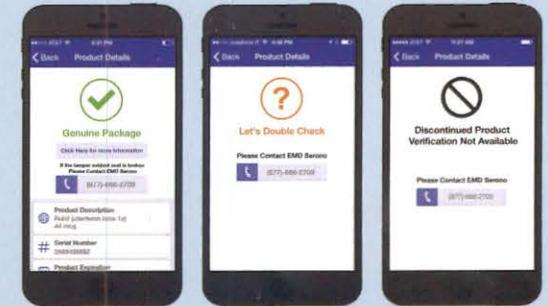
2

Once logged in to Check My Meds™, select Scan to begin authentication process.



3

Locate the two dimensional barcode on the package and select Scan at the bottom of the screen.



Verify your package: Genuine Package, Discontinued Product or Let's Double Check. When you receive a "Let's Double Check" message, you should contact EMD Serono at (877) 686-2709 to double check your package and its serial number.



Select History from main menu to view previous Scans. History will display from most recent to oldest. You can delete history by holding down a particular scan and selecting delete.

Attachment 2



Compliance, Transparency, Traceability for Dispenser-to-Dispenser Transactions

Introduction: Ron Bone, Ron N. Bone Consulting, LLC

Presenters: John Kello, CEO
Gabe Zawaideh R.Ph., President
Mike Galloway, COO



MatchRx Traceability Compliance

An Established Supply Chain Solution Providing Traceability Compliance
For Non-Controlled, Non-Expired Dispenser-To-Dispenser Transactions.



Our Mission

Enhance Access, Transparency and Compliance

Connect independent dispensers to resolve three longstanding problems:



- Eliminate costly overstock before it expires.
- Locating small quantities of difficult to find medications.
- Minimize pharmaceutical waste.

Members purchase small quantities of non-controlled, non-expired overstock from other members to:

- Satisfy specific patient requirements.
- Locate items temporarily in short supply.
- Supplement limited buying resources.
- Mitigate dramatic price increases of certain drugs.



The Result

Improved Drug Supply and Reporting

A growing community of members utilizing the marketplace to:

- Improve patient safety.
- Satisfy patient need.
- Mitigate supply chain constraints.
- Sustain the financial health of their small business.

MATCHRx		SELLER'S INVOICE										
your overstock solution		SELLER: Pharmacy ABC	BUYER: Pharmacy DEF									
218 E. 3rd St., Ste. 100 Des Moines, IA 50319 (515) 281-0000 toll free		123 Main St. City, St, Zip	456 Main St. City, St, Zip									
ORDER #	6453318	ORDER DATE	03/12/2015									
INVOICE												
ITEM	NAME	NDC	STRENGTH	FORM	EXP	LOT	PACK	PACK	UNIT	PRICE	QTY	TOTAL
16081828	DIVALPROEX SODIUM DR	2930014005	300MG	EA	201709	1123	CS	5000	5000	\$60.00	1	\$60.00
PRODUCT:											\$60.00	

Improved Agency reporting

- Transaction information stored in perpetuity.
- Data is provided within 48 hours of request in paper or electronic form.



MatchRX Statistics

- Established February 2010
- Operate in over 30 states including:
 - Nevada
 - Arizona
 - Utah
 - Oregon
 - Washington
- 3,700+ active members
- Processed over 250,000 transactions
- Average transaction is 2 bottles (containers)
- Daily Average 50,000 NDC's in the marketplace
- MatchRX does not take possession or title of the prescription medications



Affiliations & Associations



Advisors



Ron Bone

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Practice & Background: Ron Bone, recently retired from McKesson Corporation, spent 41 years with McKesson Corporation in various operations, sales, and financial management positions. His responsibilities included regulatory affairs and leading the company's product security initiatives through the use of electronic track-and-trace. Mr. Bone was a member of the Leadership Teams of GS1 Global Healthcare and GS1 US Healthcare and a Member of the Industry Relations Council of HDMA. In 2007 he received the NEXUS Award for Lifetime Achievement from HDMA which is the industry's highest honor in the healthcare industry. In 2008, he spoke in support of the Safeguarding America's Pharmaceuticals Act before the Health Subcommittee, Energy and Commerce Committee, US House of Representatives. He received his Bachelor of Science and MBA degrees from San Jose State University.



Nathan A. Brown

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Practice & Background: Nathan A. Brown advises health industry participants with regard to medical devices, drugs and biologics, as well as cosmetics and food products regulated by the U.S. Food and Drug Administration (FDA). His practice covers regulatory, compliance and policy advice.

Prior to joining the firm, Mr. Brown served in several prominent roles with the FDA. Most recently, he was detailed by the FDA to serve as health policy advisor to the Senate Health, Education, Labor and Pensions (HELP) Committee to cover FDA issues. On behalf of HELP Committee Chairman Tom Harkin (D-IA), Mr. Brown played a lead role negotiating and drafting the Drug Quality and Security Act of 2013 (drug compounding and track and trace legislation). He advised committee leadership on a broad range of FDA-related legislative and oversight matters, including device, drug and biologics issues, and met with stakeholders across the FDA-regulated industries. Education: J.D., Harvard Law School, 1999; B.S., University of Maryland, College Park, 1996; B.A., University of Maryland, College Park, 1995.



Advisors



Donnie Calhoun

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Practice & Background: Donnie Calhoun, 1987 graduate of Samford University School of Pharmacy, owns 2 pharmacies in Calhoun County. He serves on the executive committee for the National Community Pharmacists Association and as a national director for Pharmacist's Mutual Insurance Company. He served as the past President of the National Community Pharmacists Association and 2012 President of the Alabama Board of Pharmacy. He also has served on the National Home Infusion Association board of directors and Member Health's P&T committee. He has served as President of the Alabama Independent Drugstore Association and as a board member of the Alabama Pharmacy Association. He has been involved with teaching pharmacy students as an adjunct professor of Samford and Auburn Schools of Pharmacy. Donnie has served on many pharmacy committees at a local, state and national level. He has been a recipient of many awards including distinguished young pharmacist (1991) and the Alabama Pharmacy Association Pharmacist of the year award (2005).



Brian Dickerson

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Practice & Background: Brian Dickerson's experience includes the representation of domestic and international manufacturers, suppliers and distributors in defending governmental agency investigations into the manufacturing and distribution process and third party transactions causing exposure to false claims and FCPA violations. He regularly conducts internal investigations to identify areas of risk and insure compliance. He provides counsel on developing and implementing compliance programs for companies and their global operations.



Advisors



Ned Milenkovich
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Practice & Background: Ned Milenkovich is an Equity Principal of the Health, Drug & Pharmacy Practice at the Chicago office of Much Shelist, P.C. He has extensive knowledge of all segments of the drug supply chain and assists manufacturers, distributors, retailers, and pharmacy benefit managers in all facets of legal representation including regulatory, transactional, government investigation, and litigation matters. Previously, he was affiliated with the Chicago office of Roetzel & Andress as Head of Drug & Pharmacy Practice and Partner, and earlier McDermott Will & Emery and Jones Day where he practiced in health law groups. In addition to being a licensed attorney, Mr. Milenkovich is a registered pharmacist in Illinois and Ohio. Mr. Milenkovich serves as a Member in Healthcare Practice at McDonald Hopkins Co. LPA's Chicago office. He is a member of the Illinois State Board of Pharmacy in which he serves as a public official and is one of seven Illinois pharmacists charged with the public duty to protect the citizens of Illinois with respect to pharmacy matters. He is a frequent lecturer at both legal and pharmaceutical industry events and is vice-chairman of the Illinois State Board of Pharmacy. In addition, he writes a monthly legal/regulatory news column for the drug and pharmacy news magazine, Drug Topics. Mr. Milenkovich received his J. D. from The John Marshall Law School (2000), Doctor of Pharmacy from The University of Illinois-Chicago (1997) and B.S. in Pharmacy from The Ohio State University (1992).



Bob Carey
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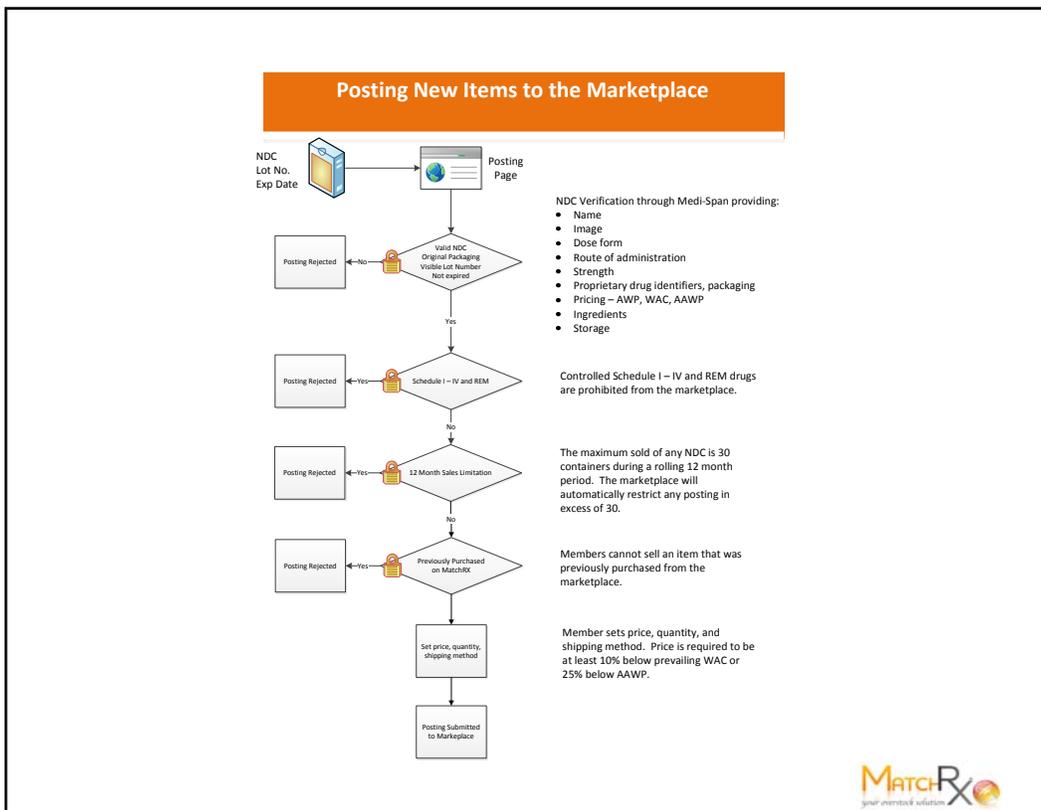
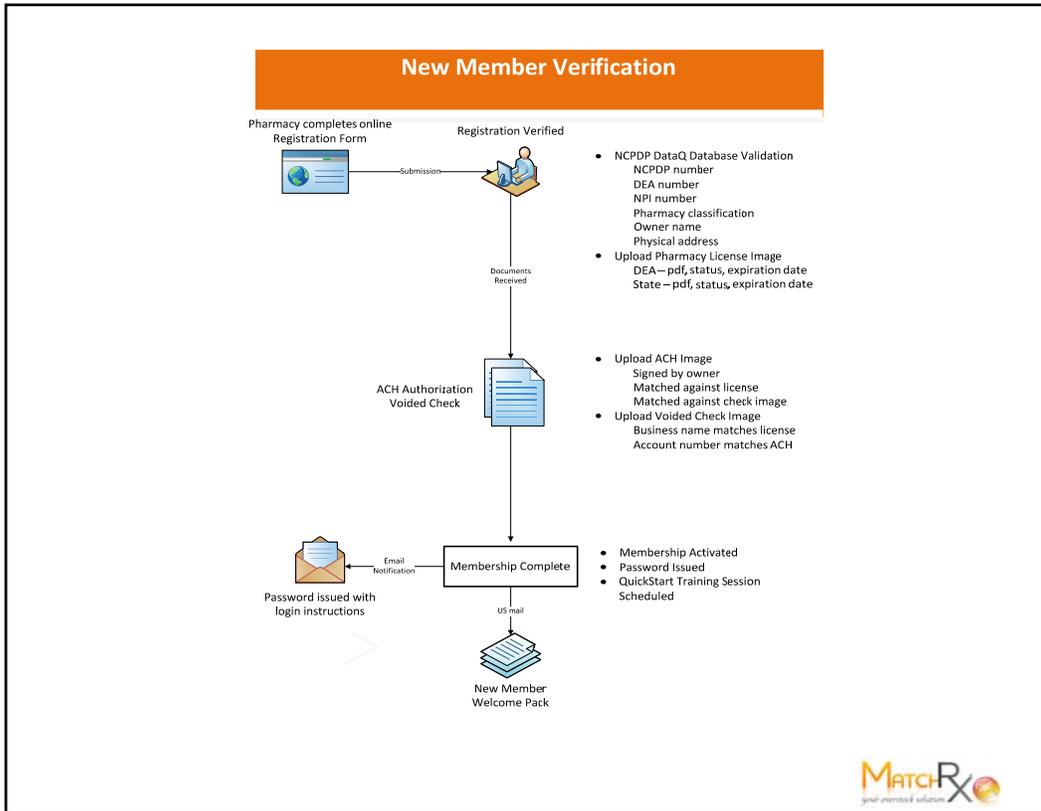
Practice & Background: Bob Carey is the President of Abraham & Roetzel. He joined the firm in May 2012 bringing more than 27 years of government, military, and private sector experience. Abraham & Roetzel is a bipartisan, full service government affairs and issue management firm, focusing on energy and natural resources, regulatory affairs, transportation and civil infrastructure, health care, pharmaceuticals, tax policy, government budgets, telecommunications, technology, defense, disaster and emergency management, crisis management, and government investigations.



TRANSACTION TRANSPARENCY AND COMPLIANCE

HOW IT WORKS





The Posting Page

You may also enter the barcode to enter NDC

NDC Number: **00591-3159-01**

Lot Number: 885145MY

Expiration Date: 05 2016 (MM/YYYY)

Pack Quantity: Full Partial 100 EA

Package Available: 2

Price Option: Fixed Decking

Pack Price: 1,300.00

Unit Price: 3.00

WAC Discount: 41% off of WAC price

AAWP Discount: 59% off of AAWP price

Package Condition: **Posted item is REQUIRED to be in the ORIGINAL PACKAGE.**

- Original/Sealed
- Original/Non-Sealed
- Damaged
- Torn Pharmacy Label
- Other (Description required below)

Description: Additional information required if the Package Condition "Other" is selected or entering multiple conditions.

I confirm this item was not purchased using a government discount program (e 340b) or preferential pricing, and was acquired from an Authorized Trading Partner per the DCCA.

Do you want to pay for ground shipping?

Yes (for orders \$200 or more)

Yes (for items \$50 or more)

No (buyer pays for shipping)

Select a Shipping Method:

Ground **FedEx** 2-Day **FedEx** Priority Overnight **FedEx**

REMEMBER: Place a MRX sticker on each posting. This provides you a reminder to modify or remove a posting if you sell or partially dispense the item through your pharmacy.

POST NEW ITEM

Product Name: **URSODIOL** Similar Items posted: **02**

Strength: 200 MG Storage: Normal

Packaging: BOTTLE (100 EA) Form: CAPS

Marketplace Comparison	Your Price	Minimum	Maximum
Price Per Unit	\$ 3.00	\$ 0.94	\$ 4.82
WAC Discount	41%	0%	10%
AAWP Discount	59%	64%	37%
Expiration Date	05/2016	10/2014	11/2016

Top Wishlist Items

Demand Level	Wishlist Item
High	ABILIFY 10 MG
High	ABILIFY 5 MG
High	ABILIFY 20 MG
High	HEXUM 40 MG
High	ABILIFY 3 MG
High	ABILIFY 15 MG

SEE MORE ITEMS



The MatchRX Marketplace

MatchRX your overstock solution **My Savings... \$4,850.04**

BUY **SELL** **MANAGE** **MESSAGES** **WISHLIST** Quick Search

A-Z Recent Postings Exp. Date Min WAC Discount Brand & Generic My Searches **SEARCH** **CLEAR** **115**

Name	Item Info Seller Rating	Strength Packaging	Exp	% off WAC	Price Unit (ea)	Qty	
WELCHOL 66597-0902-30 SANKYO	★★★★★	3.75 GM BOX (30 EA)	12/2015	25%	\$315.00 \$10.50	1	Add to Cart
VYTORIN 66582-0313-31 MERCK/SCHERING-PLoug ...	★★★★★	MULTI BOTTLE (30 EA)	09/2015	30%	\$135.00 \$4.50	1	Add to Cart
WARFARIN SODIUM 51672-4031-91 TARO	★★★★★	4 MG BOTTLE (100 EA)	07/2016	88%	\$5.00 \$0.05	1	Add to Cart



The MatchRX Marketplace

MatchRX your everstar[®] solution My Savings... \$4,850.04

BUY SELL MANAGE MESSAGES WISHLIST

A-Z Recent Postings Exp. Date Min WAC Discount Brand & Generic My Searches SEARCH CLEAR

Name	Item Info Seller Rating	Strength Packaging	Exp	% off WAC	Price Unit (ea)	Qty	
PRAZOSIN HCL 00093-4069-01 TEVA PHARMACEUTICALS ...		5 MG BOTTLE (100 EA)	12/2014	23%	\$60.00 \$0.60	1	Add to Cart

PRAZOSIN HCL

Generic Name: Prazosin HCl Cap 5 MG NDC: 00093406901
 Strength: 5 MG Lot Number: 30220795A
 Form: CAPS Package Quantity: 100 EA
 Storage: Normal Package Price: 60.00
 Packaging: BOTTLE (100 EA) Unit Price: 0.60
 Package Condition: Original Sealed WAC Discount: 23%
 Labeler/Reg: TEVA PHARMACEUTICALS USA AWP Discount: 30%
 Multi-Source Code: Y Posting Expires: 12/2014
 Repack Code: Shipping Method: Buyer Pays
 Imprint Code: Seller Notes:

Total Price: 60.00 1 [Add to Cart](#)

Buyer Checkout

MatchRX your everstar[®] solution My Savings... \$4,850.04

BUY SELL MANAGE MESSAGES WISHLIST

Current Order Your order contains the following items from this seller

Wishlist	Name	Item Info	Strength Packaging	Exp	% off WAC	Price Unit (ea)	Qty	Total
<input checked="" type="checkbox"/>	CLINDESSE 64011-0124-08 THER RX		2% TUBE (5.8 GM)	12/2014	12%	\$75.00 \$12.93	1	\$75.00
<input checked="" type="checkbox"/>	PRAZOSIN HCL 00093-4069-01 TEVA PHARMACEUTICALS ...		5 MG BOTTLE (100 EA)	12/2014	23%	\$60.00 \$0.60	1	\$60.00
<input checked="" type="checkbox"/>	FELODIPINE ER 53489-0389-01 MUTUAL PHARMACEUTICA ...		5 MG BOTTLE (100 EA)	11/2014	35%	\$70.00 \$0.70	1	\$70.00

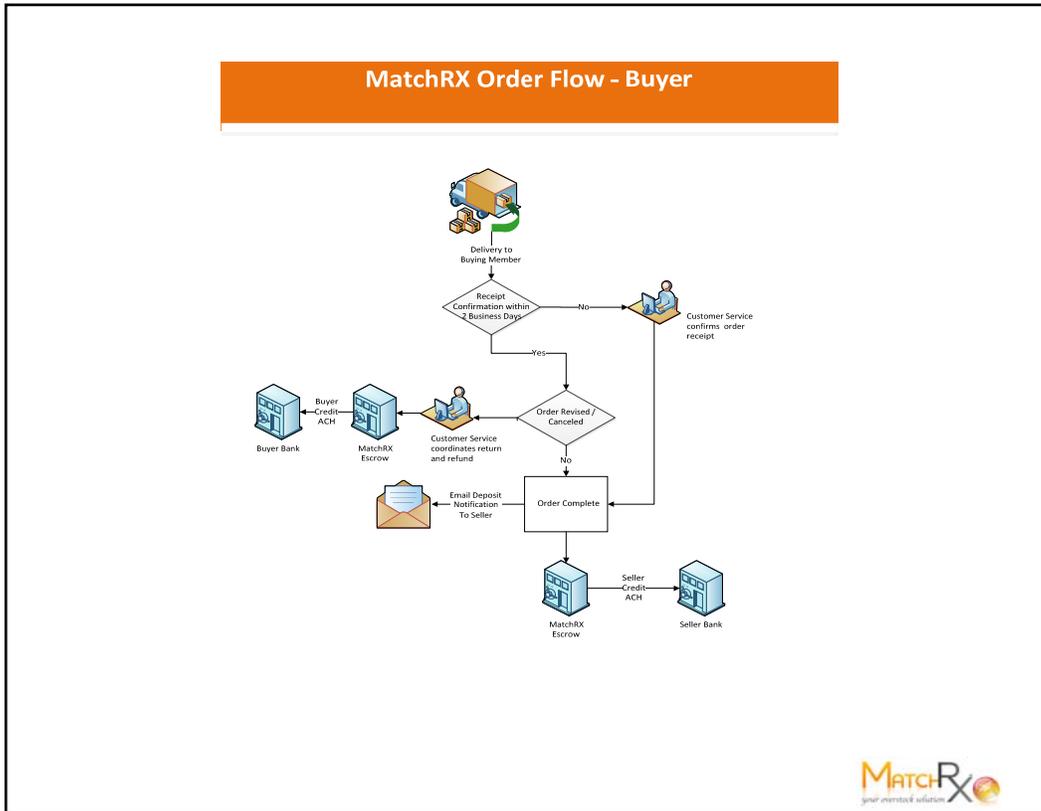
Product Cost: \$205.00

Shipping Method:
 FedEx Ground (\$7.32)
 FedEx 2 Day (\$9.99)
 FedEx Priority Overnight (\$28.90)

Shipping Cost: \$7.32

Product: \$205.00
 Shipping: \$7.32
 Processing: \$0.00
Order Total: \$212.32

[Shop More](#) [Complete Order](#)



Transaction Information

My Savings: \$4,890.04

Transaction Center

Buyer Activity | Selling Activity | My Postings | My Savings | Statements

Pending (0) | Purchase

View Invoice	Order Date	Order ID
8330779	07/17/2014	0
4700090	06/13/2014	0
4050851	06/13/2014	0
9645033	06/11/2014	0
3727230	06/09/2014	0
7833020	06/08/2014	0
7628247	06/06/2014	0
4519421	06/06/2014	0
6317409	06/04/2014	0
3166311	06/04/2014	0

BUYER'S INVOICE

SELLER: ASC Pharmacy
1800 Freedom Rd Ste D
Little Chute, WI 54143

BUYER: icobest Pharmacy
145 Main Street
Kahoa, NY 14790

ORDER # 3002005 ORDER DATE: 09/30/2014

ITEM	NAME	MC	STRENGTH	FORM	EXP	LOT	PACK SIZE	PRICE	QTY	TOTAL
7202466	AMOXIC	250MG/250	25 MG	Tablet	11/2014	1054102	New_Box	\$0.84	295.00	248.00

PRODUCT: \$269.00
 SHIPPING: \$7.32
 PROCESSING: \$0.00
TOTAL DEBIT AMOUNT: \$276.32

BANK ACCOUNT
 Account Debit# XXXXXX1041

Thank you for using MatchRX!
 Questions regarding your order, please contact customer service at customerservice@matchrx.com or call 877-560-2000

ORDER #	DATE	BUYER	SELLER	PRICE	QTY	TOTAL	STATUS
4377875	06/04/2014	06/05/2014	\$605.30	\$0.00	\$10.27	\$615.57	FeiEx Ground 06/06/2014 94257851698884 06/12/2014 06/09/2014
9863046	06/04/2014	06/09/2014	\$89.00	\$0.00	\$10.27	\$99.27	FeiEx Ground 06/09/2014 942578516984051 06/12/2014 06/10/2014
4007843	06/03/2014	06/04/2014	\$535.00	\$0.00	\$10.27	\$545.27	FeiEx Ground 06/05/2014 942578516983890 06/10/2014 06/06/2014
7773827	06/03/2014	06/03/2014	\$833.00	\$0.00	\$0.00	\$833.00	FeiEx Ground 06/04/2014 942578516978244 06/10/2014 06/04/2014

CA Enforcement & Compounding Committee

10

MatchRX Operating in California

Third Party Logistics Provider: Business and Professions Code 4045

Definition: "Third-party logistics provider" means an entity that provides or coordinates warehousing or other logistics services for a dangerous drug or dangerous device in intrastate or interstate commerce on behalf of a manufacturer, wholesaler, or dispenser of the dangerous drug or dangerous device, but does not take ownership of the dangerous drug or dangerous device, nor have responsibility to direct its sale or disposition.

Nonresident Third-Party Logistics Provider Requirements: Business and Professions Code 4161(a)

A person located outside this state that (1) ships, sells, mails, warehouses, distributes, or delivers dangerous drugs or dangerous devices into this state or (2) sells, brokers, warehouses, or distributes dangerous drugs or devices within this state shall be considered a nonresident wholesaler or a nonresident third-party logistics provider.



Questions and Next Steps



Attachment 3

16 CCR 1713

1713 Receipt and Delivery of Prescriptions and Prescription Medications Must be To or From Licensed Pharmacy

(a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.

(b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. In addition, the Board may, in its sole discretion, waive application of subdivision (a) for good cause shown.

(c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address as the licensed pharmacy premises. The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.

(d) A pharmacy may use an automated delivery device to deliver previously dispensed prescription medications provided:

(1) Each patient using the device has chosen to use the device and signed a written consent form demonstrating his or her informed consent to do so.

(2) A pharmacist has determined that each patient using the device meets inclusion criteria for use of the device established by the pharmacy prior to delivery of prescription medication to that patient.

(3) The device has a means to identify each patient and only release that patient's prescription medications.

(4) The pharmacy does not use the device to deliver previously dispensed prescription medications to any patient if a pharmacist determines that such patient requires counseling as set forth in section 1707.2(a)(2).

(5) The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.

(6) The device is located adjacent to the secure pharmacy area.

(7) The device is secure from access and removal by unauthorized individuals.

(8) The pharmacy is responsible for the prescription medications stored in the device.

(9) Any incident involving the device where a complaint, delivery error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.

(10) The pharmacy maintains written policies and procedures pertaining to the device as described in subdivision (e).

(e) Any pharmacy making use of an automated delivery device as permitted by subdivision (d) shall maintain, and on an annual basis review, written policies and procedures providing for:

(1) Maintaining the security of the automated delivery device and the dangerous drugs within the device.

(2) Determining and applying inclusion criteria regarding which medications are appropriate for placement in the device and for which patients, including when consultation is needed.

(3) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including for those delivered via the automated delivery device.

(4) Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filing procedures for the automated delivery device.

(5) Orienting participating patients on use of the automated delivery device, notifying patients when expected prescription medications are not available in the device, and ensuring that patient use of the device does not interfere with delivery of prescription medications.

(6) Ensuring the delivery of medications to patients in the event the device is disabled or malfunctions.

(f) Written policies and procedures shall be maintained at least three years beyond the last use of an automated delivery device.

(g) For the purposes of this section only, "previously-dispensed prescription medications" are those prescription medications that do not trigger a non-discretionary duty to consult under section 1707.2(b)(1), because they have been previously dispensed to the patient by the pharmacy in the same dosage form, strength, and with the same written directions.

Presentation

Study of Expanded Use of an Automated Delivery Device

26 March 2015

Jan D. Hirsch, BPharm, PhD

UCSD Skaggs School of Pharmacy & Pharmaceutical Sciences

Kim Allen, BPharm *Sharp Rees-Stealy Pharmacy*

UC San Diego
HEALTH SCIENCES



Overview

Public Board Meeting – July 31, 2013

Motion: Waive California Code of Regulations Section 1706.5 and allow Asteres to install one automated dispensing machine in Sharp Headquarters for a period of 6 month. As a provision of the waiver Asteres must provide a more substantive research report and Sharps Headquarters must become licensed as a pharmacy subject to waivers of certain conditions (i.e. bathrooms, sinks etc.)

- M/s: Zee/Veale
- Support: 8 Oppose: 1 Abstain: 0

January, 2014

Upon closer examination of the law, the board's staff could not license a kiosk in a corporate office as a pharmacy. New proposal for placement of kiosk in licensed hospital (Sharp Memorial Hospital).

March, 2014 - Sharp IRB Approval

November, 2014 - UCSD IRB Approval

Overview

- ScriptCenter *kiosk* will be placed on ground floor of secured licensed facility [Sharp Memorial Hospital (SMH)]
- Prescriptions will be filled by Sharp Rees-Stealy (SRS) & transported daily to kiosk (0.2 mi. away)
- SMH Employees and dependents volunteer to use Kiosk
- 18 month waiver request
- 6 month active study period



Sharp Memorial Hospital



Sharp Memorial Hospital employee entrance located on ground floor. Secure access only.

Patient Issues

Risks to Kiosk Participants

- May not routinely come to pharmacy for face-to-face interaction
- May be concerned about use of phone consultation and reduce # of questions

Benefits to Kiosk Participants

- Rapid & convenient access to new prescriptions following phone consultation
- Convenient 24/7 access to refill medications
- 24/7 access to a pharmacist

Study to examine benefits vs. risks

UCSD IRB Approval

140464X



UNIVERSITY OF CALIFORNIA, SAN DIEGO HUMAN RESEARCH PROTECTIONS PROGRAM

TO: Dr. Jan Hirsch

RE: Project #140464X
Experimental Program/Research Study on Automated Delivery Systems (Asteres ScriptCenter Kiosk) in a Licensed Facility for Employee Prescriptions

Dear Dr. Hirsch:

The above-referenced project was reviewed and approved by one of this institution's Institutional Review Boards in accordance with the requirements of the Code of Federal Regulations on the Protection of Human Subjects (45 CFR 46 and 21 CFR 50 and 56), including its relevant Subparts. This approval, based on the degree of risk, is for 365 days from the date of **IRB review and approval** unless otherwise stated in this letter. The regulations require that continuing review be conducted on or before the 1-year anniversary date of the IRB approval, even though the research activity may not begin until some time after the IRB has given approval.

It was determined that this project presents no more than minimal risk to human subjects in that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

This study was reviewed through the expedited review procedure as authorized by 45 CFR 46.110 and 21 CFR 56.110 and falls under the following research category: (5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

The waiver of HIPAA and consent for this study are reviewed and provided by Sharp Healthcare IRB.

Date of IRB review and approval: **11/20/2014**

On behalf of the UCSD Institutional Review Boards,

A handwritten signature in black ink that reads "A magit".

/lg

Anthony Magit, M.D.
Director
UCSD Human Research Protections Program
(858) 657-5100; hrpp@ucsd.edu

UC San Diego
SKAGGS SCHOOL OF PHARMACY
AND PHARMACEUTICAL SCIENCES

Sharp IRB Approval



March 27, 2014

Sheila Alignay-Rivera, PharmD

140182
Alignay-Rivera
01/15/2014
8-2



Institutional Review Board
8695 Spectrum Center Blvd
San Diego, CA 92123
P (858) 499-4836 / F (858) 499-3105
<http://sharpnet.irb/> www.sharp.com/research
E-mail: research@sharp.com

January 28, 2015

Sheila Alignay-Rivera, PharmD
Sharp Rees Stealy (SRS) Pharmacy
2929 Medical Center Drive

140182
Alignay-Rivera
02/18/2015
3-20

Good morning, Dr. Alignay-Rivera...

I am pleased to inform you that the above-referenced study may begin at the facility or facilities listed on the attached IRB determination letter.

The IRB approved documents for use during the conduct of this project are also attached:

- The document(s) with "CLEAN" in the file name must be used as your starting point for any future revisions
- The document(s) with "STAMPED" in the file name confirm the exact content approved by the IRB

- Pre-Implementation Recruitment Letter (18Mar2014)
- Pre-Implementation Questionnaire - Sharp Employee Preference Survey (18Mar2014)
- Post-Implementation Questionnaire (18Mar2014)

This action will be reported to all committee members at the January 15, 2014 meeting.

The following site(s) and site personnel are approved:

Sites:
Memorial
Rees-Stealy

Principal Investigator: Sheila Alignay-Rivera, PharmD

Study Coordinator: None

Sub-investigators and Other Site Personnel:

Daniels, Charles PhD Allen, Kim RPh McPherson, Emily BS
Laufer, Debby H. PharmD Morales, Hector, Jr. PharmD Khojah, Najla M. RPh, MSc

Thank you and please feel free to contact me at 858-499-4836, if you have any questions.

Sincerely,

Caryn L. Burgess, CIP
IRB Specialist

UC San Diego
SKAGGS SCHOOL OF PHARMACY
AND PHARMACEUTICAL SCIENCES

Study Intent

Examine prescription retrieval & medication information-seeking behavior

- kiosk vs. regular counter pharmacy patients

Principal Investigator

Jan D. Hirsch, BSP Pharm, PhD

Associate Professor of Clinical Pharmacy

Co-Principal Investigator

Charles Daniels, BSP Pharm, PhD

Professor of Clinical Pharmacy

University of California, San Diego

Skaggs School of Pharmacy and Pharmaceutical Sciences

- Co-Investigators:

Kim Allen BPharm. Sharp Rees-Stealy (SRS) Pharmacy Manager

Sheila Alignay-Rivera, PharmD. SRS Pharmacy

ESA and Medication Safety pharmacist

UC San Diego

SKAGGS SCHOOL OF PHARMACY
AND PHARMACEUTICAL SCIENCES

Study Rationale

- One component of patient adherence behavior is related to their ability to have timely access to medications after prescribing
- Patient access to medications at their place of work will improve their ability to start quickly, and refill regularly
- A dispensing pharmacy at most places of work is not practical
- Use of an automated delivery device may provide more timely access to prescribed medications
- Study is to observe behavior of SMH employees and dependents who have volunteered to use Kiosk
 - No informed consent for the study
 - Study uses only de-identified data from normal operations of SRS
 - Qualifies for waiver of consent (e.g. No PHI, impractical to consent in workflow)

Research Questions

Primary: Is patient *primary adherence* (prescription retrieval rate; all prescriptions) greater for kiosk vs.

- Historical and concurrent regular counter rate?
- Rx retrieval rate based on Return to Stock (RTS) rate per month

RTS rate = # Rxs RTS after 14 days/# Rxs filled

Secondary: Kiosk vs. Regular Counter Patients

- Is number or nature of questions for pharmacists during consultation for new prescriptions different? (*consultation log*)
- What is mean time from fill (RPh verified) to pick up?

Kiosk patients:

- Satisfaction with access to pharmacist for questions & convenience

Sharp Memorial Hospital employees:

- Would kiosk be beneficial and increase primary adherence?

Study Design

Quasi-experimental with non-randomized control group

- Pre-Kiosk Implementation Survey (Sharp Employees)

Kiosk Start

6 months pre-kiosk

Month 1

Month 6

Regular Counter

- RTS rate*

Kiosk

- RTS rate
- Consultation Log
- Time to Pick-up
- Kiosk Patient Satisfaction

Regular Counter

- RTS rate*
- Consultation Log (1 week sample pts w/ new Rxs)
- Time to Pick-up*

RTS = Return to Stock

* For employees and dependents

Pre-Kiosk Implementation Survey

1. Do you pick up your or your family's prescriptions from a Sharp Rees-Stealy pharmacy?
(Yes/No)
2. If no, how do you get your prescriptions? (Mail order/Pick up at another Pharmacy/I don't pick up any prescription medications)
3. I would benefit from being able to pick up prescriptions at Sharp Memorial Hospital. (Strongly Agree, Agree, Neutral, Disagree, Strongly Disagree)
4. If I had easier access to my prescriptions, I would be more likely to pick up my medications.
(Strongly Agree, Agree, Neutral, Disagree, Strongly Disagree)
5. Where is your usual work location? (Check one of 5 locations)

Study Design

Quasi-experimental with
non-randomized control group

- Pre-Kiosk Implementation Survey (Sharp Employees)

Kiosk Start

6 months pre-kiosk

Month 1

Month 6

Regular Counter

- RTS rate*

Kiosk

- RTS rate
- Consultation Log
- Time to Pick-up
- Kiosk Patient Satisfaction

Regular Counter

- RTS rate*
- Consultation Log (1 week sample pts w/ new Rxs)
- Time to Pick-up*

RTS = Return to Stock

* For employees and dependents

Consultation Log

Is number or nature of questions for pharmacists during consultation for new prescriptions different?

Patient has: (write in number) _____ New Rx's _____ Refill _____ Rx's	<u>Introduction</u> (Build a Relationship)	<u>Action</u> (Incorporate Patient's Understanding)	<u>Closing</u> (Safety Net Strategy)
Call day & time: Call duration: Consult: (check one) ___ Counter for regular patient ___ Phone for regular patient ___ Phone for kiosk patient	1. Introduce self Yes or No 2. Explain role of pharmacist Yes or No 3. Confirm patient ID Yes or No 4. Discuss consult purpose: • Structure Yes or No • Desired length Yes or No 5. Has the patient previously talked with a pharmacist about this/these medication(s)? Yes or No	1. What med is for: Yes or No 2. How to take med: Yes or No • Time of day Yes or No • Length of therapy Yes or No • Missed dose Yes or No 3. What to expect: Yes or No • Efficacy Yes or No • DDI Yes or No • S/E Yes or No 4. Invite patient to teach back: Yes or No • Patient understands Yes or No • Questions answered Yes or No 5. Lifestyle and prevention: Yes or No, N/A • Additional information Yes or No, N/A • Referral Yes or No, N/A	1. What to do if patient had difficulties following the plan: Yes or No 2. Future appointment or contact provided: Yes or No 3. Opportunity to ask additional questions: Yes or No PHARMACIST ASK PATIENT Do you have any more questions about your medication(s) I haven't answered yet? (check No/Yes and write in number) _____ No _____ Yes Write in Number of Questions _____ What questions did the patient have?
Pharmacist-Assessment	Ability to <i>build therapeutic relationship</i> with patient: Not Able Partially Able Fully Able 0 1 2 3 4	Ability to <i>establish a management plan</i> with patient: Not Able Partially Able Fully Able 0 1 2 3 4	Ability to <i>negotiate "safety netting" strategies</i> with patient: Not Able Partially Able Fully Able 0 1 2 3 4

Based on Medication-Related consultation Framework (MRCF)
 Tawab AT, et al. Patient Education and Counseling. 2011. 83 (3), 451-7.

Study Design

Quasi-experimental with non-randomized control group

- Pre-Kiosk Implementation Survey (Sharp Employees)

Kiosk Start

6 months pre-kiosk

Month 1

Month 6

Regular Counter

- RTS rate*

Kiosk

- RTS rate
- Consultation Log
- Time to Pick-up
- Kiosk Patient Satisfaction

Regular Counter

- RTS rate*
- Consultation Log (1 week sample pts w/ new Rxs)
- Time to Pick-up*

RTS = Return to Stock

* For employees and dependents

Kiosk Patient Satisfaction

Do you feel your questions were answered regarding the prescriptions you picked up today?
(Yes/No/Not Applicable)

If you have questions for a pharmacist regarding the prescriptions you picked up today, do you know where to call? (Yes/No)

Is the convenience of after-hours prescription pick up an important reason to use this pharmacy?
(Yes/No)

Is the ScriptCenter a main reason for you to use the SRS Pharmacy? (Yes/No)

Sample Size Calculation

- Based on primary outcome – Return to Stock rate
 - Mean = 5.5% (Dec 2012-Nov 2013)
 - Hypothesize for kiosk 2.0%
- Sample size estimate: 820 prescriptions
 - About 140 Rxs/month at kiosk
 - Current Rxs regular counter per 6 months = 18,000
 - 6,000 for employees/dependents
 - Assume 60% Sharp Memorial Hospital
 - 3,600 in 6 months = 600 per month
 - 140 Rxs about 20% current monthly volume to switch to kiosk
 - About 6 months kiosk operation

Projected Timetable

- Q3 2015
Pre-kiosk data collection
Invitation to participate in new program
- Q4 2015
Implement Kiosk device
Refine data collection tools & process
Deployment of program/enroll patients
- Q1 & Q2 2016
Post-kiosk implementation
Data collection and analysis
- Q3 2016
Report Results to Board



Questions?

UC San Diego
SKAGGS SCHOOL OF PHARMACY
AND PHARMACEUTICAL SCIENCES

**UCSD Experimental
Program/Research Study
on Automated Delivery
Systems in a Licensed
Facility or Employee
Prescriptions**



UNIVERSITY OF CALIFORNIA, SAN DIEGO
HUMAN RESEARCH PROTECTIONS PROGRAM

TO: Dr. Jan Hirsch

RE: Project #140464X
Experimental Program/Research Study on Automated Delivery Systems (Asteres
ScriptCenter Kiosk) in a Licensed Facility for Employee Prescriptions

Dear Dr. Hirsch:

The above-referenced project was reviewed and approved by one of this institution's Institutional Review Boards in accordance with the requirements of the Code of Federal Regulations on the Protection of Human Subjects (45 CFR 46 and 21 CFR 50 and 56), including its relevant Subparts. This approval, based on the degree of risk, is for 365 days from the date of **IRB review and approval** unless otherwise stated in this letter. The regulations require that continuing review be conducted on or before the 1-year anniversary date of the IRB approval, even though the research activity may not begin until some time after the IRB has given approval.

It was determined that this project presents no more than minimal risk to human subjects in that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

This study was reviewed through the expedited review procedure as authorized by 45 CFR 46.110 and 21 CFR 56.110 and falls under the following research category: (5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

The waiver of HIPAA and consent for this study are reviewed and provided by Sharp Healthcare IRB.

Date of IRB review and approval: 11/20/2014

On behalf of the UCSD Institutional Review Boards,

/lg

Anthony Magit, M.D.
Director
UCSD Human Research Protections Program
(858) 657-5100; hrpp@ucsd.edu

**UCSD Human Research Protections Program
New Biomedical Application
RESEARCH PLAN**

Instructions for completing the Research Plan are available on the [HRPP website](#).
The headings on this set of instructions correspond to the headings of the Research Plan.
General Instructions: Enter a response for all topic headings.
Enter "Not Applicable" rather than leaving an item blank if the item does not apply to this project.

Version date: 9/30/2013

1. PROJECT TITLE

Experimental Program/Research Study on Automated Delivery Device (Asteres ScriptCenter Kiosk) in a Licensed Facility for Employee Prescriptions

2. PRINCIPAL INVESTIGATOR

Jan D. Hirsch, BSP Pharm, PhD, Skaggs School of Pharmacy and Pharmaceutical Sciences

3. FACILITIES

Sharp Rees-Stealy Pharmacy
Sharp Memorial Hospital, San Diego, CA
UCSD Skaggs School of Pharmacy and Pharmaceutical Sciences

4. ESTIMATED DURATION OF THE STUDY

18 months

5. LAY LANGUAGE SUMMARY OR SYNOPSIS (no more than one paragraph)

Patients, or their agents, who are obtaining prescription medications from a pharmacy typically present themselves at the prescription counter of the filling pharmacy, to pick up their filled prescription. At that point they may ask questions about the prescriptions from the pharmacist who is available on-site. Some variations to this scenario include delivery to home. Most pharmacies have limited hours of operation that may limit the patient or family member from picking-up the prescription at a time that is most convenient for the patient, thus potentially causing delays or failure to pick-up new or refilled prescriptions. The investigators wish to study the impact of an existing technology on patient prescription related activity in a new setting, with 24 hour per day, 7 day per week access to improve access and potential adherence to medication regimen.

6. SPECIFIC AIMS

Examine the impact of a patient-specific, commercially available, automated prescription delivery device (kiosk), on study participant behaviors, when placed in a location with 24 hour per day, 7 day per week access. Investigators will examine subject prescription retrieval behavior, and medication information-seeking activities in this setting. This will be compared to those behaviors in a traditional regular counter pharmacy pick-up setting.

The questions to be studied are:

Primary:

Is patient prescription retrieval rate greater with 24/7 access through the automated prescription delivery device (kiosk) as compared to the historical and concurrent regular pharmacy counter rate?

Secondary:

Do employees of Sharp Memorial Hospital (SMH) believe ability to pick up prescriptions at work would be beneficial and increase their adherence to medications?

Are patients who use the automated prescription delivery kiosk satisfied with their access to a pharmacist for questions and the convenience of the kiosk?

What is the mean time from prescription fill, to patient pick-up at the automated prescription delivery kiosk as

compared to the same time interval for prescriptions at the regular pharmacy counter?

Is the number or nature of questions for the pharmacist during consultation for new prescriptions different for prescriptions obtained in an on-worksites automated prescription delivery kiosk vs. the regular pharmacy counter?

7. BACKGROUND AND SIGNIFICANCE

In the past ten years, pharmacies have incorporated automation technology to support improvements of safety and accountability¹. Automation includes barcoding for filling, restocking, returns and dispensing in order to improve efficiency, safety and accuracy². In 2005 and 2006, the California State Board of Pharmacy granted a waiver to allow the use of automated delivery systems in pharmacies to deliver refill medications even after the pharmacy has closed³. This was followed by changes in regulations to allow this on a long-term basis when placed in the pharmacy but outside of the locked prescription area.³ This allowed somewhat expanded prescription access hours within the commercial establishment. In addition, states such as Arizona⁵ and Illinois⁶ have adopted their own regulations to allow for the delivery of not only previously dispensed prescriptions but also new prescriptions after appropriate counseling has taken place and the placement of these devices away from the pharmacy.

Research indicates that low or non-adherence to medication therapy is a major healthcare cost and quality problem. Low medication adherence has clinical and economical outcomes⁷. The cost of non-adherence to the U.S healthcare system is estimated at \$100-\$300 billion annually⁸. One potential impact of prescription process automation is improved medication adherence behaviors.

Study Logic:

- One component of patient adherence behavior is related to their ability to have timely access to medications after prescribing.
- Patient access to medications at their place of work may improve their ability to start their new medications quickly and refill them regularly.
- A full scale dispensing pharmacy at most places of work is not practical.
- Use of an automated prescription delivery kiosk may provide more timely access to prescribed medications.

The intent of this study is to expand knowledge of the potential of the automated prescription delivery kiosk technology in a more accessible setting to improve patient behaviors through increased convenience, without reducing access to pharmacists for important consultation.

8. PROGRESS REPORT

Not applicable

9. RESEARCH DESIGN AND METHODS

The study will use a quasi-experimental research design (Campbell & Stanley) using a non-randomized control group. Subjects will be Sharp Memorial Hospital employees and their dependents who have volunteered to utilize an automated prescription pick-up kiosk (not randomized assignment) vs. those who chose to continue to use the standard in-pharmacy pick-up process.

UCSD researchers will be involved in design of the study, analysis of the data, development of the research report for presentation or publication.

The study period for the kiosk (ScriptCenter) stationed at Sharp Memorial Hospital (SMH) will be six months. The kiosk will be delivering both new and refilled medications to patients at all hours of the day according to SMH and Sharp Rees-Stealy (SRS) operating policy and procedures. As background information (not part of the study); new prescriptions in the kiosk require mandatory consultation with the pharmacist, and pharmacists will use their professional judgment to determine whether a refilled prescription will require consultation. All consultations for new prescriptions will take place during pharmacy business hours. For additional questions, a pharmacy service phone number will be noted on the kiosk; the call will be answered by the Sharp Rees-Stealy (SRS) Pharmacy during business hours and an on-call pharmacist after hours.

The following measures will be used:

1. A pre-kiosk implementation survey (via blast email to all SMH employees with link to Survey Monkey) will assess the needs of the employees. This 5-question survey will be conducted as part of the normal operating procedures of SMH on a completely voluntary basis. No employee identifiers will be collected. The 5 questions are:

1. Do you pick up your or your family's prescriptions from a Sharp Rees-Stealy pharmacy? (Yes/No)
2. If no, how do you get your prescriptions? (Mail order/Pick up at another Pharmacy/I don't pick up any prescription medications)
3. I would benefit from being able to pick up prescriptions at Sharp Memorial Hospital. (Strongly Agree, Agree, Neutral, Disagree, Strongly Disagree)
4. If I had easier access to my prescriptions, I would be more likely to pick up my medications. (Strongly Agree, Agree, Neutral, Disagree, Strongly Disagree)
5. Where is your usual work location? (Check one of 5 locations)

2. A post-kiosk implementation survey will assess kiosk patient satisfaction. The 4-question survey will be part of the normal operating procedures of the ScriptCenter at the completion of a kiosk session. Participation is voluntary. No patient identifiers will be collected with these questions. The 4 questions are:

Do you feel your questions were answered regarding the prescriptions you picked up today? (Yes/No/Not Applicable)

If you have questions for a pharmacist regarding the prescriptions you picked up today, do you know where to call? (Yes/No)

Is the convenience of after-hours prescription pick up an important reason to use this pharmacy? (Yes/No)

Is the ScriptCenter a main reason for you to use the SRS Pharmacy? (Yes/No)

3. A proxy for primary adherence (i.e. patient does fill prescription) will be prescription return to stock rate in pre-kiosk period, and in the post-kiosk period for kiosk prescriptions and regular counter pick-up prescriptions. This is a summary measure, based on new and refill prescriptions, that is calculated as part of SRS pharmacy normal operating procedures. No patient identifiers will be recorded.

The pre-kiosk return to stock rate will be calculated on a monthly basis over the 6 months prior to

kiosk opening as monthly # Rxs returned to stock after 14 days/# Rxs filled over month period.

The post-kiosk return to stock rates will be calculated for:

- Kiosk prescriptions over 6 months of kiosk operation, on a monthly basis, as # Rxs returned to stock after 14 days/# Rxs filled over month period.
 - Regular counter prescriptions over the same time period as the post-kiosk return to stock rate. Calculated on a monthly basis, as # Rxs returned to stock after 14 days/# Rxs filled over month period.
4. Time from prescription fill, to patient pick-up at the kiosk as compared to time from prescription fill to patient pick-up at regular pharmacy counter. This is a summary measure, including new and refill prescriptions, that is calculated as part of SRS pharmacy normal operating procedures. No patient identifiers will be recorded.
 - prescription fill defined as time when pharmacist verifies the prescription
 - this statistic will be calculated monthly only for employees or dependents at the regular counter (these patients already have a flag in the pharmacy dispensing system that is used to allow them to receive discounts)
 - the statistic will also be calculated monthly for all patients using the kiosk (who must by default be employees or dependents)
 5. A pharmacist consultation log will be used by the pharmacist to document timing and nature of patient consultation sessions for new prescriptions. (Log is attached at end of research plan) No patient identifiers will be recorded on this form.

The pharmacist consultation log will be completed by the pharmacist for each patient at the kiosk with a new prescription. While prescription counseling for new prescriptions is part of the normal operating procedures of SRS pharmacy (and required by law), documentation of the counseling sessions is not as detailed as needed for this study. Therefore a sampling plan to collect the pharmacist log information will be used for patients receiving new prescriptions at the regular pharmacy counter.

The average kiosk volume is estimated to be approximately 35 prescriptions per week (see Human Subjects sample size calculation); with about 40% being new prescriptions that require counseling (i.e. not continuing medications with new prescription number; with no change in directions etc.; based on current regular counter proportion of new vs refill). Thus the number of pharmacist consultations for new prescription at the kiosk is estimated to be about 14 per week (allowing for patients to have multiple new prescriptions but only one pharmacist consultation session). Thus, over the 6-month study period there will be approximately 336 (56/month x 6 months) pharmacist consultation sessions for new kiosk prescriptions.

A sampling plan will be used to capture an equal number of pharmacist counseling sessions for patients with new prescriptions at the pharmacy regular counter. The current weekly volume at the regular pharmacy counter is about 471 new prescriptions (1,884 new Rxs per month) pharmacy operates 5 days per week). The pharmacist will use the log to document each counseling session for a patient with a new prescription during a one-week period at the mid-point of the study. Although this is expected to exceed the needed sample size (see below), collecting data for an entire week for all new prescription counseling sessions will reduce bias that may occur if specific times or day or days were selected.

A total of 412 counseling sessions in each group will allow 90% power, alpha 0.05 to detect a 10 point difference in percentage of patients responding “no” to the question “Do you have any more questions about your medication(s) I haven’t answered yet? At the end of the counseling session (assuming 80% vs. 70%).

A pretest of the proposed log will be conducted prior to implementation. Any changes will be sent to the IRB for final approval.

10. HUMAN SUBJECTS

Employees or dependents of Sharp Healthcare who have prescriptions filled at Sharp Rees-Stealy (SRS) Pharmacy for themselves or family members during the study period using either the regular pharmacy counter or the automated prescription delivery kiosk (ScriptCenter). We expect the participant mix will be similar to the Sharp Healthcare workforce with regard to age, gender, health status, and ethnic background. With the exception of age > 18 years old, which is standard operating procedure at SRS Pharmacy, there are no restrictions on which employees or dependents can utilize either prescription pick-up method.

A total of 820 kiosk prescription release events is the estimated sample size needed for the comparison of return to stock rates (primary objective) over 6 months for the kiosk vs. regular counter: 0.9 power, alpha of 0.05 based upon baseline return to stock rate of 5% at SRS Pharmacy regular counter and a hypothesize rate of 2% at the kiosk. This target will require an average of approximately 35 prescriptions per week (140/month) at the kiosk which is reasonable to expect given current pharmacy prescription volume. During the 6 month period from 4/01/14-9/30/14, 18,000 prescriptions were dispensed at the regular pharmacy counter; 6004 of these prescriptions were for Sharp employees (employees with discount attached to their profile; but not all of these are Sharp Memorial Hospital employees; may not include dependents if employees did not add the discount plan tagged to their prescription). Assuming about 60% of these prescriptions were for Sharp Memorial Hospital employees (the target population for the kiosk) equates to 600 per month (3600/6mos). The 140/month kiosk volume would be slightly more than 20% of current volume moved to the kiosk. This estimate does not include expected increased prescription volume in the kiosk due to its convenience for employees.

11. RECRUITMENT AND PROCEDURES PREPARATORY TO RESEARCH

There will be no recruitment for this study. Study subjects will have already chosen to use either the regular pharmacy counter or the automated kiosk based on Sharp Healthcare marketing communications. This study will use retrospective de-identified data from the normal operations of the Sharp Rees-Stealy (SRS) Pharmacy.

12. INFORMED CONSENT

A waiver of informed consent is being requested. The investigators believe that this study meets the requirements for a waiver:

- a) The use or disclosure of Protected Health Information (PHI) involves no more than minimal risk.
 - There will be no identifiable data (PHI or other) provided to researchers
- b) Granting of waiver will not adversely affect privacy rights and welfare of the individuals whose records will be used.
 - There will be no effect on patients using regular counter or kiosk prescription dispensing process. There will be no identifiable data (PHI or other) provided to researchers.
- c) The project could not practicably be conducted without a waiver.
 - Due to the patient workflow in the dispensing pharmacy, it is not practical to conduct a consent process for all patients using the regular counter nor the kiosk without major inconvenience to patients and disruption of the patient care process
- d) The project could not practicably be conducted without use of PHI.
 - This research study does not involve PHI or any other person-identifiable data..

- There will be no identifiable data (PHI or other) provided to researchers.
- e) The privacy risks are reasonable relative to the anticipated benefits of research.
 - The expected knowledge to be gained from this study outweighs the very low risk posed to patients using either prescription pick-up method since there will be no identifiable data (PHI or other) provided to researchers.
- f) There is an adequate plan to protect identifiers from improper use and disclosure.
 - There will be no identifiable data (PHI or other) provided to researchers.
 Data will be kept on a password protected database and individuals responding to any of the surveys will be coded with a study identification number with no linkage to any patient identifiers (PHI or other). All research staff will have completed the human research training module and HIPAA module that covers improper use and disclosure of data.
- g) There is an adequate plan to destroy the identifiers at the earliest opportunity.
 - There will be no identifiable data (PHI or other) provided to researchers.
- h) PHI will not be re-used or disclosed for other purposes.
 - There will be no identifiable data (PHI or other) provided to researchers.

13. ALTERNATIVES TO STUDY PARTICIPATION

There will be no recruitment for this study. Study subjects will have already chosen to use either the regular pharmacy counter or the automated kiosk based on Sharp Healthcare marketing communications. This study will use retrospective de-identified data from the normal operations of the Sharp Rees-Stealy (SRS) Pharmacy.

14. POTENTIAL RISKS

There is minimal risk to patients for which retrospective, de-identified data from their use of the either prescription pick-up method will be used for this study.

- There will be no effect on patients using regular counter or kiosk prescription dispensing process.
- There is a very low risk posed to patients using either prescription pick-up method since there will be no identifiable data (PHI or other) provided to researchers

15. RISK MANAGEMENT PROCEDURES AND ADEQUACY OF RESOURCES

This study will use retrospective de-identified data from the normal operations of the Sharp Rees-Stealy (SRS) Pharmacy. There will be no identifiable data (PHI or other) provided to researchers.

Data will be kept on a password protected database, on password protected computers, and individuals responding to any of the surveys will be coded with a study identification number with no linkage to any patient identifiers (PHI or other). Any hardcopy questionnaires will be kept in a locked file cabinet within the office of the Principal Investigator. All research staff will have completed the human research training module and HIPAA module that covers improper use and disclosure of data.

16. PRIVACY AND CONFIDENTIALITY CONSIDERATIONS INCLUDING DATA ACCESS AND MANAGEMENT

This study will use retrospective de-identified data from the normal operations of the Sharp Rees-Stealy (SRS) Pharmacy. There will be no identifiable data (PHI or other) provided to researchers.

Data will be kept on a password protected database, on password protected computers, and individuals responding to any of the surveys will be coded with a study identification number with no linkage to any patient identifiers (PHI or other). Only the Principal Investigator or her designee will have access to the study data for analyses.

All research staff will have completed the human research training module and HIPAA module that covers improper use and disclosure of data.

17. POTENTIAL BENEFITS

This study is expected to provide actionable results that will better enable pharmacists in other settings to decide on the best use of automated prescription delivery systems. Patients using the automated kiosk or the regular pick-up counter will not derive direct benefits from this study. However they may benefit indirectly from future automated prescription delivery interventions developed or implemented in the Sharp Memorial Hospital system based on results of this study.

18. RISK/BENEFIT RATIO

There is a very low risk posed to patients using either prescription pick-up method since there will be no identifiable data (PHI or other) provided to researchers. The expected knowledge to be gained, and possible changes to pharmacy practice, from this study outweighs the very low risk posed to patients using either prescription pick-up method since there will be no identifiable data (PHI or other) provided to researchers

19. EXPENSE TO PARTICIPANT

Study subjects will not incur any added expense.

20. COMPENSATION FOR PARTICIPATION

No compensation will be provided to participants.

21. PRIVILEGES/CERTIFICATIONS/LICENSES AND RESEARCH TEAM RESPONSIBILITIES

- PI Dr. Hirsch is a Ph.D. on faculty at the School of Pharmacy and Pharmaceutical Sciences (SPPS) who will perform all study operational and oversight activities including directly overseeing the research project, including data collection, storage, analysis, and conclusions, protection of data, and management of the UCSD student working as research assistants on the project;
- Co-PI Charles E. Daniels, Ph.D. will serve as the co-PI and as such be involved with study design, interpretation of results and reporting.
- Co-investigator Kim Allen, Pharmacist, Manager of Sharp Rees-Stealy Pharmacy will serve as study liaison to Sharp Rees-Stealy staff;
- Co-investigator Sheila Alignay-Rivera, Pharm.D., Sharp Rees-Stealy Pharmacy will supervise data collection on site at SRS Pharmacy;
- Casee Barnes, PharmD Candidate 2016, will participate in study design, data analysis and reporting.

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23. FUNDING SUPPORT FOR THIS STUDY
Supported by SSPPS Start Up Funds
24. BIOLOGICAL MATERIALS TRANSFER AGREEMENT
Not applicable
25. INVESTIGATIONAL DRUG FACT SHEET AND IND/IDE HOLDER
Not applicable
26. IMPACT ON STAFF
None
27. CONFLICT OF INTEREST
None of the investigators have financial interest in the automated dispensing kiosk or other known related organizations. There are no known conflicts of interest.
28. SUPPLEMENTAL INSTRUCTIONS FOR CANCER-RELATED STUDIES
Not applicable
29. OTHER APPROVALS/REGULATED MATERIALS
Not applicable
30. PROCEDURES FOR SURROGATE CONSENT AND/OR DECISIONAL CAPACITY ASSESSMENT
Not applicable

Version date: May 11, 2011

Patient has: (write in number) _____ New Rxs _____ Refill Rxs	<u>Introduction</u> (Build a Relationship)	<u>Action</u> (Incorporate Patient's Understanding)	<u>Closing</u> (Safety Net Strategy)
Call day & time:	1. Introduce self Yes or No 2. Explain role of pharmacist Yes or No 3. Confirm patient ID Yes or No 4. Discuss consult purpose: Yes or No • Structure Yes or No • Desired length Yes or No 5. Has the patient previously talked with a pharmacist about this/these medication(s)? Yes or No	1. What med is for: Yes or No 2. How to take med: Yes or No • Time of day Yes or No • Length of therapy Yes or No • Missed dose Yes or No 3. What to expect: Yes or No • Efficacy Yes or No • DDI Yes or No • S/E Yes or No 4. Invite patient to teach back: Yes or No • Patient understands Yes or No • Questions answered Yes or No 5. Lifestyle and prevention: Yes or No, N/A • Additional information Yes or No, N/A • Referral Yes or No, N/A	1. What to do if patient had difficulties following the plan: Yes or No 2. Future appointment or contact provided: Yes or No 3. Opportunity to ask additional questions: Yes or No PHARMACIST ASK PATIENT Do you have any more questions about your medication(s) I haven't answered yet? (check No/Yes and write in number) _____ No _____ Yes Write in Number of Questions _____ What questions did the patient have?
Call duration:			
Consult: (check one) _____ Counter for regular patient _____ Phone for regular patient _____ Phone for kiosk patient			
Consult Initiated by: (circle one) Pharmacist Patient	6. Invite patient to discuss: Yes or No • Medication concerns Yes or No • Health related concerns Yes or No		
Pharmacist-Assessment	Ability to <i>build therapeutic relationship</i> with patient: Not Able Partially Able Fully Able 0 1 2 3 4	Ability to <i>establish a management plan</i> with patient: Not Able Partially Able Fully Able 0 1 2 3 4	Ability to <i>negotiate "safety netting" strategies</i> with patient: Not Able Partially Able Fully Able 0 1 2 3 4
Comments			

Patient has: (write in number) _____ New Rxs _____ Refill Rxs	<u>Introduction</u> (Build a Relationship)	<u>Action</u> (Incorporate Patient's Understanding)	<u>Closing</u> (Safety Net Strategy)
Call day & time:	1. Introduce self Yes or No 2. Explain role of pharmacist Yes or No 3. Confirm patient ID Yes or No 4. Discuss consult purpose: Yes or No • Structure Yes or No • Desired length Yes or No 5. Has the patient previously talked with a pharmacist about this/these medication(s)? Yes or No	1. What med is for: Yes or No 2. How to take med: Yes or No • Time of day Yes or No • Length of therapy Yes or No • Missed dose Yes or No 3. What to expect: Yes or No • Efficacy Yes or No • DDI Yes or No • S/E Yes or No 4. Invite patient to teach back: Yes or No • Patient understands Yes or No • Questions answered Yes or No 5. Lifestyle and prevention: Yes or No, N/A • Additional information Yes or No, N/A • Referral Yes or No, N/A	1. What to do if patient had difficulties following the plan: Yes or No 2. Future appointment or contact provided: Yes or No 3. Opportunity to ask additional questions: Yes or No PHARMACIST ASK PATIENT Do you have any more questions about your medication(s) I haven't answered yet? (check No/Yes and write in number) _____ No _____ Yes Write in Number of Questions _____ What questions did the patient have?
Call duration:			
Consult: (circle one) Counter Phone			
Initiated by: (circle one) Pharmacist Patient	6. Invite patient to discuss: Yes or No • Medication concerns Yes or No • Health related concerns Yes or No		
Rx Pickup: (circle one) Counter Kiosk			
Pharmacist-Assessment	Ability to <i>build therapeutic relationship</i> with patient: Not Able Partially Able Fully Able	Ability to <i>establish a management plan</i> with patient: Not Able Partially Able Fully Able	Ability to <i>negotiate "safety netting" strategies</i> with patient: Not Able Partially Able Fully Able

	0	1	2	3	4	0	1	2	3	4	0	1	2	3	4
Comments															

Attachment 4



Philadelphia Division

Home • Philadelphia • Press Releases • 2014 • Government Contractor, Its Owner, and Two Employees Charged in Multi-Million-Dollar Fraud Scheme

Government Contractor, Its Owner, and Two Employees Charged in Multi-Million-Dollar Fraud Scheme

U.S. Attorney's Office
October 29, 2014

Eastern District of Pennsylvania
(215) 861-8200

PHILADELPHIA—Devos Ltd., doing business as Guaranteed Returns (“Guaranteed Returns”), in Holbrook, NY, its Chief Executive Officer, Dean Volkes, and two others were charged by indictment, unsealed today, in a multi-million dollar scheme to defraud customers, including the government. Volkes, 51, of Port Jefferson, NY, Donna Fallon, 50, of Miller Place, NY, and Ronald Carlino, 66, of Deer Park, NY, are all charged in a conspiracy to obstruct justice and were arrested this morning, announced United States Attorney Zane David Memeger.

The indictment alleges that more than \$116 million worth of drug products had been returned for refund and more than \$14 million of those drugs belonged to federal government agencies, including the Department of Defense and the Veterans Administration. Other victims include numerous hospitals, pharmacies, and long-term care facilities.

Fallon serves as Chief Financial Officer for Guaranteed Returns and Carlino is an Information Technology employee. All four defendants are charged with conspiring to obstruct justice by concealing and destroying records involved in a Defense Department investigation, six counts of obstruction of justice, and three counts of lying to federal agents about those records. Volkes, Guaranteed Returns, and Fallon are also charged with money laundering conspiracy. Volkes and Guaranteed Returns are charged in 18 counts of wire fraud, 14 counts of mail fraud and one count of conversion of government property.

According to the indictment, Guaranteed Returns was in the business of managing the returns of pharmaceutical products for healthcare providers, including the Department of Defense (DoD) and the Veterans Administration. Manufacturers of pharmaceutical products frequently allow expired drugs to be returned for a refund. Guaranteed Returns handled this process for healthcare provider clients in exchange for a fee based on a percentage of the return value.

The indictment charges that Guaranteed Returns promised its clients that it would hold the clients’ “indate” (not yet expired) drug products until they expired, and then return them on the clients’ behalf, in exchange for a fee. Instead, according to the indictment, Guaranteed Returns, at the direction of CEO Dean Volkes, stole a significant portion of the “indate” drug products that it received from its clients; returned the drugs to the manufacturers; and kept the resulting refund money for itself and Dean Volkes.

The indictment further alleges that during the course of the scheme, a federal grand jury sitting in this district began investigating the diversion of funds under a contract with the DoD. During that investigation, an agent from the Defense Criminal Investigative Service met with Dean Volkes and served him with a grand jury subpoena requiring Guaranteed Returns to turn over records related to the DoD contract. Volkes and other Guaranteed Returns employees stated that they would comply with the subpoena. Instead, it is charged that with the help of Donna Fallon and Ronald Carlino, they destroyed some records and concealed others, and then lied to the investigating agents about why the records were not produced.

“The defendants in this case found a way to defraud the government, hospitals, pharmacies, and long-term care facilities by exploiting the system for returning expired drugs to pharmaceutical companies,” said Memeger. “My office will continue to aggressively prosecute and seek to recover illegal proceeds from those who use our precious health care dollars to enrich themselves at the expense of everyone else.”

“Fraud against the government amounts to stealing from American taxpayers, in service of pure greed,” said FBI Special Agent-in-Charge Edward J. Hanko said. “The FBI takes that very seriously, and we’re committed to tracking and shutting down financial fraud schemes.”

If convicted of all charges, defendant Guaranteed Returns faces a possible fine of over \$200 million along with a \$4,400 special assessment; Volkes faces a maximum possible statutory sentence of 810 years in prison, a fine of over \$200 million, three years of supervised release, and a \$4,400 special assessment; Fallon faces a maximum possible statutory sentence of 160 years in prison, a fine of over \$200 million, three years of supervised release, and a \$1,100 special assessment; and Carlino faces a maximum possible statutory sentence of 140 years in prison, a \$2.5 million fine, three years of supervised release, and a \$1,000 special assessment.

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This case was investigated by the Defense Criminal Investigative Service and the Federal Bureau of Investigation. It is being prosecuted by Assistant United States Attorneys Nancy Rue and Paul Shapiro.

An indictment is an accusation. A defendant is presumed innocent unless and until proven guilty.

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U.S. NEWS

U.S. to Allow Pharmacies to Take Back Unused Prescription Drugs

New Regulation Will Allow People to Mail Back Unused Pills

By DEVLIN BARRETT

Updated Sept. 8, 2014 7:42 p.m. ET

The government will now allow pharmacies and clinics to accept unused prescription medicine as a way to stop them from ending up on the street. WSJ's Devlin Barrett discusses on the News Hub with Sara Murray. Photo: AP

Federal authorities will soon allow pharmacies and clinics to take back customers' unused prescription drugs such as opioid painkillers in an effort to get addictive medications off the street.

The change, to be issued in new Drug Enforcement Administration regulations effective next month, will address a long-standing complaint from people fighting opioid addiction that government rules make it difficult to safely dispose of unused pills.

Under current rules for controlled substances, even a pharmacy that fills a painkiller prescription can't take back unused pills. Instead, consumers can flush unused drugs or throw them out in the trash, though both those options are discouraged because of environmental worries. They can also hand in unused pills to law-enforcement agencies that participate in special drug-take-back programs.

While pharmacies haven't generally wanted the hassle of being responsible for old pills, some are expected to heed the government's call, in part to show they are making a good-faith effort to keep drugs out of the wrong hands.

WSJ Radio

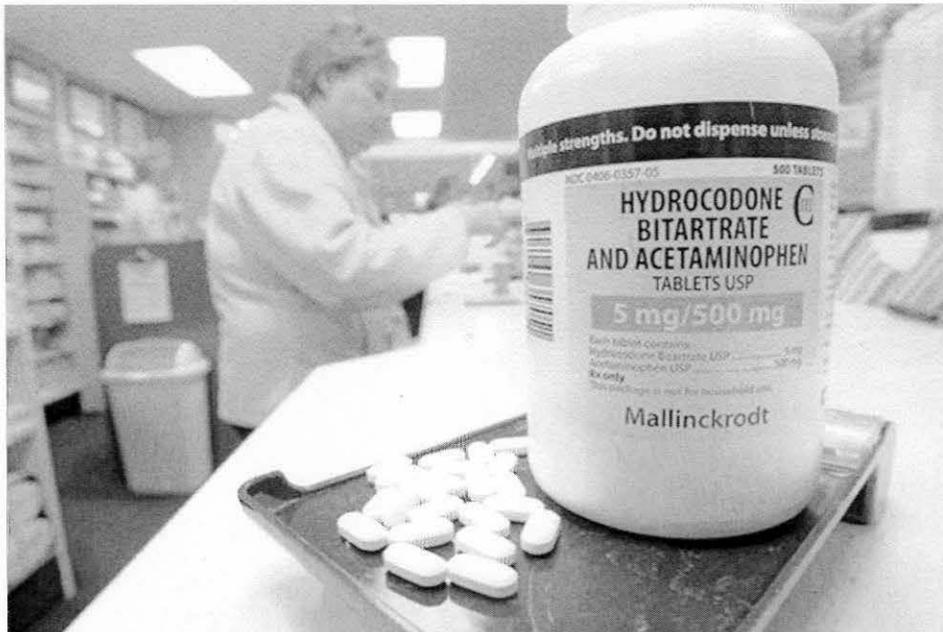
Devlin Barrett and WSJ This Morning's
Gordon Deal discuss this pill return program

00:00 |
06:15

Attorney General [Eric Holder](#) announced the new rule in a [video posted](#) on the Justice Department's website, noting that close to four in 10 teens who misused prescription drugs obtained them from family medicine cabinets. "These shocking statistics illustrate that prescription drug addiction and abuse represent nothing less than a public health crisis," he said in the video message. "Every day, this crisis

touches—and devastates—the lives of Americans from every state, in every region, and from every background and walk of life."

The new rule, which covers all prescription drugs, will also allow people to mail unused pills for collection. It wasn't immediately clear how many businesses would offer the service to its customers. Any pills collected will be destroyed.



Hydrocodone pills, also known as Vicodin, are arranged for a photo at a pharmacy in Montpelier, Vt. on Tuesday, Feb. 19, 2013. *ASSOCIATED PRESS*

The DEA runs its own pill-take-back events. A nationwide effort in April brought in 390 tons of prescription drugs at more than 6,000 sites, according to the Justice Department.

CVS Health Corp. is considering the new regulations, a spokeswoman said, noting the company already participates in drug take-back programs involving local police departments and the DEA. The chain also offers customers postage-paid envelopes to mail back unused pills.

A Walgreen Co. spokesman said the company's pharmacies offer a product that renders pills unusable and safe to toss in the trash, as well as envelopes to mail them to a disposal facility. "We are studying the DEA's new regulatory requirements and considering the options they present to us," he said.

In 2011, more than half of the 41,300 unintentional overdose deaths in the U.S. involved prescription drugs, and opioids—a group of painkillers that include oxycodone and hydrocodone—were involved in nearly 17,000 of those, according to the Justice Department.

Laurey Collins Burris of Shelburne, Vt., who lost her 25-year-old son to an overdose, called the government move "an amazing step forward in getting these drugs off the streets."

Painkiller addiction has led some addicts to seek cheaper highs from heroin, and that is what killed Ms. Burris' son Zachary last October. Getting pills out of homes will make it harder for teenagers and adults to start down that road, she said.

Avi Israel, a Buffalo, N.Y., man whose son killed himself after a battle with prescription drug addiction, said he was skeptical of the rule change, and feared it will invite new forms of abuse.

"Taking the pills back to pharmacies, I think that will open a Pandora's box. It's going to create problems where there's temptation there, there's money to be made," said Mr. Israel, who has advocated instead for every police station to have a drop-off box for prescription drugs.

Write to Devlin Barrett at devlin.barrett@wsj.com

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Rule Text

List of Subjects

21 CFR Part 1300

Chemicals, Drug traffic control.

21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Security measures.

21 CFR Part 1304

Drug traffic control, Reporting and recordkeeping requirements.

21 CFR Part 1305

Drug traffic control.

21 CFR Part 1307

Drug traffic control.

21 CFR Part 1317

Drug traffic control, Security measures.

For the reasons stated in the preamble, the DEA amends 21 CFR chapter II as follows:

PART 1300—DEFINITIONS

1-2. The authority citation for part 1300 is revised to read as follows:

Authority: 21 U.S.C. 802, 821, 822, 829, 871(b), 951, 958(f).

3. In § 1300.01, amend paragraph (b) as follows:

- a. Revise the introductory text;
- b. Add a definition of “Collection” in alphabetical order;
- c. Revise the last sentence in the definition of “Freight forwarding facility”;
- d. Add a definition of “Reverse distribute” in alphabetical order; and

e. Revise the definition of “Reverse distributor”.

The revisions and additions read as follows:

§ 1300.01 Definitions relating to controlled substances.

* * * * *

(b) As used in parts 1301 through 1308, 1312, and 1317 of this chapter, the following terms shall have the meanings specified:

* * * * *

Collection means to receive a controlled substance for the purpose of destruction from an ultimate user, a person lawfully entitled to dispose of an ultimate user decedent’s property, or a long-term care facility on behalf of an ultimate user who resides or has resided at that facility. The term *collector* means a registered manufacturer, distributor, reverse distributor, narcotic treatment program, hospital/clinic with an on-site pharmacy, or retail pharmacy that is authorized under this chapter to so receive a controlled substance for the purpose of destruction.

* * * * *

Freight forwarding facility * * * For purposes of this definition, a distributing registrant is a person who is registered with the Administration as a manufacturer, distributor (excluding reverse distributor), and/or importer.

* * * * *

Reverse distribute means to acquire controlled substances from another registrant or law enforcement for the purpose of:

- (1) Return to the registered manufacturer or another registrant authorized by the manufacturer to accept returns on the manufacturer’s behalf; or
- (2) Destruction.

Reverse distributor is a person registered with the Administration as a reverse distributor.

* * * * *

4. Add § 1300.05 to read as follows:

§ 1300.05 Definitions relating to the disposal of controlled substances.

(a) Any term not defined in this part or elsewhere in this chapter shall have the definition set forth in section 102 of the Act (21 U.S.C. 802).

(b) As used in part 1317 of this chapter, the following terms shall have the meanings specified:

Employee means an employee as defined under the general common law of agency.

Some of the factors relevant to the determination of employee status include: the hiring party's right to control the manner and means by which the product is accomplished; the skill required; the source of the instrumentalities and tools; the location of the work; the duration of the relationship between the parties; whether the hiring party has the right to assign additional projects to the hired party; the extent of the hired party's discretion over when and how long to work; the method of payment; the hired party's role in hiring and paying assistants; whether the work is part of the regular business of the hiring party; whether the hiring party is in business; the provision of employee benefits; and the tax treatment of the hired party. Other applicable factors may be considered and no one factor is dispositive. The following criteria will determine whether a person is an *employee* of a registrant for the purpose of disposal: the person is directly paid by the registrant; subject to direct oversight by the registrant; required, as a condition of employment, to follow the registrant's procedures and guidelines pertaining to the handling of controlled substances; subject to receive a performance rating or performance evaluation on a regular/routine basis from the registrant; subject to disciplinary action by the registrant; and

required to render services at the registrant's registered location.

Law enforcement officer means a person who is described in paragraph (1), (2) or (3) of this definition:

(1) Meets all of the following criteria:

(i) Employee of either a law enforcement agency, or law enforcement component of a Federal agency;

(ii) Is under the direction and control of a Federal, State, tribal, or local government;

(iii) Acting in the course of his/her official duty; and

(iv) Duly sworn and given the authority by a Federal, State, tribal, or local government to carry firearms, execute and serve warrants, make arrests without warrant, and make seizures of property;

(2) Is a Veterans Health Administration (VHA) police officer authorized by the Department of Veterans Affairs to participate in collection activities conducted by the VHA; or

(3) Is a Department of Defense (DOD) police officer authorized by the DOD to participate in collection activities conducted by the DOD.

Non-retrievable means, for the purpose of destruction, the condition or state to which a controlled substance shall be rendered following a process that permanently alters that controlled substance's physical or chemical condition or state through irreversible means and thereby renders the controlled substance unavailable and unusable for all practical purposes. The process to achieve a non-retrievable condition or state may be unique to a substance's chemical or physical properties. A controlled substance is considered "non-retrievable" when it cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue. The purpose of destruction is to render the controlled substance(s) to a non-

retrievable state and thus prevent diversion of any such substance to illicit purposes.

On-site means located on or at the physical premises of the registrant's registered location. A controlled substance is destroyed *on-site* when destruction occurs on the physical premises of the destroying registrant's registered location. A hospital/clinic has an *on-site* pharmacy when it has a pharmacy located on the physical premises of the registrant's registered location.

PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

5. The authority citation for part 1301 is revised to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 831, 871(b), 875, 877, 886a, 951, 952, 953, 956, 957, 958, 965.

6. In § 1301.13, revise paragraphs (e)(1)(i) and (ii) to read as follows:

§ 1301.13 Application for registration; time for application; expiration date; registration for independent activities; application forms, fees, contents and signature; coincident activities.

* * * * *

(e) * * *

(1)

Business Activity	Controlled Substances	DEA Application Forms	Application Fee (\$)	Registration Period (years)	Coincident Activities Allowed
(i) Manufacturing	Schedules I–V	New–225 Renewal–225a	3,047	1	Schedules I–V: May distribute that substance or class for which registration

<p>(ii) Distributing</p> <p>*****</p>	<p>Schedules I-V</p>	<p>New-225 Renewal-225a</p>	<p>1,523</p>	<p>1</p>	<p>was issued; may not distribute any substance or class for which not registered. Schedules II-V: May conduct chemical analysis and preclinical research (including quality control analysis) with substances listed in those schedules for which authorization as a mfr. was issued.</p> <p>May acquire Schedules II-V controlled substances from collectors for the purposes of destruction.</p>
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* * * * *

7. In § 1301.25, revise paragraph (i) to read as follows:

§ 1301.25 Registration regarding ocean vessels, aircraft, and other entities.

* * * * *

(i) Controlled substances acquired and possessed in accordance with this section shall be

distributed only to persons under the general supervision of the medical officer employed by the owner or operator of the vessel, aircraft, or other entity, except in accordance with part 1317 of this chapter.

8. Revise § 1301.51 to read as follows:

§ 1301.51 Modification in registration.

(a) Any registrant may apply to modify his/her registration to authorize the handling of additional controlled substances or to change his/her name or address by submitting a written request to the Registration Unit, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. Additionally, such a request may be submitted on-line at www.DEAdiversion.usdoj.gov.

(1) The request shall contain:

(i) The registrant's name, address, and registration number as printed on the certificate of registration;

(ii) The substances and/or schedules to be added to the registration or the new name or address; and

(iii) A signature in accordance with § 1301.13(j).

(2) If the registrant is seeking to handle additional controlled substances listed in Schedule I for the purpose of research or instructional activities, the registrant shall attach three copies of a research protocol describing each research project involving the additional substances, or two copies of a statement describing the nature, extent, and duration of such instructional activities, as appropriate.

(b) Any manufacturer, distributor, reverse distributor, narcotic treatment program, hospital/clinic with an on-site pharmacy, or retail pharmacy registered pursuant to this part, may

apply to modify its registration to become authorized as a collector by submitting a written request to the Registration Unit, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. Additionally, such request may be submitted on-line at www.DEAdiversion.usdoj.gov.

(1) The request shall contain:

(i) The registrant's name, address, and registration number as printed on the certificate of registration;

(ii) The method(s) of collection the registrant intends to conduct (collection receptacle and/or mail-back program); and

(iii) A signature in accordance with § 1301.13(j).

(2) If a hospital/clinic with an on-site pharmacy or retail pharmacy is applying for a modification in registration to authorize such registrant to be a collector to maintain a collection receptacle at a long-term care facility in accordance with § 1317.80 of this chapter, the request shall also include the name and physical location of each long-term care facility at which the hospital/clinic with an on-site pharmacy, or the retail pharmacy, intends to operate a collection receptacle.

(c) No fee shall be required for modification. The request for modification shall be handled in the same manner as an application for registration. If the modification of registration is approved, the Administrator shall issue a new certificate of registration (DEA Form 223) to the registrant, who shall maintain it with the old certificate of registration until expiration.

9. In § 1301.52, revise the last sentence of paragraph (c) and add paragraph (f) to read as follows:

§ 1301.52 Termination of registration; transfer of registration; distribution upon

discontinuance of business.

* * * * *

(c) * * * Any controlled substances in his/her possession may be disposed of in accordance with part 1317 of this chapter.

* * * * *

(f) Any registrant that has been authorized as a collector and desires to discontinue its collection of controlled substances from ultimate users shall notify the Administration of its intent by submitting a written notification to the Registration Unit, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. Additionally, such notice may be submitted on-line at www.DEAdiversion.usdoj.gov. When ceasing collection activities of an authorized mail-back program, the registrant shall provide the Administration with the name, registered address, and registration number of the collector that will receive the remaining mail-back packages in accordance with § 1317.70(e)(3) of this chapter.

10. In § 1301.71, add paragraph (f) to read as follows:

§ 1301.71 Security requirements generally.

* * * * *

(f) A collector shall not employ, as an agent or employee who has access to or influence over controlled substances acquired by collection, any person who has been convicted of any felony offense relating to controlled substances or who, at any time, had an application for registration with DEA denied, had a DEA registration revoked or suspended, or has surrendered a DEA registration for cause. For purposes of this subsection, “for cause” means in lieu of, or as a consequence of, any Federal or State administrative, civil, or criminal action resulting from an

investigation of the individual's handling of controlled substances.

11. In § 1301.72, revise paragraph (a) introductory text to read as follows:

§ 1301.72 Physical security controls for non-practitioners; narcotic treatment programs, and compounders for narcotic treatment programs; storage areas.

(a) *Schedules I and II.* Raw material, bulk materials awaiting further processing, finished products which are controlled substances listed in Schedule I or II (except GHB that is manufactured or distributed in accordance with an exemption under section 505(i) of the Federal Food Drug and Cosmetic Act which shall be subject to the requirements of paragraph (b) of this section), and sealed mail-back packages and inner liners acquired in accordance with part 1317 of this chapter, shall be stored in one of the following secured areas:

* * * * *

12. In § 1301.74, add paragraph (m) to read as follows:

§ 1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs.

* * * * *

(m) A reverse distributor shall not employ, as an agent or employee who has access to or influence over controlled substances, any person who has been convicted of any felony offense relating to controlled substances or who, at any time, had an application for registration with the DEA denied, had a DEA registration revoked or suspended, or has surrendered a DEA registration for cause. For purposes of this subsection, "for cause" means in lieu of, or as a consequence of, any Federal or State administrative, civil, or criminal action resulting from an investigation of the individual's handling of controlled substances.

13. In § 1301.75, redesignate paragraphs (c) and (d) as paragraphs (d) and (e) and add a new

paragraph (c) to read as follows:

§ 1301.75 Physical security controls for practitioners.

* * * * *

(c) Sealed mail-back packages and inner liners collected in accordance with part 1317 of this chapter shall only be stored at the registered location in a securely locked, substantially constructed cabinet or a securely locked room with controlled access, except as authorized by § 1317.80(d).

* * * * *

14. In § 1301.76, revise paragraph (c) to read as follows:

§ 1301.76 Other security controls for practitioners.

* * * * *

(c) Whenever the registrant distributes a controlled substance (without being registered as a distributor as permitted in §§ 1301.13(e)(1), 1307.11, 1317.05, and/or 1317.10 of this chapter), he/she shall comply with the requirements imposed on non-practitioners in § 1301.74(a), (b), and (e).

* * * * *

PART 1304—RECORDS AND REPORTS OF REGISTRANTS

15. The authority citation for part 1304 is revised to read as follows:

Authority: 21 U.S.C. 821, 827, 831, 871(b), 958(e)–(g), and 965, unless otherwise noted.

16. Amend § 1304.03 by revising the first and second sentences of paragraph (a) to read as follows:

§ 1304.03 Persons required to keep records and file reports.

(a) Every registrant, including collectors, shall maintain the records and inventories and

shall file the reports required by this part, except as exempted by this section. Any registrant that is authorized to conduct other activities without being registered to conduct those activities, pursuant to §§ 1301.22(b), 1307.11, 1307.13, or part 1317 of this chapter, shall maintain the records and inventories and shall file the reports required by this part for persons registered or authorized to conduct such activities. * * *

* * * * *

17. In § 1304.04, add paragraph (a)(3) to read as follows:

§ 1304.04 Maintenance of records and inventories.

(a) * * *

(3) A collector that is authorized to maintain a collection receptacle at a long-term care facility shall keep all records required by this part relating to those collection receptacles at the registered location, or other approved central location.

* * * * *

18. In § 1304.11, revise paragraphs (e) introductory text and (e)(2) and (3) and add paragraphs (e)(6) and (7) to read as follows:

§ 1304.11 Inventory requirements.

* * * * *

(e) *Inventories of manufacturers, distributors, registrants that reverse distribute, importers, exporters, chemical analysts, dispensers, researchers, and collectors.* Each person registered or authorized (by §§ 1301.13, 1307.11, 1307.13, or part 1317 of this chapter) to manufacture, distribute, reverse distribute, dispense, import, export, conduct research or chemical analysis with controlled substances, or collect controlled substances from ultimate users, and required to keep records pursuant to § 1304.03 shall include in the inventory the

information listed below.

* * * * *

(2) *Inventories of distributors.* Each person registered or authorized to distribute controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1)(iii) and (iv) of this section.

(3) *Inventories of registrants that reverse distribute.* Each person registered or authorized to reverse distribute controlled substances shall include in the inventory, the following information:

(i) The name of the substance, and

(ii) The total quantity of the substance:

(A) For controlled substances in bulk form, to the nearest metric unit weight consistent with unit size;

(B) For each controlled substance in finished form: each finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter); the number of units or volume of each finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial); and the number of commercial containers of each such finished form (e.g., four 100-tablet bottles or six 3-milliliter vials); and

(C) For controlled substances in a commercial container, carton, crate, drum, or other receptacle that has been opened: if the substance is listed in Schedule I or II, make an exact count or measure of the contents; or if the substance is listed in Schedule III, IV, or V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case an exact count of the contents shall be made; or

(iii) For controlled substances acquired from collectors and law enforcement: the

number and size (e.g., five 10-gallon liners, etc.) of sealed inner liners on hand, or

(iv) For controlled substances acquired from law enforcement: the number of sealed mail-back packages on hand.

* * * * *

(6) *Inventories of dispensers and researchers.* Each person registered or authorized to dispense or conduct research with controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1)(iii) and (iv) of this section. In determining the number of units of each finished form of a controlled substance in a commercial container that has been opened, the dispenser or researcher shall do as follows:

(i) If the substance is listed in Schedules I or II, make an exact count or measure of the contents; or

(ii) If the substance is listed in Schedule III, IV, or V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case he/she must make an exact count of the contents.

(7) *Inventories of collectors.* Each registrant authorized to collect controlled substances from ultimate users shall include in the inventory the following information:

(i) For registrants authorized to collect through a mail-back program, the record shall include the following information about each unused mail-back package and each returned mail-back package on hand awaiting destruction:

(A) The date of the inventory;

(B) The number of mail-back packages; and

(C) The unique identification number of each package on hand, whether unused or awaiting destruction.

(ii) For registrants authorized to collect through a collection receptacle, the record shall include the following information about each unused inner liner on hand and each sealed inner liner on hand awaiting destruction:

- (A) The date of the inventory;
- (B) The number and size of inner liners (e.g., five 10-gallon liners, etc.);
- (C) The unique identification number of each inner liner.

19. In § 1304.21, revise paragraphs (a), (c), and (d) and add paragraph (e) to read as follows:

§ 1304.21 General requirements for continuing records.

(a) Every registrant required to keep records pursuant to § 1304.03 shall maintain, on a current basis, a complete and accurate record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of by him/her, and each inner liner, sealed inner liner, and unused and returned mail-back package, except that no registrant shall be required to maintain a perpetual inventory.

* * * * *

(c) Separate records shall be maintained by a registrant for each independent activity and collection activity for which he/she is registered or authorized, except as provided in § 1304.22(d).

(d) In recording dates of receipt, importation, distribution, exportation, other transfers, or destruction, the date on which the controlled substances are actually received, imported, distributed, exported, otherwise transferred, or destroyed shall be used as the date of receipt, importation, distribution, exportation, transfer, or destruction (e.g., invoices, packing slips, or DEA Form 41).

(e) *Record of destruction.* In addition to any other recordkeeping requirements, any

registered person that destroys a controlled substance pursuant to § 1317.95(d), or causes the destruction of a controlled substance pursuant to § 1317.95(c), shall maintain a record of destruction on a DEA Form 41. The records shall be complete and accurate, and include the name and signature of the two employees who witnessed the destruction. Except, destruction of a controlled substance dispensed by a practitioner for immediate administration at the practitioner's registered location, when the substance is not fully exhausted (e.g., some of the substance remains in a vial, tube, or syringe after administration but cannot or may not be further utilized), shall be properly recorded in accordance with § 1304.22(c), and such record need not be maintained on a DEA Form 41.

20. In § 1304.22, revise the section heading, introductory text, and paragraph (e) and add paragraph (f) to read as follows:

§ 1304.22 Records for manufacturers, distributors, dispensers, researchers, importers, exporters, registrants that reverse distribute, and collectors.

Each person registered or authorized (by §§ 1301.13(e), 1307.11, 1307.13, or part 1317 of this chapter) to manufacture, distribute, dispense, import, export, reverse distribute, destroy, conduct research with controlled substances, or collect controlled substances from ultimate users, shall maintain records with the information listed in paragraphs (a) through (f) of this section.

* * * * *

(e) *Records for registrants that reverse distribute.* Each person registered or authorized to reverse distribute controlled substances shall maintain records with the following information for each controlled substance:

(1) For controlled substances acquired for the purpose of return or recall to the manufacturer or another registrant authorized by the manufacturer to accept returns on the

manufacturer's behalf pursuant to part 1317 of this chapter:

(i) The date of receipt; the name and quantity of each controlled substance received; the name, address, and registration number of the person from whom the substance was received; and the reason for return (e.g., recall or return); and

(ii) The date of return to the manufacturer or other registrant authorized by the manufacturer to accept returns on the manufacturer's behalf; the name and quantity of each controlled substance returned; the name, address, and registration number of the person from whom the substance was received; the name, address, and registration number of the registrant to whom the substance was returned; and the method of return (e.g., common or contract carrier).

(2) For controlled substances acquired from registrant inventory for destruction pursuant to § 1317.05(a)(2), (b)(2), and (b)(4) of this chapter:

(i) The date of receipt; the name and quantity of each controlled substance received; and the name, address, and registration number of the person from whom the substance was received; and

(ii) The date, place, and method of destruction; the name and quantity of each controlled substance destroyed; the name, address, and registration number of the person from whom the substance was received; and the name and signatures of the two employees of the registrant that witnessed the destruction.

(3) The total quantity of each controlled substance shall be recorded in accordance with the following:

(i) For controlled substances in bulk form: to the nearest metric unit weight or volume consistent with unit size;

(ii) For controlled substances in finished form: each finished form (e.g., 10-milligram

tablet or 10-milligram concentration per fluid ounce or milliliter); the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial); and the number of commercial containers of each such finished form (e.g., four 100-tablet bottles or six 3-milliliter vials); and

(iii) For controlled substances in a commercial container, carton, crate, drum, or other receptacle that has been opened: if the substance is listed in Schedule I or II make an exact count or measure of the contents; or if the substance is listed in Schedule III, IV, or V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case an exact count of the contents shall be made.

(4) For each sealed inner liner acquired from collectors or law enforcement and each sealed mail-back package acquired from law enforcement pursuant to § 1317.55 of this chapter:

(i) The number of sealed inner liners acquired from other persons, including the date of acquisition, the number and, for sealed inner liners the size (e.g., five 10-gallon liners, etc.), of all sealed inner liners and mail-back packages acquired to inventory, the unique identification number of each sealed inner liner and mail-back package, and the name, address, and, for registrants, the registration number of the person from whom the sealed inner liners and mail-back packages were received, and

(ii) The date, place, and method of destruction; the number of sealed inner liners and mail-back packages destroyed; the name, address, and, for registrants, the registration number of the person from whom the sealed inner liners and mail-back packages were received; the number and, for sealed inner liners the size (e.g., five 10-gallon liners, etc.), of all sealed inner liners and mail-back packages destroyed; the unique identification number of each sealed inner liner and sealed mail-back package destroyed; and the name and signatures of the two employees of the

registrant that witnessed the destruction.

(5) For all records, the record of receipt shall be maintained together with the corresponding record of return or destruction (DEA Form 41).

(f) *Records for collectors.* Each person registered or authorized to collect controlled substances from ultimate users shall maintain the following records:

(1) Mail-Back Packages:

(i) For unused packages that the collector makes available to ultimate users and other authorized non-registrants at the collector's registered address: the date made available, the number of packages, and the unique identification number of each package;

(ii) For unused packages provided to a third party to make available to ultimate users and other authorized non-registrants: the name of the third party and physical address of the location receiving the unused packages, date sent, and the number of unused packages sent with the corresponding unique identification numbers;

(iii) For sealed mail-back packages received by the collector: date of receipt and the unique identification number on the individual package; and

(iv) For sealed mail-back packages destroyed on-site by the collector: number of sealed mail-back packages destroyed, the date and method of destruction, the unique identification number of each mail-back package destroyed, and the names and signatures of the two employees of the registrant who witnessed the destruction.

(2) Collection receptacle inner liners:

(i) Date each unused inner liner acquired, unique identification number and size (e.g., 5-gallon, 10-gallon, etc.) of each unused inner liner acquired;

(ii) Date each inner liner is installed, the address of the location where each inner liner is

installed, the unique identification number and size (e.g., 5-gallon, 10-gallon, etc.) of each installed inner liner, the registration number of the collector, and the names and signatures of the two employees that witnessed each installation;

(iii) Date each inner liner is removed and sealed, the address of the location from which each inner liner is removed, the unique identification number and size (e.g., 5-gallon, 10-gallon, etc.) of each inner liner removed, the registration number of the collector, and the names and signatures of the two employees that witnessed each removal;

(iv) Date each sealed inner liner is transferred to storage, the unique identification number and size (e.g., 5-gallon, 10-gallon, etc.) of each sealed inner liner stored, and the names and signatures of the two employees that transferred each sealed inner liner to storage;

(v) Date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealed inner liner was transferred, the unique identification number and the size (e.g., 5-gallon, 10-gallon, etc.) of each sealed inner liner transferred, and the names and signatures of the two employees that transferred each sealed inner liner to the reverse distributor or distributor; and

(vi) For sealed inner liners destroyed on-site by the collector: the same information required of reverse distributors in paragraph (e)(4)(ii) of this section.

21. In § 1304.25, revise the section heading and paragraphs (a)(9) and (b)(9) to read as follows:

§ 1304.25 Records for treatment programs that compound narcotics for treatment programs and other locations.

* * * * *

(a) * * *

(9) The quantity disposed of by destruction, including the reason, date, and manner of

destruction.

(b) * * *

(9) The number of units of finished forms and/or commercial containers destroyed in any manner by the registrant, including the reason, date, and manner of destruction.

22. Amend § 1304.33 by revising the section heading and paragraph (f) and adding paragraph (g) to read as follows:

§ 1304.33 Reports to Automation of Reports and Consolidated Orders System (ARCOS).

* * * * *

(f) *Exceptions.* (1) A registered institutional practitioner that repackages or relabels exclusively for distribution or that distributes exclusively to (for dispensing by) agents, employees, or affiliated institutional practitioners of the registrant may be exempted from filing reports under this section by applying to the ARCOS Unit of the Administration.

(2) Registrants that acquire recalled controlled substances from ultimate users pursuant to § 1317.85 of this chapter may report as a single transaction all recalled controlled substances of the same name and finished form (e.g., all 10-milligram tablets or all 5-milligram concentration per fluid ounce or milliliter) received from ultimate users for the purpose of reporting acquisition transactions.

(g) *Exemptions.* (1) Collectors that acquire controlled substances from ultimate users are exempt from the ARCOS reporting requirements only with respect to controlled substances collected through mail-back programs and collection receptacles for the purpose of disposal.

(2) Reverse distributors and distributors that acquire controlled substances pursuant to § 1317.55(a) or (b) of this chapter are exempt from the ARCOS reporting requirements in this section with regard to any controlled substances acquired pursuant to § 1317.55(a) or (b) of this

chapter.

* * * * *

PART 1305—ORDERS FOR SCHEDULE I AND II CONTROLLED SUBSTANCES

23. The authority citation for part 1305 continues to read as follows:

Authority: 21 U.S.C. 821, 828, 871(b), unless otherwise noted.

24. In § 1305.03, add paragraphs (e), (f), and (g) to read as follows:

§ 1305.03 Distributions requiring a Form 222 or a digitally signed electronic order.

* * * * *

(e) Deliveries to an authorized DEA registrant by an ultimate user, a long-term care facility on behalf of an ultimate user who resides or has resided at that facility, or a person authorized to dispose of the ultimate user decedent's property.

(f) Distributions to reverse distributors and distributors by collectors and law enforcement pursuant to § 1317.55 of this chapter.

(g) Deliveries of controlled substances from ultimate users for the purpose of recalls pursuant to § 1317.85 of this chapter.

PART 1307—MISCELLANEOUS

25. The authority citation for part 1307 continues to read as follows:

Authority: 21 U.S.C. 821, 822(d), 871(b), unless otherwise noted.

26. In § 1307.11, revise section heading and remove and reserve paragraph (a)(2).

The revision reads as follows:

§ 1307.11 Distribution by dispenser to another practitioner.

* * * * *

§ 1307.12 [Removed]

27. Remove § 1307.12.

28. Revise § 1307.13 to read as follows:

§ 1307.13 Incidental manufacture of controlled substances.

Any registered manufacturer who, incidentally but necessarily, manufactures a controlled substance as a result of the manufacture of a controlled substance or basic class of controlled substance for which he is registered and has been issued an individual manufacturing quota pursuant to part 1303 of this chapter (if such substance or class is listed in Schedule I or II) shall be exempt from the requirement of registration pursuant to part 1301 of this chapter and, if such incidentally manufactured substance is listed in Schedule I or II, shall be exempt from the requirement of an individual manufacturing quota pursuant to part 1303 of this chapter, if such substances are disposed of in accordance with part 1317 of this chapter.

§ 1307.21 [Removed]

29. Remove § 1307.21.

30. In § 1307.22, revise the section heading and the first sentence to read as follows:

§ 1307.22 Delivery of surrendered and forfeited controlled substances.

Any controlled substance surrendered by delivery to the Administration under part 1317 of this chapter or forfeited pursuant to section 511 of the Act (21 U.S.C. 881) may be delivered to any department, bureau, or other agency of the United States or of any State upon proper application addressed to the Office of Diversion Control, Drug Enforcement Administration.

* * *

31. Add part 1317 to read as follows:

PART 1317—DISPOSAL

Sec.

1317.01 Scope.

SUBPART A—DISPOSAL OF CONTROLLED SUBSTANCES BY REGISTRANTS

- 1317.05 Registrant disposal.
- 1317.10 Registrant return or recall.
- 1317.15 Reverse distributor registration requirements and authorized activities.

SUBPART B—DISPOSAL OF CONTROLLED SUBSTANCES COLLECTED FROM ULTIMATE

USERS AND OTHER NON-REGISTRANTS

- 1317.30 Authorization to collect from non-registrants.
- 1317.35 Collection by law enforcement.
- 1317.40 Registrants authorized to collect and authorized collection activities.
- 1317.55 Reverse distributor and distributor acquisition of controlled substances from collectors or law enforcement.
- 1317.60 Inner liner requirements.
- 1317.65 Take-back events.
- 1317.70 Mail-back programs.
- 1317.75 Collection receptacles.
- 1317.80 Collection receptacles at long-term care facilities.
- 1317.85 Ultimate user delivery for the purpose of recall or investigational use of drugs.

SUBPART C—DESTRUCTION OF CONTROLLED SUBSTANCES

- 1317.90 Methods of destruction.
- 1317.95 Destruction procedures.

Authority: 21 U.S.C. 821, 822, 823, 827, 828, 871(b), and 958.

§ 1317.01 Scope.

This part sets forth the rules for the delivery, collection, and destruction of damaged, expired, returned, recalled, unused, or otherwise unwanted controlled substances that are lawfully possessed by registrants (subpart A) and non-registrants (subpart B). The purpose of such rules is to provide prompt, safe, and effective disposal methods while providing effective controls against the diversion of controlled substances.

SUBPART A—DISPOSAL OF CONTROLLED SUBSTANCES BY REGISTRANTS

§ 1317.05 Registrant disposal.

(a) *Practitioner inventory.* Any registered practitioner in lawful possession of a controlled substance in its inventory that desires to dispose of that substance shall do so in one of the following ways:

(1) Promptly destroy that controlled substance in accordance with subpart C of this part using an on-site method of destruction;

(2) Promptly deliver that controlled substance to a reverse distributor's registered location by common or contract carrier pick-up or by reverse distributor pick-up at the registrant's registered location;

(3) For the purpose of return or recall, promptly deliver that controlled substance by common or contract carrier pick-up or pick-up by other registrants at the registrant's registered location to: the registered person from whom it was obtained, the registered manufacturer of the substance, or another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf; or

(4) Request assistance from the Special Agent in Charge of the Administration in the area in which the practitioner is located.

(i) The request shall be made by submitting one copy of the DEA Form 41 to the Special Agent in Charge in the practitioner's area. The DEA Form 41 shall list the controlled substance or substances which the registrant desires to dispose.

(ii) The Special Agent in Charge shall instruct the registrant to dispose of the controlled substance in one of the following manners:

(A) By transfer to a registrant authorized to transport or destroy the substance;

(B) By delivery to an agent of the Administration or to the nearest office of the Administration; or

(C) By destruction in the presence of an agent of the Administration or other authorized person.

(5) In the event that a practitioner is required regularly to dispose of controlled substances, the Special Agent in Charge may authorize the practitioner to dispose of such substances, in accordance with subparagraph (a)(4) of this section, without prior application in each instance, on the condition that the practitioner keep records of such disposals and file periodic reports with the Special Agent in Charge summarizing the disposals. The Special Agent in Charge may place such conditions as he/she deems proper on practitioner procedures regarding the disposal of controlled substances.

(b) *Non-practitioner inventory.* Any registrant that is a non-practitioner in lawful possession of a controlled substance in its inventory that desires to dispose of that substance shall do so in one of the following ways:

(1) Promptly destroy that controlled substance in accordance with subpart C of this part using an on-site method of destruction;

(2) Promptly deliver that controlled substance to a reverse distributor's registered location by common or contract carrier or by reverse distributor pick-up at the registrant's registered location;

(3) For the purpose of return or recall, promptly deliver that controlled substance by common or contract carrier or pick-up at the registrant's registered location to: the registered person from whom it was obtained, the registered manufacturer of the substance, or another

registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf; or

(4) Promptly transport that controlled substance by its own means to the registered location of a reverse distributor, the location of destruction, or the registered location of any person authorized to receive that controlled substance for the purpose of return or recall as described in paragraph (b)(3) of this section.

(i) If a non-practitioner transports controlled substances by its own means to an unregistered location for destruction, the non-practitioner shall do so in accordance with the procedures set forth at § 1317.95(c).

(ii) If a non-practitioner transports controlled substances by its own means to a registered location for any authorized purpose, transportation shall be directly to the authorized registered location and two employees of the transporting non-practitioner shall accompany the controlled substances to the registered destination location. Directly transported means the substances shall be constantly moving towards their final location and unnecessary or unrelated stops and stops of an extended duration shall not occur.

(c) *Collected controlled substances.* Any collector in lawful possession of a controlled substance acquired by collection from an ultimate user or other authorized non-registrant person shall dispose of that substance in the following ways:

(1) *Mail-back program.* Upon receipt of a sealed mail-back package, the collector shall promptly:

(i) Destroy the package in accordance with subpart C of this part using an on-site method of destruction; or

(ii) Securely store the package and its contents at the collector's registered location in a manner consistent with § 1301.75(c) of this chapter (for practitioners), or in a manner consistent with the security requirements for Schedule II controlled substances (for non-practitioners) until prompt on-site destruction can occur.

(2) *Collection receptacles.* Upon removal from the permanent outer container, the collector shall seal it and promptly:

(i) Destroy the sealed inner liner and its contents;

(ii) Securely store the sealed inner liner and its contents at the collector's registered location in a manner consistent with § 1301.75(c) of this chapter (for practitioners), or in a manner consistent with § 1301.72(a) of this chapter (for non-practitioners) until prompt destruction can occur; or

(iii) Securely store the sealed inner liner and its contents at a long-term care facility in accordance with § 1317.80(d).

(iv) *Practitioner methods of destruction.* Collectors that are practitioners (i.e., retail pharmacies and hospitals/clinics) shall dispose of sealed inner liners and their contents by utilizing any method in paragraph (a)(1), (a)(2), or (a)(4) of this section, or by delivering sealed inner liners and their contents to a distributor's registered location by common or contract carrier pick-up or by distributor pick-up at the collector's authorized collection location.

(v) *Non-practitioner methods of destruction.* Collectors that are non-practitioners (i.e., manufacturers, distributors, narcotic treatment programs, and reverse distributors) shall dispose of sealed inner liners and their contents by utilizing any method in paragraph (b)(1), (b)(2), or (b)(4) of this section, or by delivering sealed inner liners and their contents to a distributor's registered location by common or contract carrier or by distributor pick-up at the collector's

authorized collection location for destruction. Freight forwarding facilities may not be utilized to transfer sealed inner liners and their contents.

§ 1317.10 Registrant return or recall.

(a) Each registrant shall maintain a record of each return or recall transaction in accordance with the information required of manufacturers in § 1304.22(a)(2)(iv) of this chapter.

(b) Each registrant that delivers a controlled substance in Schedule I or II for the purpose of return or recall shall use an order form in the manner described in part 1305 of this chapter.

(c) Deliveries for the purpose of return or recall may be made through a freight forwarding facility operated by the person to whom the controlled substance is being returned provided that advance notice of the return is provided and delivery is directly to an agent or employee of the person to whom the controlled substance is being returned.

§ 1317.15 Reverse distributor registration requirements and authorized activities.

(a) Any person that reverse distributes a controlled substance shall be registered with the Administration as a reverse distributor, unless exempted by law or otherwise authorized pursuant to this chapter.

(b) A reverse distributor shall acquire controlled substances from a registrant pursuant to §§ 1317.05 and 1317.55(a) and (c) in the following manner:

(1) Pick-up controlled substances from a registrant at the registrant's registered location or authorized collection site; or

(2) Receive controlled substances delivered by common or contract carrier or delivered directly by a non-practitioner registrant.

(i) Delivery to the reverse distributor by an authorized registrant directly or by common or contract carrier may only be made to the reverse distributor at the reverse distributor's

registered location. Once en route, such deliveries may not be re-routed to any other location or person, regardless of registration status.

(ii) All controlled substance deliveries to a reverse distributor shall be personally received by an employee of the reverse distributor at the registered location.

(c) Upon acquisition of a controlled substance by delivery or pick-up, a reverse distributor shall:

(1) Immediately store the controlled substance, in accordance with the security controls in parts 1301 and 1317 of this chapter, at the reverse distributor's registered location or immediately transfer the controlled substance to the reverse distributor's registered location for secure storage, in accordance with the security controls in parts 1301 and 1317 of this chapter, until timely destruction or prompt return of the controlled substance to the registered manufacturer or other registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf;

(2) Promptly deliver the controlled substance to the manufacturer or another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf; or

(3) Timely destroy the controlled substance in a manner authorized in subpart C of this part.

(d) A reverse distributor shall destroy or cause the destruction of any controlled substance received for the purpose of destruction no later than 30 calendar days after receipt.

**SUBPART B—DISPOSAL OF CONTROLLED SUBSTANCES COLLECTED FROM ULTIMATE USERS
AND OTHER NON-REGISTRANTS**

§ 1317.30 Authorization to collect from non-registrants.

(a) The following persons are authorized to collect controlled substances from ultimate

users and other non-registrants for destruction in compliance with this chapter:

(1) Any registrant authorized by the Administration to be a collector pursuant to § 1317.40; and

(2) Federal, State, tribal, or local law enforcement when in the course of official duties and pursuant to § 1317.35.

(b) The following non-registrant persons in lawful possession of a controlled substance in Schedules II, III, IV, or V may transfer that substance to the authorized persons listed in paragraph (a) of this section, and in a manner authorized by this part, for the purpose of disposal:

(1) An ultimate user in lawful possession of a controlled substance;

(2) Any person lawfully entitled to dispose of a decedent's property if that decedent was an ultimate user who died while in lawful possession of a controlled substance; and

(3) A long-term care facility on behalf of an ultimate user who resides or resided at such long-term care facility and is/was in lawful possession of a controlled substance, in accordance with § 1317.80 only.

§ 1317.35 Collection by law enforcement.

(a) Federal, State, tribal, or local law enforcement may collect controlled substances from ultimate users and persons lawfully entitled to dispose of an ultimate user decedent's property using the following collection methods:

(1) Take-back events in accordance with § 1317.65;

(2) Mail-back programs in accordance with § 1317.70; or

(3) Collection receptacles located inside law enforcement's physical address.

(b) Law enforcement that conducts a take-back event or a mail-back program or maintains a collection receptacle should maintain any records of removal, storage, or destruction

of the controlled substances collected in a manner that is consistent with that agency's recordkeeping requirements for illicit controlled substances evidence.

(c) Any controlled substances collected by law enforcement through a take-back event, mail-back program, or collection receptacle should be stored in a manner that prevents the diversion of controlled substances and is consistent with that agency's standard procedures for storing illicit controlled substances.

(d) Any controlled substances collected by law enforcement through a take-back event, mail-back program, or collection receptacle should be transferred to a destruction location in a manner that prevents the diversion of controlled substances and is consistent with that agency's standard procedures for transferring illicit controlled substances.

(e) Law enforcement that transfers controlled substances collected from ultimate users pursuant to this part to a reverse distributor for destruction should maintain a record that contains the following information: if a sealed inner liner as described in § 1317.60 is used, the unique identification number of the sealed inner liner transferred, and the size of the sealed inner liner transferred (e.g., 5-gallon, 10-gallon, etc.); if a mail-back package as described in § 1317.70 is used, the unique identification number of each package; the date of the transfer; and the name, address, and registration number of the reverse distributor to whom the controlled substances were transferred.

§ 1317.40 Registrants authorized to collect and authorized collection activities.

(a) Manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies that desire to be collectors shall modify their registration to obtain authorization to be a collector in accordance with § 1301.51 of this chapter. Authorization to be a collector is subject to renewal. If a registrant that is

authorized to collect ceases activities as a collector, such registrant shall notify the Administration in accordance with § 1301.52(f) of this chapter.

(b) Collection by registrants shall occur only at the following locations:

(1) Those registered locations of manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies that are authorized for collection; and

(2) Long-term care facilities at which registered hospitals/clinics or retail pharmacies are authorized to maintain collection receptacles.

(c) Collectors may conduct the following activities:

(1) Receive and destroy mail-back packages pursuant to § 1317.70 at an authorized registered location that has an on-site method of destruction;

(2) Install, manage, and maintain collection receptacles located at their authorized collection location(s) pursuant to §§ 1317.75 and 1317.80; and

(3) Promptly dispose of sealed inner liners and their contents as provided for in § 1317.05(c)(2).

§ 1317.55 Reverse distributor and distributor acquisition of controlled substances from collectors or law enforcement.

(a) A reverse distributor is authorized to acquire controlled substances from law enforcement that collected the substances from ultimate users. A reverse distributor is authorized to acquire controlled substances collected through a collection receptacle in accordance with §§ 1317.75 and 1317.80.

(b) A distributor is authorized to acquire controlled substances collected through a collection receptacle in accordance with §§ 1317.75 and 1317.80.

(c) A reverse distributor or a distributor that acquires controlled substances in accordance with paragraph (a) or (b) of this section shall:

(1) Acquire the controlled substances in the manner authorized for reverse distributors in § 1317.15(b)(1) and (2);

(2) Dispose of the controlled substances in the manner authorized for reverse distributors § 1317.15(c) and (d); and

(3) Securely store the controlled substances in a manner consistent with the security requirements for Schedule II controlled substances until timely destruction can occur.

§ 1317.60 Inner liner requirements.

(a) An inner liner shall meet the following requirements:

(1) The inner liner shall be waterproof, tamper-evident, and tear-resistant;

(2) The inner liner shall be removable and sealable immediately upon removal without emptying or touching the contents;

(3) The contents of the inner liner shall not be viewable from the outside when sealed;

(4) The size of the inner liner shall be clearly marked on the outside of the liner (e.g., 5-gallon, 10-gallon, etc.); and

(5) The inner liner shall bear a permanent, unique identification number that enables the inner liner to be tracked.

(b) Access to the inner liner shall be restricted to employees of the collector.

(c) The inner liner shall be sealed by two employees immediately upon removal from the permanent outer container and the sealed inner liner shall not be opened, x-rayed, analyzed, or otherwise penetrated.

§ 1317.65 Take-back events.

(a) Federal, State, tribal, or local law enforcement may conduct a take-back event and collect controlled substances from ultimate users and persons lawfully entitled to dispose of an ultimate user decedent's property in accordance with this section. Any person may partner with law enforcement to hold a collection take-back event in accordance with this section.

(b) Law enforcement shall appoint a law enforcement officer employed by the agency to oversee the collection. Law enforcement officers employed and authorized by the law enforcement agency or law enforcement component of a Federal agency conducting a take-back event shall maintain control and custody of the collected substances from the time the substances are collected from the ultimate user or person authorized to dispose of the ultimate user decedent's property until secure transfer, storage, or destruction of the controlled substances has occurred.

(c) Each take-back event should have at least one receptacle for the collection of controlled substances. The collection receptacle should be a securely locked, substantially constructed container with an outer container and a removable inner liner as specified in § 1317.60 of this chapter. The outer container should include a small opening that allows contents to be added to the inner liner, but that does not allow removal of the inner liner's contents.

(d) Only those controlled substances listed in Schedule II, III, IV, or V that are lawfully possessed by an ultimate user or person entitled to dispose of an ultimate user decedent's property may be collected. Controlled and non-controlled substances may be collected together and be comingled, although comingling is not required.

(e) Only ultimate users and persons entitled to dispose of an ultimate user decedent's property in lawful possession of a controlled substance in Schedule II, III, IV, or V may transfer

such substances to law enforcement during the take-back event. No other person may handle the controlled substances at any time.

§ 1317.70 Mail-back programs.

(a) A mail-back program may be conducted by Federal, State, tribal, or local law enforcement or any collector. A collector conducting a mail-back program shall have and utilize at their registered location a method of destruction consistent with § 1317.90 of this chapter.

(b) Only those controlled substances listed in Schedule II, III, IV, or V that are lawfully possessed by an ultimate user or person lawfully entitled to dispose of an ultimate user decedent's property may be collected. Controlled and non-controlled substances may be collected together and be comingled, although comingling is not required.

(c) Collectors or law enforcement that conduct a mail-back program shall make packages available (for sale or for free) as specified in this paragraph to ultimate users and persons lawfully entitled to dispose of an ultimate user decedent's property, for the collection of controlled substances by common or contract carrier. Any person may partner with a collector or law enforcement to make such packages available in accordance with this section. The packages made available shall meet the following specifications:

(1) The package shall be nondescript and shall not include any markings or other information that might indicate that the package contains controlled substances;

(2) The package shall be water- and spill-proof; tamper-evident; tear-resistant; and sealable;

(3) The package shall be preaddressed with and delivered to the collector's registered address or the participating law enforcement's physical address;

(4) The cost of shipping the package shall be postage paid;

(5) The package shall have a unique identification number that enables the package to be tracked; and

(6) The package shall include instructions for the user that indicate the process for mailing back the package, the substances that can be sent, notice that packages may only be mailed from within the customs territory of the United States (the 50 States, the District of Columbia, and Puerto Rico), and notice that only packages provided by the collector will be accepted for destruction.

(d) Ultimate users and persons lawfully entitled to dispose of an ultimate user decedent's property shall not be required to provide any personally identifiable information when mailing back controlled substances to a collector. The collector or law enforcement may implement a system that allows ultimate users or persons lawfully entitled to dispose of an ultimate user decedent's property to notify the collector or law enforcement that they are sending one of the designated packages by giving the unique identification number on the package.

(e) A collector that conducts a mail-back program pursuant to paragraph (a) shall:

(1) Accept only those controlled substances contained within packages that the collector made available for the collection of controlled substances by mail and packages that are lawfully forwarded to the collector pursuant to paragraph (e)(3) of this section.

(2) Within three business days of receipt, notify the Field Division Office of the Administration in their area of the receipt of a package that likely contains controlled substances that the collector did not make available or did not agree to receive pursuant to subparagraph (e)(3) of this section.

(3) When discontinuing activities as a collector or ceasing an authorized mail-back program:

(i) Make a reasonable effort to notify the public prior to discontinuing such activities or ceasing the authorized mail-back program; and

(ii) Obtain the written agreement of another collector that has and utilizes at its registered location a method of destruction consistent with § 1317.90 of this chapter to receive all remaining mail-back packages that were disseminated but not returned and arrange for the forwarding of only such packages to that location.

(f) Only law enforcement officers employed by the law enforcement agency or law enforcement component of a Federal agency and employees of the collector shall handle packages received through an authorized mail-back program. Upon receipt of a mail-back package by a collector conducting a mail-back program, the package shall not be opened, x-rayed, analyzed, or otherwise penetrated.

§ 1317.75 Collection receptacles.

(a) Collectors or Federal, State, tribal, or local law enforcement may manage and maintain collection receptacles for disposal.

(b) Only those controlled substances listed in Schedule II, III, IV, or V that are lawfully possessed by an ultimate user or other authorized non-registrant person may be collected. Controlled and non-controlled substances may be collected together and be comingled, although comingling is not required.

(c) Collectors shall only allow ultimate users and other authorized non-registrant persons in lawful possession of a controlled substance in Schedule II, III, IV, or V to deposit such substances in a collection receptacle at a registered location. Collectors shall not permit an ultimate user to transfer such substance to any person for any reason. Once a substance has been deposited into a collection receptacle, the substance shall not be counted, sorted, inventoried, or

otherwise individually handled.

(d) Collection receptacles shall be securely placed and maintained:

(1) Inside a collector's registered location, inside law enforcement's physical location, or at an authorized long-term care facility;

(2) At a registered location, be located in the immediate proximity of a designated area where controlled substances are stored and at which an employee is present (e.g., can be seen from the pharmacy counter). Except as follows:

(i) At a hospital/clinic: a collection receptacle shall be located in an area regularly monitored by employees, and shall not be located in the proximity of any area where emergency or urgent care is provided;

(ii) At a narcotic treatment program: a collection receptacle shall be located in a room: that does not contain any other controlled substances and is securely locked with controlled access;

(iii) At a long-term care facility: a collection receptacle shall be located in a secured area regularly monitored by long-term care facility employees.

(e) A controlled substance collection receptacle shall meet the following design specifications:

(1) Be securely fastened to a permanent structure so that it cannot be removed;

(2) Be a securely locked, substantially constructed container with a permanent outer container and a removable inner liner as specified in § 1317.60 of this chapter;

(3) The outer container shall include a small opening that allows contents to be added to the inner liner, but does not allow removal of the inner liner's contents;

(4) The outer container shall prominently display a sign indicating that only Schedule II-

V controlled and non-controlled substances, if a collector chooses to comingle substances, are acceptable substances (Schedule I controlled substances, controlled substances that are not lawfully possessed by the ultimate user, and other illicit or dangerous substances are not permitted); and

(f) Except at a narcotic treatment program, the small opening in the outer container of the collection receptacle shall be locked or made otherwise inaccessible to the public when an employee is not present (e.g., when the pharmacy is closed), or when the collection receptacle is not being regularly monitored by long-term care facility employees.

(g) The installation and removal of the inner liner of the collection receptacle shall be performed by or under the supervision of at least two employees of the authorized collector.

§ 1317.80 Collection receptacles at long-term care facilities.

(a) A long-term care facility may dispose of controlled substances in Schedules II, III, IV, and V on behalf of an ultimate user who resides, or has resided, at such long-term care facility by transferring those controlled substances into an authorized collection receptacle located at that long-term care facility. When disposing of such controlled substances by transferring those substances into a collection receptacle, such disposal shall occur immediately, but no longer than three business days after the discontinuation of use by the ultimate user. Discontinuation of use includes a permanent discontinuation of use as directed by the prescriber, as a result of the resident's transfer from the long-term care facility, or as a result of death.

(b) Only authorized retail pharmacies and hospitals/clinics with an on-site pharmacy may install, manage, and maintain collection receptacles at long-term care facilities and remove, seal, transfer, and store, or supervise the removal, sealing, transfer, and storage of sealed inner liners at long-term care facilities. Collectors authorized to install, manage, and maintain collection

receptacles at long-term care facilities shall comply with all requirements of this chapter, including §§ 1317.60, 1317.75, and 1317.80.

(c) The installation, removal, transfer, and storage of inner liners shall be performed either: by or under the supervision of one employee of the authorized collector and one supervisor-level employee of the long-term care facility (e.g., a charge nurse or supervisor) designated by the authorized collector; or, by or under the supervision of two employees of the authorized collector.

(d) Upon removal, sealed inner liners may only be stored at the long-term care facility for up to three business days in a securely locked, substantially constructed cabinet or a securely locked room with controlled access until transfer in accordance with § 1317.05(c)(2)(iv).

(e) Neither a hospital/clinic with an on-site pharmacy nor a retail pharmacy shall operate a collection receptacle at a long-term care facility until its registration has been modified in accordance with § 1301.51 of this chapter.

§ 1317.85 Ultimate user delivery for the purpose of recall or investigational use of drugs.

(a) In the event of a product recall, an ultimate user in lawful possession of a controlled substance listed in Schedule II, III, IV, or V may deliver the recalled substance to the manufacturer of the substance or another registrant authorized by the manufacturer to accept recalled controlled substances on the manufacturer's behalf.

(b) An ultimate user who is participating in an investigational use of drugs pursuant to 21 U.S.C. 355(i) and 360b(j) and wishes to deliver any unused controlled substances received as part of that research to the registered dispenser from which the ultimate user obtained those substances may do so in accordance with regulations promulgated by the Secretary of Health and Human Services pursuant to 21 U.S.C. 355(i) and 360b(j).

SUBPART C—DESTRUCTION OF CONTROLLED SUBSTANCES

§ 1317.90 Methods of destruction.

(a) All controlled substances to be destroyed by a registrant, or caused to be destroyed by a registrant pursuant to § 1317.95(c), shall be destroyed in compliance with applicable Federal, State, tribal, and local laws and regulations and shall be rendered non-retrievable.

(b) Where multiple controlled substances are comingled, the method of destruction shall be sufficient to render all such controlled substances non-retrievable. When the actual substances collected for destruction are unknown but may reasonably include controlled substances, the method of destruction shall be sufficient to render non-retrievable any controlled substance likely to be present.

(c) The method of destruction shall be consistent with the purpose of rendering all controlled substances to a non-retrievable state in order to prevent diversion of any such substance to illicit purposes and to protect the public health and safety.

§ 1317.95 Destruction procedures.

The destruction of any controlled substance shall be in accordance with the following requirements:

(a) *Transfer to a person registered or authorized to accept controlled substances for the purpose of destruction.* If the controlled substances are transferred to a person registered or authorized to accept the controlled substances for the purpose of destruction, two employees of the transferring registrant shall load and unload or observe the loading and unloading of any controlled substances until transfer is complete.

(b) *Transport to a registered location.* If the controlled substances are transported by a registrant to a registered location for subsequent destruction, the following procedures shall be

followed:

(1) Transportation shall be directly to the registered location (the substances shall be constantly moving towards their final location and unnecessary or unrelated stops and stops of an extended duration shall not occur);

(2) Two employees of the transporting registrant shall accompany the controlled substances to the registered location;

(3) Two employees of the transporting registrant shall load and unload or observe the loading and unloading of the controlled substances until transfer is complete;

(c) *Transport to a non-registered location.* If the controlled substances are transported by a registrant to a destruction location that is not a registered location, the following procedures shall be followed:

(1) Transportation shall be directly to the destruction location (the substances shall be constantly moving towards their final destruction location and unnecessary or unrelated stops and stops of an extended duration shall not occur);

(2) Two employees of the transporting registrant shall accompany the controlled substances to the destruction location;

(3) Two employees of the transporting registrant shall load and unload or observe the loading and unloading of the controlled substances;

(4) Two employees of the transporting registrant shall handle or observe the handling of any controlled substance until the substance is rendered non-retrievable; and

(5) Two employees of the transporting registrant shall personally witness the destruction of the controlled substance until it is rendered non-retrievable.

(d) *On-site destruction.* If the controlled substances are destroyed at a registrant's

registered location utilizing an on-site method of destruction, the following procedures shall be followed:

- (1) Two employees of the registrant shall handle or observe the handling of any controlled substance until the substance is rendered non-retrievable; and
- (2) Two employees of the registrant shall personally witness the destruction of the controlled substance until it is rendered non-retrievable.

Dated: August 25, 2014

Michele M. Leonhart,
Administrator.

[FR Doc. 2014-20926 Filed 09/08/2014 at 8:45 am; Publication Date: 09/09/2014]

DEA Drug Take Back Requirements

Virginia Herold

December 17, 2014

DEA Regulations

- Released in early September 2014.

Who May Donate Drugs to Take Back

- Patients
- Estate
- Long-Term Care

Generally

- Do not count or sort collected drugs
- Do not store “liners” that have been filled and removed from the locked and secured containers (receptacles) more than 3 days in secure, locked locations
- “Employees” are specifically defined in the requirements, and collectors cannot employ anyone convicted of a felony related to controlled substances, or had a DEA permit denied, surrendered or revoked

Who Can Operate Drug Take Back

- Law Enforcement
- Manufacturers
- Distributors
- Reverse Distributors
- Narcotic Treatment Programs,
- Hospitals /Clinics with Onsite Pharmacies
- Retail Pharmacies

Law Enforcement

- Through take-back events
- Mail Back
- Collection Receptacles inside their facilities

- Must maintain records of removal, storage and destruction.
- Must store in a manner to prevent diversion and consistent for storing illicit controlled substances

Law Enforcement

- Items collected by law enforcement and transferred to reverse distributors shall be recorded and maintained in records

Manufacturers, Distributors
Reverse Distributors, Narcotic
Treatment Programs, Hospitals /Clinics
with Onsite Pharmacies, Retail
Pharmacies

Requirements

- Must obtain collector status from DEA, and notify DEA if cease to collect
- Hospital/clinic with pharmacy or retail pharmacy may operate collection receptacles at long-term care facilities

Collectors

- Collectors may
 - Receive and destroy mail back IF onsite destruction exists at location
 - Install, manage and maintain collection receptacles
 - Promptly dispose of sealed liners

Collection Receptacles

- Only authorized and DEA registered entities may use
- Once drug is placed in receptacle, the item cannot be counted or removed separately

Location of Receptacles

- Must be securely installed so the container cannot be removed
- Placed in an inside location
- Visible to employees, but not in emergency areas

Receptacles

- Be locked, with an inner liner
- Receptacle shall allow deposit of drugs into inner liner, without removal or access to drugs already deposited
- Outside container shall have text advising it is OK to collect Schedule II-V drugs, but not Schedule I drugs

Inner Liners

Must be:

- waterproof, tamper evident and tear resistant
- Removable and sealable without emptying
- Able to prevent viewing of contents when removed from collection receptacles
- Size of liner must be clearly marked (e.g., in gallons)
- Bear a permanent, unique identification number

Inner Liners

- Access to liner must be restricted to employees of the collector (“employees” are defined in the act)
- Inner liner must be sealed and witnessed by 2 employees upon removal from collection receptacle.
- Liners shall not be opened, x-rayed, analyzed or penetrated

Mail Back

- Any entity accepting mail back envelopes/packages containing drugs must have a method onsite appropriate to destroy the drugs
- Packages shall be nondescript and not include markings
- Packages must be water and spill proof, tamper evident, tear resistant and sealable
- Packages must be preaddressed and delivered to collectors registered address

Mail Back

- Postage prepaid
- Unique identification number for each package
- Contain instructions for users to mail back drugs
- Patients and estates do not need to identify themselves

Collectors with Mail Back

- Collect envelopes and packages
- Advise DEA of receipt of packages that did not agree to receive

Collection at Long-Term Care

- Within 3 days of discontinuance, death or discharge of a patient, unused drugs must be inserted into the collection bin
- Only a pharmacy or hospital/clinic with a pharmacy may install manage and maintain a collection bin in a long-term care facility (these entities must also become registered with the DEA as collectors)

Long-Term Care

- Only DEA registered entities as collectors may remove drugs from receptacles
 - Removal of liner may occur only with two employees
 - One employee may be a supervisor of employee at the collector location and one of long-term care facility
- Or
- 2 employees of the collector location

Long-Term Care

- Upon removal, sealed liners may only be stored at long-term care facility up to 3 business days in a securely locked cabinet

Reverse Distributors

- Requirements established for drugs collected from pharmacies (not take back from patients)
 - These requirements are separate from drug take back requirements
- Requirements establish if Rev Dist. accept mail back packages and liners

Reverse Distributors

- Requirements established if Rev Dist. accept mail back packages and liners
 - Date of receipt of sealed liners or mail back packages, and quantity
 - Unique identifier of each liner or package
 - Size of sealed liner (e.g., 5 or 10 gallon)
 - Name and registration number of entity submitting

Record Keeping Requirements

- Collectors must record and keep for 3 years
 - Number of liners obtained
 - Date of acquisition, capacity size (e.g., 5 or 10 gallon)
 - Unit identifier of each liner
 - Name, address and DEA registration number of from whom the liner was received
 - Names of signatures of 2 employees of registrant witnessing destruction.

Destruction

- 2 employees must load or unload any controlled substances until the transfer is complete
- When transferred to destruction location:
 2 employees must transport or
use of a common carrier

Miscellaneous & Generally

- Sealed mail back packages and inner liners shall ONLY be stored at registered location in a securely locked cabinet or room
- Every registrant who is a collector shall retain records and inventories and file reports. Records must be kept for 3 years

The Future

- The board will develop regulations for its licensees involved in drug take back
 - Reverse distributors
 - Pharmacies
- Work needs to be done on liners and unique identifiers for the liners
- For immediacy, encourage the use of mail back envelopes

Attachment 5

B&PC 4074

BUSINESS AND PROFESSIONS CODE - BPC

DIVISION 2. HEALING ARTS [500 - 4999.129] (*Division 2 enacted by Stats. 1937, Ch. 399.*)

CHAPTER 9. Pharmacy [4000 - 4426] (*Chapter 9 repealed and added by Stats. 1996, Ch. 890, Sec. 3.*)

ARTICLE 4. Requirements for Prescriptions [4070 - 4078] (*Article 4 added by Stats. 1996, Ch. 890, Sec. 3.*)

(a) A pharmacist shall inform a patient orally or in writing of the harmful effects of a drug 4074. dispensed by prescription if both of the following apply:

(1) The drug poses substantial risk to the person consuming the drug when taken in combination with alcohol or the drug may impair a person's ability to drive a motor vehicle, whichever is applicable.

(2) The drug is determined by the board pursuant to subdivision (c) to be a drug or drug type for which this warning shall be given.

(b) In addition to the requirement described in subdivision (a), on and after July 1, 2014, if a pharmacist exercising his or her professional judgment determines that a drug may impair a person's ability to operate a vehicle or vessel, the pharmacist shall include a written label on the drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel. The label required by this subdivision may be printed on an auxiliary label that is affixed to the prescription container.

(c) The board may by regulation require additional information or labeling.

(d) This section shall not apply to a drug furnished to a patient in conjunction with treatment or emergency services provided in a health facility or, except as provided in subdivision (e), to a drug furnished to a patient pursuant to subdivision (a) of Section 4056.

(e) A health facility shall establish and implement a written policy to ensure that each patient shall receive information regarding each drug given at the time of discharge and each drug given pursuant to subdivision (a) of Section 4056. This information shall include the use and storage of each drug, the precautions and relevant warnings, and the importance of compliance with directions. This information shall be given by a pharmacist or registered nurse, unless already provided by a patient's prescriber, and the written policy shall be developed in collaboration with a physician, a pharmacist, and a registered nurse. The written policy shall be approved by the medical staff. Nothing in this subdivision or any other law shall be construed to require that only a pharmacist provide this consultation.

(Amended by Stats. 2013, Ch. 304, Sec. 1. Effective January 1, 2014.)

16 CCR 1744

**Proposed 1744 Language
with Comments From
Pharmacy Schools**

Proposed Language with Comments from Pharmacy Schools

1744. Drug Warnings.

Pursuant to Business and Professions Code Section 4074, a pharmacist shall inform the patient or his or her representative of the harmful effects of certain drugs dispensed by prescription.

(a) The following classes of drugs may impair a person's ability to drive a motor vehicle or operate machinery when taken alone or in combination with alcohol:

(1) Muscle relaxants.

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

(3) Antipsychotic drugs with central nervous system depressant effects including phenothiazines. (one commenter left the strike out in)

(4) Antidepressants with central nervous system depressant effects.

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

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

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

(8) Ramelteon (Sedation)

(9) Minoxidil (Hypotension)

(10) Phosphodiesterase V inhibitors (hearing and visual impairment)

(11) Bromocriptine (dizziness and fatigue exacerbates alcohol)

(b) The following are examples of drugs which may have harmful effects when taken in combination with alcohol. These may or may not affect a person's ability to operate a motor vehicle.

(1) Disulfiram and other drugs (e.g. ~~chlorpropamide~~, sulfonylureas, cephalosporins, trimethoprim, isoniazid, isotretinoin, griseofulvin, ketoconazole, metronidazole) which may cause a disulfiram-like reaction.

(2) Mono amine oxidase inhibitors.

(3) Nitrates.

(4) Cycloserine

(5) Verapamil (enhanced alcohol intoxication)

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

(7) Niacin (increased risk of flushing and pruritis)

(8) Erythromycin (may increase absorption of alcohol

Or/and

(b)(2) Monoamine oxidase inhibitors (due to the risk of hypertensive crisis if the alcohol contains significant amounts of tyramine (some beer, red wine)

(b)(3) Nitrates due to the risk of additive cardiovascular effects.

Or/And

(c) Corticosteroids (BEERS list to avoid in the elderly)

(d) Dipyridamole (BEERS list to avoid in the elderly)

**Proposed 1744 Language
from the September 2014
Committee Meeting**

Proposed Language – September 2014

1744. Drug Warnings.

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

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

(1) Muscle relaxants.

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

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

(4) Antidepressants with central nervous system depressant effects.

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

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

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

(b) The following are examples of drugs which may have harmful effects when taken in combination with alcohol. These may or may not affect a person's ability to operate a motor vehicle:

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

(2) Mono amine oxidase inhibitors.

(3) Nitrates.

(4) Cycloserine.

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

Attachment 6

DEA 106 Reports by License Category

Category	2011	2012	2013	2014
Pharmacy	376	460	943	1,437
Hospital	115	104	230	195
Wholesaler	33	35	58	84
Out of State Distributor	1	6	8	4
Correctional Facility	10	5	2	9
Clinic	1	2	0	2
Non Resident Pharmacy	0	1	0	0
Drug Room	0	0	1	0
Other	0	0	2	1
Totals	536	613	1,244	1,732

Sum of Units by Loss Type - 2014

Loss Type	Sum of Quantity	% of Grand Total
Employee Pilferage	487,712	32%
Night Break-In	452,360	29.8%
Other	257,488	16.9%
Armed Robbery	238,036	15.7%
Lost In Transit	54,094	3.6%
Customer Theft	30,502	2%
Totals	1,520,192	100%

**Proposed Language from
the September 2014
Committee Meeting**

Proposed Language - September 2014

1715.65 Monthly Inventory Counts of Fastest Moving Controlled Substances

- (a) Every June 30th, each pharmacy and clinic licensed by the board shall identify its top 10 controlled substances dispensed by the licensee as measured in dosage units in the prior 12 months (July 1 – June 30).
- (b) Effective July 1 and each month thereafter until the next June 30 (for a total of 12 months), the pharmacy or clinic shall count and reconcile the inventory of the top 10 controlled substances identified pursuant to subdivision (a). This reconciliation shall include for each of the controlled substances:
 - (1) The inventory recorded on the first of the preceding month
 - (2) The additions to inventory made in the preceding month (e.g., purchases, transfers in, will-call items that were never handed out that were counted as dispositions the prior month)
 - (3) The dispositions (e.g., dispensing, saleable returns to a wholesaler, drugs provided to a reverse distributor for destruction) from inventory made in the preceding month
 - (4) The drugs in quarantine waiting for the reverse distributor,
 - (5) The final inventory count on the first of the month
 - (6) The pharmacy shall attempt to reconcile overages or shortages. Shortages must be reported to the board.
 - (7) The name of the individual conducting the inventory and date the inventory required by this subdivision was performed
- (c) Losses of controlled substances identified from the monthly audit shall be reported to the board as required by section 1716.5 and Business and Professions Code section 4104.
- (d) The pharmacist-in-charge or consultant pharmacist for the clinic shall sign each monthly inventory performed under this section indicating he or she has reviewed the inventory taken.
- (e) The pharmacist-in-charge or consultant pharmacist shall perform a quality assurance review of the monthly and annual inventories to establish secure methods to prevent losses of all dangerous drugs.

**Proposed Language from
the December 2014
Committee Meeting**

Proposed Language – December 2014

1715.65 Monthly Inventory Counts of Fastest Moving Controlled Substances

- (a) Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall maintain a perpetual inventory for all controlled substances acquired by the licensee.
- (b) As an alternative to the maintenance of a perpetual inventory, a pharmacy or clinic must have a policy that identifies a monthly reconciliation process for the ten highest volume controlled substances purchased by the licensee. This policy shall address reconciliation of all purchases and acquisitions, dispenses, pharmacy inventory, including inventory in quarantine for the reverse distributor for the previous 30-day period.
- (c) Losses of controlled substances identified from the monthly audit shall be reported to the board as required by section 1716.5 and Business and Professions Code section 4104.
- (d) The pharmacist-in-charge or consultant pharmacist for the clinic shall sign and date each monthly reconciliation within 14-days of completion.
- (e) The pharmacist-in-charge or consultant pharmacist shall perform a quality assurance review of all inventories and reconciliations to establish and maintain secure methods to prevent losses of all dangerous drugs.

Attachment 7

Maximize the security, availability and predictability of medications

CUBIE® system for Pyxis® technologies

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

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



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

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

Pyxis®

 CareFusion

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

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



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

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

Facilitating medication safety, CUBIE system helps:

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

Increasing choice and storage capacity to optimize customization

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

Half-height CUBIE pockets

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

Available for all Pyxis MedStation systems.

Full-height CUBIE pockets

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

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

CareFusion
San Diego, CA

carefusion.com



Diversion prevention and detection

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

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

The purpose of this document is to:

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

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

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

- **Pyxis Profile:** Profile limits user access to those medications that were ordered for a specific patient and were verified and entered into the pharmacy information system by the pharmacist. This prevents the user from removing a controlled substance that was not ordered by the physician. The exception would be those medications available via override that the user has the privilege to remove.
- **BioID fingerprint identification system:** Use of this system physically verifies a user's identity with a fingerprint scan prior to granting access to the station. The system enhances security by decreasing the chances of diversion due to lost, stolen or shared passwords or swipe cards. Use of the BioID system meets state regulatory requirements for physical identification of users.
- **Clinical Data Categories (CDCs):** CDCs can be used to require a reason for overriding a medication. This may help reduce chances of diversion because of the perception of increased monitoring of the user and override reason.
- **Too Close removal warning:** A Too Close removal warning can be set to appear when a user removes a medication on a patient that previously had the same medication removed within a defined time frame. The warning will appear even if the medication was removed at another Pyxis MedStation system, as long as it is the same med ID and within the defined time frame. The warning will appear at both profile and non-profile Pyxis MedStation systems. Users can override the remove warnings, but they are required to document a reason (select from predetermined list or type in) before continuing with the removal. A report of the warning overrides can be printed at the console and reviewed for appropriateness. This feature will discourage a diverter from removing multiple doses in a short period of time.
- **Override settings:** The Override settings allow a user to remove a medication from a profile Pyxis MedStation system prior to a pharmacist review and verification of the order. The ability to remove a drug via override can be limited by drug and by user. Limiting the number of controlled substances available via override (especially oral medications) can decrease the potential for diversion.
- **Witness on Override:** When the Witness on Override setting is turned on at the console, a witness is required

each time a medication is removed from a profile Pyxis MedStation system via override. This feature will stop a diverter from removing controlled substances via override independently. Consider the availability of a witness to override before deciding to use this feature.

- **Return bins:** Return bins are a standard feature of the Pyxis MedStation system. Returning all controlled substances to the return bin for inspection by pharmacy personnel prevents a tampered with medication from being returned to stock.
- **Witness to Empty Return Bins:** The Witness to Empty Return Bins setting can be turned on at the console. Requiring a witness protects the pharmacy technician and the user from suspicion of diversion.
- **Menu Time Out:** The Menu Time Out is set at the console for each Pyxis MedStation system and will automatically log out the user if there is no activity during this time. Set the menu time out for 1 minute 30 seconds or less. A time out of two minutes or more gives a diverter ample time to remove a controlled substance under another user's name, if that user does not exit prior to walking away from the Pyxis MedStation system.
- **Discharge Delay:** Discharge Delay is set at the console for each Pyxis MedStation system to allow a user to return or waste a medication on a patient that was recently discharged. Set the discharge delay for two hours or less. A long discharge delay provides a diverter an opportunity to remove controlled substances on a patient that is discharged.
- **Lock Loops:** Security Lock Loops can be installed on Pyxis MedStation systems that are located in areas that are not staffed 24 hours per day.

Policies that help deter controlled substance diversion

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

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

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

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

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

Reports used to monitor for diversion

Pyxis MedStation system station reports

- **Activities reports:**

- **Run reports:** Encourage staff to print an Activity report by user at the end of each shift to verify activity. This identifies problems with password security and failure to log off of the system. Users may also print an Activity report for controlled substances on their patients. This will identify another user removing controlled substances for their patients.
- **Review reports:** Encourage nurse managers to review Activity reports for controlled substances to verify that activity is limited to nurses assigned to the unit and shift. Activity reports can also be used to conduct concurrent audits of activity by drug, user or patient. Printed activity for one of these parameters can be compared with the patient's orders to assure the removal matched the order, the removal matched the order time frame, documentation of administration matched the order and removal, waste matched the order and removal and there was a clinical indication for the ordered medication.

- **Discrepancy reports:**

- **Run reports:** All discrepancies should be resolved according to hospital policy (usually by the end of each shift). The oncoming and offgoing charge nurses should check to make sure there are no icons on the Pyxis devices, which indicate an open discrepancy. Some hospitals have the charge nurse leave documentation that they looked for open discrepancies and that all are resolved. They run an Open Discrepancy report at the end of the shift, review and sign the report and leave it for the nurse manager to review. There should be no open discrepancies on the report.

- **Review reports:** Encourage nurse managers to review the discrepancy report on the Pyxis MedStation system for compliance with hospital policy and to look for trends and patterns. The nurse managers need to know the number of discrepancies occurring on their units. This includes resolved and unresolved discrepancies. When reviewing each discrepancy, note the reason for the discrepancy and whether it makes sense. Look for the same user or pairs of users consistently creating/resolving discrepancies.

- **Return/Waste reports:** Recommend nurse managers routinely print the Return/Waste report by user and perform random audits of nurses for accurate documentation of controlled substances removed from and wasted at the Pyxis MedStation system. Wastage of partial controlled drugs can be performed either at the time of withdrawal or after administration. Predetermined waste locations can be added to the waste CDC to avoid having to type in the location.
- **Override report:** Removing controlled substances via override can be a source of diversion. Nurse managers can monitor the Override report at the station to assure there is an order for the medication removed on override and that the circumstances warrant an override. Also look for users that override medications even though there is a profiled order for that medication.

Pyxis MedStation system console reports

- **Daily reports:**

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

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

- **Weekly reports:**

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

- **On-demand reports:**

- **All Station Events by User report:** Run this report to review user-specific transactions. (Use Pyxis C¹Safe system Proactive Diversion Search report to identify high-access users.)
- **All Station Events by Station/Med report:** Run this report as needed for specific medication/nursing unit to aid in discrepancy resolution.

Pyxis C¹Safe system reports

See Pyxis C¹Safe system reporting clinical white paper on the CareFusion Customer Connection website at pyxis.com/CustomerConnection.aspx.

- **Open Discrepancies report:** This report lists items in the Pyxis C¹Safe system with counts different than what's expected. Run this report at the end of each shift.
- **All Pyxis C¹Safe Events report:** This report shows all Pyxis C¹Safe system drug transactions for the prior 24-hour period. The report automatically runs at midnight.
- **Pyxis C¹Safe Compare report:** Run this report after all deliveries are completed to make sure all controlled substances sent from the Pyxis C¹Safe system were placed into the appropriate Pyxis MedStation system. It assists in detecting potential diversion as well as detecting pocket refill, unload or load errors.
- **Reconcile Physical Counts report:** Use this report to verify and document the counts of the controlled substance vault.
- **Pyxis MedStation system Transaction report:** This report provides a record of the Pyxis MedStation system transactions that happened prior to the last 31 days. It can be used to research outliers found on the Proactive Diversion Search report and to review Pyxis MedStation system cancelled transactions.
- **Review Transaction Corrections report:** This report provides a list of the corrections that have been made to certain transactions (i.e., compound, prescription, receive, return, sale, send or waste). It provides specific details for the transaction such as who corrected it, why and witness if applicable. This report allows management to monitor any transaction corrections.
- **Review Resolve Discrepancies report:** This report prints all discrepancies that have been documented using the discrepancy resolution feature on the Pyxis C¹Safe system. The Resolve Discrepancy function should be reserved to those circumstances when the controlled substance transaction cannot be fixed (with a second transaction) or corrected (via the Transaction Correction routine), and is therefore irresolvable.

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

Integrated Analytics Solutions

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

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

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

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CareFusion
San Diego, CA

carefusion.com





Medication Management and Diversion

California Board of Pharmacy

March 2015
Crystal Woodward
Shari Gaukroger



Agenda

- Introduction
- System basics
- Drawer types
- Configuration options
- Reporting options
- Q & A Session

Pyxis technologies

Designed to meet customer challenges



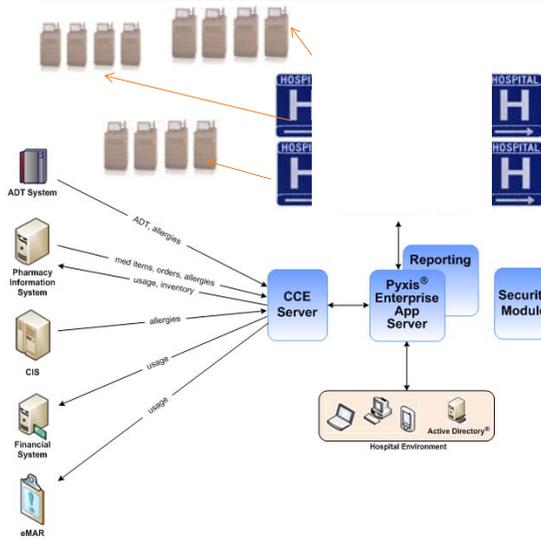
Strength of a platform

- Power of **one** database
- **Web-accessible** for more access to system & reporting
- Leverage a single source for formulary or user information
- Better manage **user privileges** and **security groups**- across multiple sites
- **Integrate with Pharmacy Information System** to standardize formulary management
- **Integrate with Active Directory** to standardize user management

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Flexible System Management



- Central Enterprise Databases
- Users – Active Directory
- Formulary
- Interfaces – One Enterprise Set
- IT – VM in IT Environment
- Server - Web Access

- Standardized Data
- One Source of Truth
- Enterprise Visibility
- Single Interface Feed
- High Security
- Ease of Deployment & Upkeep
- Browser-Based Remote Access

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Pyxis technologies

Designed to meet customer challenges



MedStation Drawer Types

- Improved secure storage with new CUBIE® pockets
- Mini drawer configured in single dose or multi dose mode

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Pyxis CUBIE® pockets

- Secure access to single, larger medications
- Enhanced security supports diversion prevention
- Quicker, more reliable access to medications
- Improved serviceability

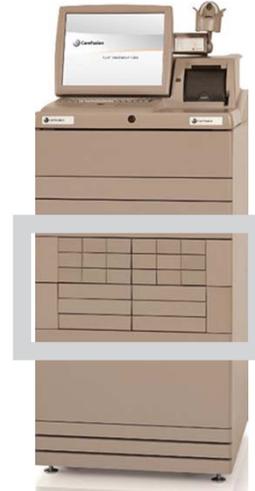
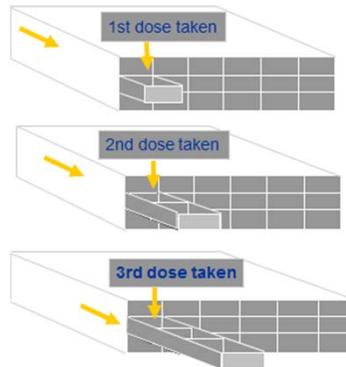


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Pyxis MiniDrawer

- Single dose or multi dose modes
- Different sizes of trays/pockets available



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Configuration options

Helping to prevent diversion

- Formulary management
 - Security groups
 - Override groups
 - Witness required on waste and inventory workflows
 - Verify count and blind count
- User setup
 - Require biometric technology for login activities
 - Require witness for failed biometric logon attempts
 - Create standard user templates
 - Limit who can add users

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Configuration options

Helping to prevent diversion

- Device management
 - Use the witness to empty return bin feature
 - Enforce waste upon remove workflows
 - Menu timeout
 - Open drawer timeout
 - Discharge delay
 - BioID Push with Witness
 - Too Close Remove Warning
 - Clinical Data Categories
 - LockLoop

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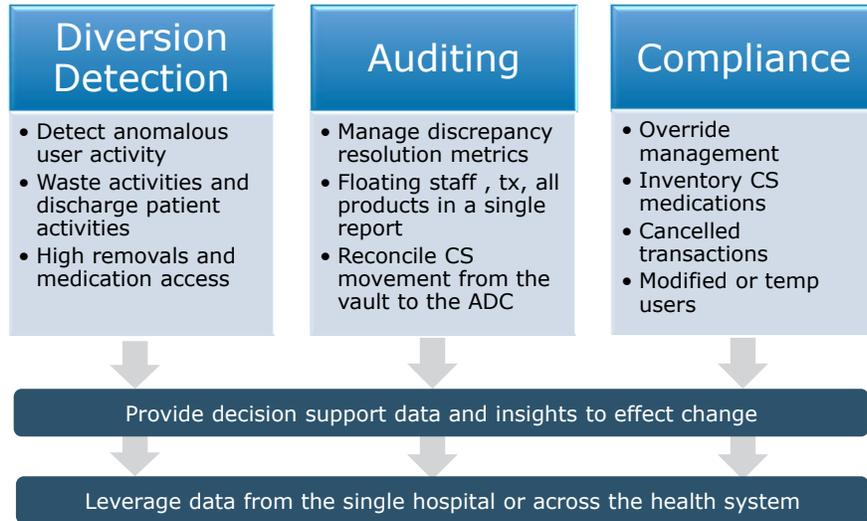
Diversion reporting

Shari Gaukroger
Market Manager
Dispensing Analytics and Hosted
Solutions



Benefits of analytical insights

Diversion detection and reporting



Diversion Detection

- Detect anomalous user activity
- Waste activities and discharge patient activities
- High removals and medication access

Auditing

- Manage discrepancy resolution metrics
- Floating staff , tx, all products in a single report
- Reconcile CS movement from the vault to the ADC

Compliance

- Override management
- Inventory CS medications
- Cancelled transactions
- Modified or temp users

Provide decision support data and insights to effect change

Leverage data from the single hospital or across the health system

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Diversion detection

Enhanced anomalous user activity

Statistical Outliers By Station									
5.0 or Greater Units of Standard Deviation Above Mean									
Station	Med Group	User Name	Count	Mean	UAM	% TDC	TriageRx	TrendRx	ProjectRx
MEDSURG	Hydroxyzine	DEBLASIO, YOLANDA	134	16.735	6.110	16.341%	▲	3.51 6.11	—
MEDSURG	Meperidine	DEBLASIO, YOLANDA	44	6.524	5.331	16.058%	▲	4.74 5.33	—
4.0 - 4.9 Units of Standard Deviation Above Mean									
Station	Med Group	User Name	Count	Mean	UAM	% TDC	TriageRx	TrendRx	ProjectRx
MEDSURG	Percocet	DEBLASIO, YOLANDA	50	6.733	4.754	24.752%	▲	4.10 4.75	—
3.0 - 3.9 Units of Standard Deviation Above Mean									
Station	Med Group	User Name	Count	Mean	UAM	% TDC	TriageRx	TrendRx	ProjectRx
ICU	Fentanyl	HURKE, ANTHONY	13	1.611	3.937	44.828%	▲	— 3.94	—
ICU	Tramadol	HAMMOND, BRANDY	10	2.675	3.911	9.346%	▲	— 3.91	—
ICU	Morphine	HULL, DOROTHY	23	6.320	3.753	4.852%	▲	— 3.75	—
MEDSURG	Morphine	DEBLASIO, YOLANDA	41	10.149	3.745	8.595%	▲	5.16 4.93 3.74	3.0160

- Classifies controlled substance outliers by statistical risk in descending order
- TriageRx triangulates the users controlled substance activity by analyzing house-wide, by care area and daily average usage by days worked compared to their peers.
- Help prioritize internal audits based on user activity

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Benchmark users activities

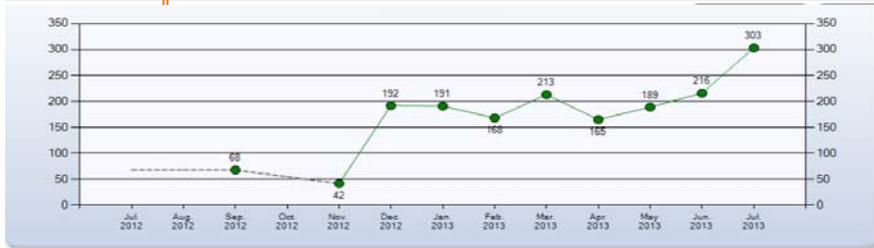
Visibility into usage and workflow

Barber, Ella

Table View Chart View

Doses Dispensed from Pyxis MedStation® system

Station Name	Station Type	# of Vends	# of Doses Dispensed	
MS4000-013	Med Station - Profile	57	601	Trend
MS4000-014	Med Station - Profile	10	14	Trend
MS4000-015	Med Station - Profile	5	8	Trend



Diversion monitoring

Report examples

Waste Station	Type of Waste	Waste Amount	Waste User ID	Waste User Name	Waste User Type	Witness User ID	Witness User Name	Witness User Type	Waste Transaction Date/Time	Duration to Waste	Dispense User = Witness User
Stn24	WASTE	(AMT WASTED: 0.1 MG)	DNE8904	Dawson, Eleanor	RN	Scott.Broc	Scott, Brock	CHARGE NURSE	09/06/2013 22:17:23	02:27:26	N
Stn56	WASTE	(AMT WASTED: 2 MG)	CNK5415	Herrera, Perry	CRNA	Mclaughlin	Mclaughlin, Marshall	CRNA	09/06/2013 17:27:21	02:55:13	N
Stn13	WASTE	(AMT WASTED: 1 MG)	BIL9027	Donaldson, Orli	RN	Hines.Lynn	Hines, Lynn	RN-RAPID RESPONSE	09/06/2013 16:05:43	01:00:50	N
Stn8	WASTE	(AMT WASTED: 790 MG)	FFA9440	Morgan, Hop	RN	Mendoza.Ha	Mendoza, Hakeem	IV START TEAM - RN	09/06/2013 15:24:06	08:33:26	N
Stn43	WASTE	(AMT WASTED: 50 MCG)	VZJ9153	Waller, Eric	RN	Aguilar.El	Aguilar, Elijah	RN	09/06/2013 15:15:31	04:53:47	N
Stn112	WASTE	(AMT WASTED: 100 MCG)	YNH4011	Randall, Martina	RAD TECH	Carney.Upt	Carney, Upton	CHARGE NURSE	09/06/2013 14:50:12	01:11:20	N

Suggested reports

Reports	Frequency
Compare CS Vault removes to ADC refills and loads	Every shift or at least daily
Review CS override removals	Daily
Check modifications in user access	Daily
Review CS discrepancy report (all)	Daily
Review compliance with CS inventory counts	Weekly
Evaluate cancelled transactions	Daily
Review remove reports for high activity	Monthly
Review waste activities for completeness and look for user/witness pairs	Monthly

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Questions?



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Attachment 8

Article 10. ~~Wholesalers~~ Dangerous Drug Distributors

1780. Minimum Standards for ~~Wholesalers~~

The following minimum standards shall apply to all wholesale and third-party logistics provider establishments for which permits have been issued by the Board:

- (a) A wholesaler and a third-party logistics provider shall store dangerous drugs in a secured and lockable area.
- (b) All wholesaler and third-party logistics provider premises, fixtures and equipment therein shall be maintained in a clean and orderly condition. Wholesale and third-party logistics provider premises shall be well ventilated, free from rodents and insects, and adequately lighted. Plumbing shall be in good repair. Temperature and humidity monitoring shall be conducted to assure compliance with the United States Pharmacopeia Standards (1990, 22nd Revision).
- (c) Entry into areas where prescription drugs are held shall be limited to authorized personnel.
 - (1) All facilities shall be equipped with an alarm system to detect entry after hours.
 - (2) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.
 - (3) The outside perimeter of the wholesaler premises shall be well-lighted.
- (d) All materials must be examined upon receipt or before shipment.
 - (1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.
 - (2) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.
- (e) The following procedures must be followed for handling returned, damaged and outdated prescription drugs.
 - (1) Prescription drugs that are outdated, damaged, deteriorated, misbranded or adulterated shall be placed in a quarantine area and physically separated from other drugs until they are destroyed or returned to their supplier.
 - (2) Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be placed in a quarantine area and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.
 - (3) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the drug shall be destroyed or returned to the supplier unless testing or other investigation proves that the drug meets appropriate United States Pharmacopeia Standards (1990, 22nd Revision).
- (f) Policies and procedures must be written and made available upon request by the board.
 - (1) Wholesale and third-party logistics provider drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, for correcting all errors and inaccuracies in inventories, and for maintaining records to document proper storage.

- (2) The records required by paragraph (1) shall be in accordance with Title 21, Code of Federal Regulations, Section 205.50(g). These records shall be maintained for three years after disposition of the drugs.
 - (3) Wholesale and third-party logistics provider drug distributors shall establish and maintain lists of officers, directors, managers and other persons in charge of ~~wholesale~~ drug distribution, storage and handling, including a description of their duties and a summary of their qualifications.
 - (4) Each wholesaler and third-party logistics provider shall provide adequate training and experience to assure compliance with licensing requirements by all personnel.
- (g) The board shall require an applicant for a licensed premise or for renewal of that license to certify that it meets the requirements of this section at the time of licensure or renewal.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4043, 4051, 4053, 4054, 4059, 4120, 4160, 4161 and 4304, Business and Professions Code.

1780.1. Minimum Standards for Veterinary Food-Animal Drug Retailers.

Not relevant to third-party logistics providers

1781. Exemption Certificate.

A registered pharmacist, ~~or an~~ designated representative or designated representative –3PL certified in accordance with Section 4053, 4053.1 or 4054 of the Business and Professions Code shall be present and in control of a manufacturer's ~~or~~ wholesaler's or a third-party logistics provider's licensed premises during the conduct of business.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4053, 4053.1 or 4054, Business and Professions Code.

1782. Reporting Sales of Drugs Subject to Abuse.

All manufacturers, ~~and~~ wholesalers and third-party logistics providers shall report to the Board or its designee, up to twelve (12) times a year, all sales of dangerous drugs subject to abuse as designated by the Board for reporting, in excess of amounts to be determined by the Board from time to time. Reports shall be made within thirty (30) days of the request in the form specified by the Board.

Authority cited: Section 4005, Business and Professions Code; and Section 26692, Health and Safety Code. Reference: Sections 4081 and 4332, Business and Professions Code; and Section 26692, Health and Safety Code.

1783. Manufacturer, ~~or~~ Wholesaler or Third-Party Logistics Provider Furnishing Drugs and Devices.

(a) A manufacturer, ~~or~~ wholesaler or third-party logistics provider shall furnish dangerous drugs or devices only to an authorized person; prior to furnishing dangerous drugs and devices to a person not known to the furnisher, the manufacturer, ~~or~~ wholesaler or third-party logistics provider shall contact the board or, if the person is licensed or registered by another government entity, that entity, to confirm the recipient is an authorized person.

(b) “Authorized person” means a person to whom the board has issued a permit which enables the permit holder to purchase dangerous drugs or devices for use within the scope of its permit. “Authorized person” also means any person in this state or in another jurisdiction within the United States to the extent such furnishing is authorized by the law of this state, any applicable federal law, and the law of the jurisdiction in which that person is located. The manufacturer or wholesaler furnishing to such person shall, prior to

furnishing the dangerous drugs and devices, establish the intended recipient is legally authorized to receive the dangerous drugs or devices.

(c) Dangerous drugs or devices furnished by a manufacturer, ~~or wholesaler~~ or third-party logistics provider shall be delivered only to the premises listed on the permit; provided that a manufacturer, ~~or wholesaler~~ or third-party logistics provider may furnish drugs to an authorized person or an agent of that person at the premises of the manufacturer, ~~or wholesaler~~ if (1) the identity and authorization of the recipient is properly established and (2) this method of receipt is employed only to meet the immediate needs of a particular patient of the authorized person. Dangerous drugs or devices may be furnished to a hospital pharmacy receiving area provided that a pharmacist or authorized receiving personnel signs, at the time of delivery, a receipt showing the type and quantity of the dangerous drugs or devices so received. Any discrepancy between the receipt and the type and quantity of dangerous drugs and devices actually received shall be reported to the delivering manufacturer, ~~or wholesaler~~ or third-party logistics provider by the next business day after the delivery to the pharmacy receiving area.

(d) A manufacturer, ~~or wholesaler~~ or third-party logistics provider shall not accept payment for or allow the use of an entity's credit to establish an account for the purchase of dangerous drugs or devices from any person other than: (1) the owner(s) of record, chief executive officer, or chief financial officer listed on the permit for the authorized person; and (2) on an account bearing the name of the permittee.

(e) All records of dangerous drugs or devices furnished by a manufacturer, ~~or wholesaler~~ or third-party logistics provider to an authorized person shall be preserved by the authorized person for at least three years from the date of making and shall, at all times during business hours, be open to inspection by authorized officers of the law at the licensed premises. The manufacturer, ~~or wholesaler~~ or third-party logistics provider shall also maintain all records of dangerous drugs or devices furnished pursuant to this section for at least three years from the date of making and shall, at all times during business hours, keep them open to inspection by authorized officers of the law at the premises from which the dangerous drugs or devices were furnished.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4043, 4059, 4059.5, 4080, 4081, 4120, 4160, 4161, 4163 and 4304, Business and Professions Code; and Section 11209, Health and Safety Code.

1784. Self-Assessment of a Wholesaler by the Designated Representative-in-Charge.

This section will be modified to also establish a self assessment process for the third-party logistics provider by the responsible manager. The changes have not been incorporated below

(a) The designated representative-in-charge of each wholesaler as defined under section 4160 of the Business and Professions Code shall complete a self-assessment of the wholesaler's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the designated representative-in-charge shall complete a self-assessment within 30 days whenever:

(1) A new wholesaler permit is issued, or

(2) There is a change in the designated representative-in-charge. The new designated representative-in-charge of a wholesaler is responsible for compliance with this subdivision.

(3) There is a change in the licensed location of a wholesaler to a new address.

(c) The components of this assessment shall be on Form 17M-26 (Rev. 01/11) entitled "Wholesaler Dangerous Drugs & Dangerous Devices Self-Assessment" which is hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.

- (d) Each self-assessment shall be kept on file in the licensed wholesale premises for three years after it is completed.
- (e) The wholesaler is jointly responsible with the designated representative-in-charge for compliance with this section.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4043, 4053, 4059, 4120, 4160, 4161, 4201, 4301 and 4305.5, Business and Professions Code.



Third-Party Logistics Provider DANGEROUS DRUGS & DANGEROUS DEVICES SELF-ASSESSMENT

All legal references used throughout this self-assessment form are explained on page 21.

All references to “drugs” throughout this self-assessment refer to dangerous drugs and dangerous devices as defined in Business & Professions Code (B&PC) section 4022.
(http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf).

Third-Party Logistics Provider’s Name _____

Address _____

Phone _____

Third-Party Logistics Provider’s e-mail address _____

Ownership: Please mark one

- sole owner partnership corporation LLC
- non- licensed owner Other (please specify) _____

CA 3PL Permit # _____ Expiration Date _____

Other Permit # _____ Expiration Date _____
(Use additional sheets if needed.)

DEA Registration # _____ Expiration Date _____

VAWD Accreditation # _____ Expiration Date _____

Date of most recent DEA Inventory _____

Hours: Weekdays _____ Sat _____ Sun _____ 24 Hours

Responsible Manager / pharmacist (RPH) _____

Responsible Manager’s Designated Representative – 3PL License # / RPH

License# _____

Expiration Date _____

Website Address (optional): _____

Licensed 3PL Staff (designated representative -3PL (DR-3PL), pharmacist):

- 1. _____ DR-3PL#/RPH# _____ Exp. Date _____
- 2. _____ DR-3PL#/RPH# _____ Exp. Date _____
- 3. _____ DR-3PL#/RPH# _____ Exp. Date _____
- 4. _____ DR-3PL#/RPH# _____ Exp. Date _____
- 5. _____ DR-3PL#/RPH# _____ Exp. Date _____
- 6. _____ DR-3PL#/RPH# _____ Exp. Date _____
- 7. _____ DR-3PL#/RPH# _____ Exp. Date _____
- 8. _____ DR-3PL#/RPH# _____ Exp. Date _____
- 9. _____ DR-3PL#/RPH# _____ Exp. Date _____
- 10. _____ DR-3PL#/RPH# _____ Exp. Date _____

Please mark the appropriate box for each question. If “NO,” enter an explanation on the “CORRECTIVE ACTION OR ACTION PLAN” lines at the end of the section. If more space is needed, add additional sheets.

1. Ownership/Location

Yes No N/A

- 1.1. Review the current third-party logistics provider permit for this business. Are the listed owners correct and is the listed address correct? If not, please indicate discrepancy. If either is incorrect, notify the board in writing immediately. (B&PC 4160[a][c][f]) **Attach a copy of the notification letter to the board to this document.**
- 1.2. Have you established and do you maintain a list of officers, directors, managers and other persons in charge of drug distribution, handling and storage? The list must contain a summary of the duties and qualifications for each job listed. ~~(CCR~~ (CCR 1780[f][3]) **Please attach a copy of the list to this document.** (This list should be dated.)

Note: Upon request, the owner must provide the board with the names of the owners, managers and employees and a brief statement of the capacity in which they are employed. (B&PC 4082)

CORRECTIVE ACTION OR ACTION PLAN _____

2. Facility

2.1. Premises, fixtures and equipment:

Yes No N/A

- 2.1.1. Are clean and orderly
- 2.1.2. Are well ventilated
- 2.1.3. Are free from rodents and insects
- 2.1.4. Are adequately lit
- 2.1.5. Have plumbing in good repair
- 2.1.6. Have temperature & humidity monitoring to assure compliance with USP Standards. (The standards for various drugs may differ, see USP 1990 22nd Edition) (CCR 1780[b])

- 2.2. Is there a quarantine area for outdated, damaged, deteriorated, or misbranded drugs, drugs with the outer or secondary seal broken, partially used containers, or any drug returned under conditions that cast doubt on the drugs safety, identity, strength, quality or purity? (CCR 1780[e])

Yes No N/A

2.3. Are dangerous drugs and dangerous devices stored in a secured and locked area? (CCR 1780[a])

2.4. Is access to areas where dangerous drugs are stored limited to authorized personnel? (CCR 1780[c])

List personnel with keys to the area(s) where drugs are stored (list by name or job title):

Yes No N/A

2.5. Does this business operate only when a designated representative -3PL or pharmacist is on the premises? (CCR 1781)

2.6. The third-party logistic provider’s premises is equipped with the following specific security features:

2.6.1. There is an alarm to detect after-hours entry. (CCR 1780[c][1]).

2.6.2. The outside perimeter of the building is well lit (CCR 1780[c][3]).

2.6.3. The security system provides protection against theft and diversion including tampering with computers and or electronic records. (CCR 1780[c][2]).

Explain how your security system complies with these requirements.

Yes No N/A

2.7. Is this business a “reverse distributor,” that is, does the business act as an agent for pharmacies, drug wholesalers, manufacturers and others, by receiving, inventorying and managing the disposition of outdated or nonsalable drugs? (B&PC 4040.5, 4044.5) **List Code section**

CORRECTIVE ACTION OR ACTION PLAN _____

Yes No N/A

2.8. The facility is subscribed to the board's e-mail notifications. (B&PC 4013)

Date Last Notification Received: _____

E-mail address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN _____

Yes No N/A

2.9. The facility receives the board's e-mail notifications through the owner's electronic notice system. (B&PC 4013[c])

Date Last Notification Received: _____

E-mail address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN _____

Note: There are specific requirements for distribution of controlled substances – these additional requirements are in Section 11 of this document.

3. Designated Representative-in-Charge - 3PL / Owner Responsibilities

Yes No N/A

3.1. The responsible manager of the third-party logistics provider is licensed as a designated representative -3PL and maintains this licensure while serving as the responsible manager of the third-party logistics provider premises. (B&PC 4060[e])

Yes No N/A

3.2. The owner and the responsible manager are both equally responsible for maintenance of the records and inventory. (B&PC 4081[b])

3.3. The responsible manager is at least 18 years of age and is responsible for the third-party logistic provider's compliance with all state and federal laws for the distribution of drugs? **The responsible manager may be a pharmacist.** (B&PC 4160[e])

3.4. The owner must notify the board within 30 days of termination of the responsible manager **or pharmacist.** (B&PC 4305.5[a])

3.5. The owner must identify and notify the board of the appointment of a new responsible manager within 30 days of the termination of the former responsible manager. (B&PC 4160[g], 4331[c]) The appropriate form for this notification is a "Change of Facility Manager for Third-Party Logistics Provider Premises," which is available on the board's website.

Yes No N/A

3.6. The responsible manager who ends his or her employment at a third-party logistics provider, must notify the board within 30 days. (B&PC 4305.5[c], 4101[c]). This notification is in addition to that required of the owner.

CORRECTIVE ACTION OR ACTION PLAN _____

4. Designated Representative-3PL/Pharmacist

Yes No N/A

If a designated representative -3PL or pharmacist changes his/her name or personal address of record, he/she must notify the board in writing within 30 days. (B&PC 4100, CCR 1704)

CORRECTIVE ACTION OR ACTION PLAN _____

5. Ordering Drugs by this Business for Future Sale/Transfer or Trade

Yes No N/A

5.1. Are drugs obtained only from a business licensed by this board or from a licensed manufacturer? (B&PC 4163[b], 4169)

5.2. If drugs are returned to your premises by a business to whom you had shipped the drugs, you document the return with an acquisition record for your business and a disposition record for the business returning the drugs? (B&PC 4081, 4332)

5.3. For license verification, the third-party logistics provider may use the licensing information displayed on the board's Internet web site. (B&PC 4106)

CORRECTIVE ACTION OR ACTION PLAN _____

Note: There are specific requirements for handling controlled substances – these additional requirements are in Section 11 of this document.

6. Receipt of Drugs by this Business

Yes No N/A

- 6.1. When drugs are received by your business, are they delivered to the licensed secured premises of the third-party logistics provided, and received by and signed for only by a designated representative -3PL or a pharmacist? (B & P 4059.5[a])
- 6.2. When drugs are received by your business, are the outside containers visibly inspected to identify the drugs and prevent acceptance of contaminated drugs by detecting container damage? (CCR 1780[d][1])

CORRECTIVE ACTION OR ACTION PLAN _____

Note: There are specific requirements for handling controlled substances – these additional requirements are in Section 11 of this document.

7. Drug Stock

Yes No N/A

- 7.1. Is all drug stock open for inspection during regular business hours? (B&PC 4081[a])
- 7.2. Are all drugs you receive and store maintained in a secure manner at your licensed third-party logistics provider premises? You cannot order, obtain or receive drugs that you are not able to store on your licensed premises. (B&PC 4167)
- 7.3. Do all drugs you distribute conform to the standards and tests for quality and strength provided in the latest edition of United States Pharmacopoeia or Sherman Food Drug and Cosmetic Act? (B&PC 4342[a])
- 7.4. Do all drug containers you store on your premises have a manufacturer's expiration date? Any drug without an expiration date is considered expired and may not be distributed. (CCR 1718.1)
- 7.5. Are outdated, damaged, deteriorated or misbranded drugs held in a quarantine area physically separated from other drugs until returned to the supplier or sent for destruction? (CCR 1780[e], CFR 1307.21)
- 7.6. Are drugs with the outer or secondary seal broken, or partially used or returned drugs held in a quarantine area and physically separated from other drugs until returned to the supplier or sent for destruction? (CCR 1780[e], CFR1307.21)

Yes No N/A

- 7.7. When the conditions under which drugs were returned to your premises cast doubt on the drugs' safety, identity, strength, quality or purity, are the drugs quarantined and either returned to your supplier or destroyed? If testing or investigation proves the drugs meet USP standards, the drugs may be returned to normal stock. (CCR 1780[e], CFR 1307.21)

CORRECTIVE ACTION OR ACTION PLAN _____

Note: There are specific requirements for distributing controlled substances – these additional requirements are in Section 11 of this document.

8. Sale or Transfer of Drugs by this Business

Yes No N/A

- 8.1. Are drugs sold distributed only to businesses or persons licensed by this board, licensed by a prescriber board, licensed as a manufacturer, or to a licensed health care entity authorized to receive drugs?

8.2. Describe how you verify a business or person is appropriately licensed. (B&PC 4059.5[a] [b][d], B&PC 4169) \

8.3. List any businesses or individuals that order drugs from you that are not licensed according to the list above:

Yes No N/A

- 8.4. Are drugs only furnished by your business to an authorized person? (B&PC 4166[b]) Note: An authorized person can be a business or natural person.

- 8.5. Does your business only receive drugs from a pharmacy if:
 - 8.5.1. the pharmacy originally purchased the drugs from you?
 - 8.5.2. your business is a “reverse distributor”?
 - 8.5.3. the drugs are needed to alleviate a shortage? (and only a quantity sufficient to alleviate a specific shortage). (B&PC 4126.5[a])

Yes No N/A

- 8.6 Are all drugs that are acquired by your business acquired from another business that is appropriated licensed?
- 8.6.1. transacted with a business licensed with this board as a manufacturer, wholesaler or pharmacy?
- 8.6.2. free of adulteration as defined by the CA Health & Safety Code section 111250?
- 8.6.3. free of misbranding as defined by CA Health & Safety Code section 111335?
- 8.6.4. **confirmed** to not be beyond their use date (expired drugs)? (B&PC 4169)

8.7. List any incidents where adulterated, misbranded or expired drugs were received, shipped, stored or transferred by this business in the past 2 years.

8.8. If your business sells, transfers, or delivers dangerous drugs or devices outside of California, either to another state within the United States or a foreign country, do you:

Yes No N/A

- 8.8.1. comply with all CA pharmacy laws related to the distribution of drugs?
- 8.8.2. comply with the pharmacy law of the receiving state within the United States?
- 8.8.3. comply with the statues and regulations of the Federal Food and Drug Administration and the Drug Enforcement Administration relating to the distribution of drugs?
- 8.8.4. comply with all laws of the receiving foreign country related to the wholesale distribution of drugs?
- 8.8.5. comply with all applicable federal regulations regarding the exportation of dangerous drugs?

8.9. Describe how you determine a business in a foreign country is authorized to receive dangerous drugs or dangerous devices. (B&PC 4059.5[e])

Yes No N/A

- 8.10. When you are not an authorized distributor for a drug, a pedigree must accompany the product when sold, traded, or transferred (Prescription Drug Marketing Act of 1987).

Yes No N/A

8.11. If preferentially priced drugs are sold by your business, that sale complies with the Prescription Drug Marketing Act of 1987 and CA Pharmacy Law. (B&PC 4380)

Yes No N/A

8.12. Does your business' advertisements for dangerous drugs or devices contain false, fraudulent, misleading or deceptive claims? (B&PC 4341, B&PC 651, CCR 1766)

8.13. Do you offer or receive any rebates, refunds, commissions or preferences, discounts or other considerations for referring patients or customers? If your business has any of these arrangements, please list with whom. (B&PC 650)

CORRECTIVE ACTION OR ACTION PLAN _____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

9. Outgoing Shipments of Drugs

Yes No N/A

9.1 Before you ship drugs to a purchaser, do you inspect the shipment to assure the drugs were not damaged while stored by your business? (CCR 1780[d][2])

9.2. Does your business use a common carrier (a shipping or delivery company — UPS, US Mail, FedEx, DHL) for delivery of drug orders to your customers? (B&PC 4166[b])

9.3 List the common carriers (shipping or delivery companies) you use.

CORRECTIVE ACTION OR ACTION PLAN _____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

10. Delivery of Drugs

Yes No N/A

- 10.1 Are all drugs ordered by a pharmacy or another wholesaler delivered to the address of the buyer's licensed premises and signed for and received by a pharmacist or designated representative where allowed? (

B&PC 4059.5[a])

Yes No N/A

- 10.2. Are all drugs ordered by a manufacturer or prescriber delivered to the manufacturer's or prescriber's licensed business address and signed for by a person duly authorized by the manufacturer or prescriber? (**B&PC 4059.5[d]**)

- 10.3. All drugs delivered to a hospital are delivered either to the pharmacy premises or to a central receiving area within the hospital. (**B&PC 4059.5[c]**)

- 10.4 If drugs are delivered to a pharmacy when the pharmacy is closed and a pharmacist is not on duty, documents are left with the delivery in the secure storage facility, indicating the name and amount of each dangerous drug delivered. (**B&PC 4059.5[f]**)

CORRECTIVE ACTION OR ACTION PLAN _____

11. Controlled Substances

Yes No N/A

- 11.1. Are there effective controls to prevent theft or diversion of controlled substances? (CFR 1301.71)

- 11.2. Are DEA requirements for storage of Schedule II controlled substances being met? (specific requirements are listed in CFR 1301.72[a])

- 11.3. Are DEA requirements for storage of Schedule ~~III~~ III, IV and V controlled substances being met? (specific requirements are listed in CFR 1301.72[b])
- 11.4. Is a DEA inventory completed by your business every two years for all schedules (II - V) of controlled substances? (CFR 1304.11[a][c][e])
- 11.5. Is the biennial record of the DEA inventory required for Schedule II – V controlled substances conducted every 2 years, retained for 3 years? (CFR 1304.11, CCR 1718, 1780(f)[2])
- 11.6. Does the biennial inventory record document that the inventory was taken at the “close of business” or “opening of Business.” (CFR 1304.11)
- 11.7. Has the person within your business who signed the original DEA registration, or the last DEA registration renewal, created a power of attorney for each person allowed to order Schedule II controlled substances for this business? (CFR 1305.05)

11.7.1. List the individuals at this location authorized by power of attorney to order controlled substances.

Yes No N/A

- 11.8. Does your business follow employee-screening procedures required by DEA to assure the security of controlled substances? (CFR 1301.90)
- 11.9. If any employee of this business possesses, sells, uses or diverts controlled substances, in addition to the criminal liability, you must evaluate the circumstances of the illegal activity and determine what action you should take against the employee. (CFR 1301.92)
- 11.10. Are all controlled substances stored and shipped by your business, done so for legitimate medical purposes? (H & S 11153.5[a][b][c])
- 11.11. If your business distributes controlled substances through an agent (i.e. detail person), do you have adequate security measures in place to prevent theft or diversion of those controlled substances (CFR 1301.74[f])
- 11.12. If a person attempts to purchase or secure a shipment of controlled substances from your business and the person is unknown to you, you make a good faith effort to determine the person (individual or business) is appropriately licensed to purchase controlled substances. (CFR 1301.74 [a], 4166)
- 11.13. Explain how your business determines an unknown business or individual is appropriately licensed to purchase controlled substances

Yes No N/A

- 11.14. If your business uses a common carrier to deliver controlled substances, your business determines the common carrier has adequate security to prevent the theft or diversion of controlled substances. (CFR 1301.74[f])
- 11.15. If your business uses a common carrier to deliver controlled substances, are the shipping containers free of any outward indication that there are controlled substances within, to guard against storage or in-transit theft? (CFR 1301.74[e])
- 11.16. Are all Schedule II controlled substances ordered from your business using a fully completed DEA 222 order form? (CFR 1305.03, 1305.06)
- 11.17. When your business fills orders for Schedule II controlled substances, is the date filled and the number of containers filled recorded on copies 1 and 2 of DEA 222 from? Is copy 1 retained and copy 2 sent to DEA at the close of the month the controlled substance order was filled? (CFR 1305.13 [b])
- 11.18. If a Schedule II controlled substance order cannot be filled, does your business return copy 1 and 2 of the DEA 222 order form to the buyer with a letter indicating why the order could not be filled? (CFR 1305.15)
- 11.19. When your business partially fills Schedule II controlled substances, is the balance provided within 60 days of the date of the order form? After the final partial filling, is copy 1 retained in your files and copy 2 of the completed DEA 222 order form sent to DEA by the close of that month? (~~CFR 1309.13[b]~~)
(CFR 1305.13[b])
- 11.20. For all Schedule II controlled substances received by your business, is copy 3 of the DEA 222 order form completed by writing in for each item received, the date received and the number of containers received? (CFR 1305.13[e])
- 11.21. Does your business use the online CSOS secure transmission system offered by the Drug Enforcement Administration in place of a paper DEA 222 Form for Schedule II controlled substances? (CFR 1305.21, 1305.22)
- 11.22. Does your business follow the procedure outlined by DEA to obtain Schedule II controlled substances when the original DEA 222 order form is lost or stolen? (CFR 1305.16(a))
- 11.23. Are all records of purchase and sale for all schedules of controlled substances for your business kept on your licensed business premises for 3 years from the making? (B&PC 4081, CCR 1718, ~~CFR 1305.09[d]~~, CFR 1305.17[c], 1305.17[a] [b], and ~~H&S~~ H&SC 11252, 11253, 1304.03)

Yes No N/A

- 11.24. Are records of Schedule II controlled substances stored separate from all others? (CFR 1304.04 [f][1])
- 11.25. Are records for Schedule III-V controlled substances stored so that they are easily retrievable? (CFR 1304.04 [f][2])
- 11.26. Before your business distributes carfentanil etorphine HCL and or diprenorphine, do you contact the DEA to determine the person (individual or business) is authorized to receive these drugs? (CFR 1301.75[g], 1305.16[b])
- 11.27. Do you separate records for the sale of carfentanil etorphine hydrochloride and or diprenorphine from all other records? (~~CFR 1305.16~~) (CFR 1305.17[d])
- 11.28. Does the owner of your business notify the DEA, on a DEA 106 form, of any theft or significant loss of controlled substances upon discovery of the theft? (CFR 1301.74[c])
- 11.29. Does the owner of your business notify the board of any loss of controlled substances within 30 days of discovering the loss? (CCR 1715.6)

CORRECTIVE ACTION OR ACTION PLAN _____

12. Policies and Procedures

12.1. Does this business maintain and adhere to policies and procedures for:
(CCR 1780[f])

Yes No N/A

- 12.1.1. Receipt of drugs?
- 12.1.2. Security of drugs?
- 12.1.3. Storage of drugs? (including maintaining records to document proper storage)
- 12.1.4. Inventory of drugs? (including correcting inaccuracies in inventories)
- 12.1.5. Distributing drugs?
- 12.1.6. Identifying, recording and reporting theft or losses?
- 12.1.7. Correcting errors and inaccuracies in inventories?
- Physically quarantining and separating:
- 12.1.8. returned, damaged, outdated, deteriorated, misbranded or adulterated drugs?
- 12.1.9. drugs that have been partially used?
- 12.1.10. drugs where the outer or secondary seals on the container have been broken?

- 12.1.11. drugs returned to your business, when there is doubt about the safety, identity, strength, quality, or purity of the drug?
- 12.1.12. drugs where the conditions of return cast doubt on safety, identity, strength, quality or purity? (CCR 1780[e][f])

CORRECTIVE ACTION OR ACTION PLAN _____

14. Training

Yes No N/A

- 13.1 Are training and experience provided to all employees to assure all personnel comply with all licensing requirements? (CCR 1780[f][4])

List the types of training you have provided to staff in the last calendar year and the dates of that training.

CORRECTIVE ACTION OR ACTION PLAN _____

14. Record Keeping Requirements

Yes No N/A

- 14.1. Do your business records for receipt, storage and shipping of dangerous drugs include date of sale, your business name and address, the business name and address of the buyer, and the names and quantities of the drugs sold? (B&PC 4081)
- 14.2 Are acquisition and shipping records for all transactions retained on your licensed premises for 3 years from the date of making? (B&PC 4081[a], 4105[c], 4081, 4332) Note: A drug pedigree is considered to be a part of the records of purchase and sale and must be retained for three years from the making.
- 14.3 Are all purchase, receipt and shipping sales records retained in a readily retrievable form? (B&PC 4105)
- 14.4. Is a current accurate inventory maintained for all dangerous drugs? (B&PC 4081, 4332, 1718)

14.5 If you temporarily remove acquisition or disposition records from your business, does your business retain on your licensed premises at all times, a photocopy of each record temporarily removed? (B&PC 4105[b])

14.6 Are required records stored off-site only if a board issued written waiver has been granted?

14.7 If your business has a written waiver, write the date the waiver was approved and the off-site address where the records are stored below. (CCR 1707[a])

Date _____ Address _____

Yes No N/A

14.8 Is an off-site written waiver in place and is the storage area secure from unauthorized access? (CCR 1707[b][1])

14.9 If an off-site written waiver is in place, are the records stored off-site retrievable within 2 business days? (CCR 1707[b][2])

14.10 Can the records that are retained electronically be produced immediately in hard copy form by any designated representative – 3PL, if the responsible manager is not present? (B & P 4105[d])

14.11 Are records of training provided to employees to assure compliance with licensing requirements, retained for 3 years? (CCR 1780[f][4])

Yes No N/A

- 14.12 Has this licensed premises, or the designated representative-in-charge - 3PL or pharmacist, been cited, fined or disciplined by this board or any other state or federal agency within the last 3 years? If so list each incident with a brief explanation (B&PC 4162[a][4]):
-
-

Yes No N/A

- 14.13 Has the licensed premises received any orders of correction from this board? A copy of the order and the corrective action plan must be on the licensed premises for 3 years. (B&PC 4083)

- 14.14 Has this business received a letter of admonishment from this board? A copy must be retained on the premises for 3 years from the date of issue. (B&PC 4315[e])

- 14.15 If this business dispenses dialysis drugs directly to patients, are the prescription records retained for 3 years, including refill authorizations and expanded invoices for dialysis patients? (CCR 1787[c], 1790)

CORRECTIVE ACTION OR ACTION PLAN _____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

15. Reporting Requirements to the Board

Yes No N/A

- 15.1 A responsible manager who terminates employment at this business, must notify the board within 30 days of the termination (B&PC 4101[b], 4305.5[c]).
- 15.2 The owner must report to the board within 30 days the termination of the responsible manager or pharmacist (B&PC 4305.5[a])
- 15.3 The owner must report to the board within 30 days of discovery, any loss of controlled substances, including amounts and strengths of the missing drugs. (CCR 1715.6)
- 15.4 The owner must notify the DEA, on a DEA form 106, any theft or significant loss of controlled substances upon discovery. (CFR 1301.74[c])

Yes No N/A

- 15.5 Do your employees know about their obligation to report any known diversion or loss of controlled substances to a responsible person within your business? (CFR 1301.91)
- 15.6 The owner must notify the board within 30 days of any change in the beneficial ownership of this business. (B&PC 4201[i], CCR 1709[b])
- 15.7 When called upon by the board, your business can report all sales of dangerous drugs or controlled substances subject to abuse. (B&PC 4164[a])
- 15.8 I understand that this wholesaler license is not transferable to a new owner. A change of ownership must be reported to this board, as soon as the parties have agreed to the sale. Before the ownership actually changes, an additional application for a temporary permit must be submitted to the board if the new owner wants to conduct business while the board is processing the change of ownership application and until the new permanent permit is issued. A company cannot transfer the ownership of the business via a contract with another individual or business, without the board's approval (B&PC 4201[g])
- 15.9 The owner of this business must immediately notify the board in writing if any assignment is made for the benefit of creditors, if the business enters into any credit compromise arrangement, files a petition in bankruptcy, has a receiver appointed, or enters into liquidation or any other arrangement that might result in the sale or transfer of drugs. (CCR 1705)
- 15.10 If this business is discontinued, the owner must notify the board in writing before the actual discontinuation of business. (CCR 1708.2). If the business holds a DEA registration, the owner must notify the DEA promptly of the discontinuation of business and all unused DEA 222 order forms must be returned to the DEA. (CFR 1301.52[a], 1305.14)

CORRECTIVE ACTION OR ACTION PLAN _____

17. 18. Additional Licenses/Permits Required

18.1. List all licenses and permits required to conduct this business, including local business licenses, wholesale licenses held in other states, permits or licenses required by foreign countries or other entities (B&PC 4059.5[e], 4107, CFR 1305.11[a]) Use additional sheets if necessary.

Add requirements for wholesalers and 3PLs co-located.

DESIGNATED REPRESENTATIVE-IN-CHARGE / PHARMACIST CERTIFICATION:

I, (please print) _____, DRIC# / RPH # _____
hereby certify that I have completed the self-assessment of this wholesale business of which I am the
designated representative-in-charge (DRIC) / pharmacist (RPH). I understand that all responses are
subject to verification by the Board of Pharmacy. I further state under penalty of perjury that the
information contained in this self-assessment form is true and correct.

Signature _____ Date _____
Designated Representative-in-Charge (DRIC) / Pharmacist (RPH)

ACKNOWLEDGEMENT BY OWNER, PARTNER OR CORPORATE OFFICER:

I, (please print) _____, hereby certify under penalty of perjury of
the laws of the State of California that I have read and reviewed this completed self-assessment. I
understand that failure to correct any deficiency identified in this self-assessment could result in the
revocation of the pharmacy's license issued by the California State Board of Pharmacy.

Signature _____ Date _____

Legal References

The following Legal References are used in the self-assessment form. Many of these references
can be viewed on the Board of Pharmacy Web site at www.pharmacy.ca.gov (see *Laws and
Regulations*), at the California State Law Library, or at other libraries or Internet Web sites:

California Code of Regulations (CCR), Title 16, unless otherwise noted

Business and Professions Code (B&PC), Chapter 9, Division 2, unless otherwise noted

Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act

Health and Safety Code (H&SC), Division 104, Part 5, Sherman Food, Drug and Cosmetic
Laws

United States Code of Federal Regulations (CFR), Title 21, Chapter II, Part 1300, Drug
Enforcement Administration, Food and Drugs and Codified Controlled Substances Act
(CSA)

California Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834
Phone: (916) 574-7900
Fax: (916) 574-8618
www.pharmacy.ca.gov

Pharmacy Law may be obtained by contacting:
LawTech Publishing Co.
1060 Calle Cordillera, Suite 105
San Clements, CA 92673
Phone: (800) 498-0911 Ext. 5
www.lawtechpublishing.com

Pharmacist Recovery Program
Phone: (800) 522-9198 (24 hours a day)

Prescriber Boards:

Medical Board of California
2005 Evergreen St., Suite 1200
Sacramento, CA 95815
Phone: (800) 633-2322
Phone: (916) 263-2382
Fax: (916) 263-2944
<http://www.mbc.ca.gov>

Dental Board of California
2005 Evergreen St., Suite 1550
Sacramento, CA 95815
Phone: (916) 263-2300
Fax: (916) 263-2140
<http://www.dbc.ca.gov>

Board of Registered Nursing
1625 N. Market Blvd., Suite N217
Sacramento, CA 95834
Phone: (916) 322-7697
Fax: (916) 574-8637
<http://www.rn.ca.gov/>

Board of Optometry
2420 Del Paso Road, Suite 255
Sacramento, CA 95834
Phone: (916) 575-7170
Fax: (916) 575-7292
<http://www.optometry.ca.gov/>

Osteopathic Medical Board of California
1300 National Drive, Suite 150
Sacramento, CA 95834
Phone: (916) 928-8390
Fax: (916) 928-8392
<http://www.ombc.ca.gov>

Physician Assistant Committee
2005 Evergreen St., Suite 1100
Sacramento, CA 95815
Phone: (916) 561-8780
Fax: (916) 263-2671
<http://www.pac.ca.gov>

Board of Podiatric Medicine
2005 Evergreen St., Suite 1300
Sacramento, CA 95815
Phone: (916) 263-2647
Fax: (916) 263-2651
<http://www.bpm.ca.gov>

Veterinary Medical Board

2005 Evergreen St., Suite 2250
Sacramento, CA 95815
Phone: (916) 263-2610
Fax: (916) 263-2621
<http://www.vmb.ca.gov>

Federal Agencies:

Food and Drug Administration

– Industry Compliance

<http://www.fda.gov/oc/industry/centerlinks.html#drugs>

The **Drug Enforcement Administration** may be contacted at:

DEA Website:

<http://www.deadiversion.usdoj.gov>

Online Registration – New Applicants:

http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm

Online Registration - Renewal:

www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm

Registration Changes (Forms):

http://www.deadiversion.usdoj.gov/drugreg/change_requests/index.html

Online DEA 106 Theft/Loss Reporting:

<https://www.deadiversion.usdoj.gov/webforms/pp106Login.jsp>

Controlled Substance Ordering System

(CSOS): <http://www.deacom.gov/>

DEA Registration Support (all of CA):

(800) 882-9539

DEA - Los Angeles

255 East Temple Street, 20th Floor
Los Angeles, CA 90012
Registration: (888) 415-9822 or (213) 621-6960
Diversion or Investigation: (213) 621-6942

DEA – San Francisco

450 Golden Gate Avenue, 14th Floor
San Francisco, CA 94102
Registration: (888) 304-3251
Theft Reports or Diversion: (415) 436-7900

DEA - Sacramento

4328 Watt Avenue
Sacramento, CA 95821
Registration: (888) 304-3251 or (415) 436-7900
Diversion or Investigation: (916) 480-7250

DEA - Riverside

4470 Olivewood Avenue
Riverside, CA 92501-6210
Registration: (888) 415-9822 or (213) 621-6960
Diversion or Investigation: (951) 328-6200

DEA - Fresno

2444 Main Street, Suite 240
Fresno, CA 93721
Registration: (888) 304-3251 or (415) 436-7900
Diversion or Investigation: (559) 487-5406

DEA – San Diego and Imperial Counties

4560 Viewridge Avenue
San Diego, CA 92123-1637
Registration: (800) 284-1152
Diversion or Investigation: (858) 616-4100

DEA – Oakland

1301 Clay Street, Suite 460N
Oakland, CA 94612
Registration: (888) 304-3251
Diversion or Investigation: (510) 637-5600

DEA – San Jose

One North First Street, Suite 405
San Jose, CA 95113
Registration: (888) 304-3251
Diversion or Investigation: (408) 291-2631

DEA – Redding

310 Hensted Drive, Suite 310
Redding, CA 96002
Registration: (888) 304-3251 or (415) 436-7900
Diversion or Investigation: (530) 246-5043

Attachment 9

Products	Prescriptions Dispensed	
	10/01/2013 - 03/01/2014	10/01/2014 - 03/01/2015
Hydrocodone & Combination Drugs	6,454,789	5,136,787
Oxycodone & Combination Drugs	1,338,876	1,367,048

Number of Reports made to the CA Board of Pharmacy with Hydrocodone and Oxycodone Product Losses During 2014

Hydrocodone Products	January 1, 2014 - September 30, 2014		October 1, 2014 - December 31, 2014	
	Loss Type	Number of Reports	Quantity of Loss* (All Units)	Number of Reports
<i>Employee pilferage</i>	30	346,458	12	61,837
<i>Night break in</i>	41	94,389	10	36,420
<i>Other</i>	157	128,901	185	30,815
<i>Armed robbery</i>	15	23,132	19	17,287
<i>Lost in transit</i>	40	8,665	7	7,134
<i>Customer theft</i>	5	11,543	14	2,082
Total:	288	613,088	247	155,575

Oxycodone Products	January 1, 2014 - September 30, 2014		October 1, 2014 - December 31, 2014	
	Loss Type	Number of Reports	Quantity of Loss* (All Units)	Number of Reports
<i>Employee pilferage</i>	10	273	2	1,549
<i>Night break in</i>	15	24,504	5	8,391
<i>Other</i>	219	9,823	111	2,117
<i>Armed robbery</i>	10	11,750	15	18,066
<i>Lost in transit</i>	19	2,971	6	871
<i>Customer theft</i>	1	60	1	295
Total:	274	49,381	140	31,289

*Note: These totals may not match the data in CURES since these numbers represent only the losses reported to the Board of Pharmacy.

Attachment 10

Effective Date: 08/27/2013

Title: Section 80.63 - Prescribing

80.63 Prescribing. (a) A prescription as defined by the Public Health Law means:

(1) an official New York State prescription;

(2) an electronic prescription;

(3) an oral prescription; or

(4) an out-of-state prescription, which means a prescription issued in lieu of an official prescription by a practitioner in another state who is licensed by that state to prescribe controlled substances.

(b) The use of preprinted prescriptions which indicate the controlled substance or the strength, dosage and/or quantity of the controlled substance is prohibited. Such prohibition shall not apply to printed prescriptions generated by means of a computer or an electronic medical record system, provided such printed prescriptions are generated at the time a practitioner prescribes a controlled substance for a patient.

(c)(1) Prior to prescribing for or dispensing to a patient any controlled substance listed on schedule II, III, or IV of section 3306 of the public health law, every practitioner shall consult the prescription monitoring program registry for the purpose of reviewing that patient's controlled substance history. The patient's controlled substance history shall be obtained from the prescription monitoring program registry no more than 24 hours prior to the practitioner prescribing or dispensing any controlled substance to that patient. A practitioner shall document such consultation in the patient's medical chart or, if the practitioner does not consult the prescription monitoring program registry, the practitioner shall document in the patient's medical chart the reason such consultation was not performed. Such documentation shall include the specific exception listed in paragraph (2) of this Subdivision.

(i) When such consultation is not performed due to circumstances specified in subparagraph (2)(vii) of this Subdivision, the practitioner shall further document in the patient's medical chart the conditions, occurrences, or circumstances that caused such consultation in a timely manner to be unreasonable. Such documentation shall include a description of the barrier(s) to accessing the registry, and the efforts made by the practitioner to contact other designees.

(ii) When such consultation is not performed due to circumstances specified in subparagraph (2)(viii) of this Subdivision, the practitioner shall further document in the patient's medical chart a description of the circumstances supporting the practitioner's conclusion that consultation of the registry would adversely impact the patient's ability to obtain a prescription in a timely manner and the relationship between that delay and the patient's medical condition.

(2) The duty to consult the prescription monitoring program registry shall not apply to:

(i) veterinarians;

(ii) a practitioner dispensing pursuant to public health law section 3351(3);

(iii) a practitioner administering a controlled substance, as defined in public health law section 3302

(2);

(iv) a practitioner prescribing or ordering a controlled substance pursuant to public health law section 3342(1) for a patient of an institutional dispenser as defined by public health law section 3302 for use on the premises of, or during an emergency transfer from, the institutional dispenser;

(v) a practitioner prescribing a controlled substance in the emergency department of a general hospital, provided that the quantity of controlled substance prescribed does not exceed a five-day supply if the controlled substance were used in accordance with the directions for use;

(vi) a practitioner prescribing a controlled substance to a patient under the care of a hospice, as defined by public health law section 4002;

(vii) a practitioner when:

(a) it is not reasonably possible for the practitioner to access the registry in a timely manner;

(b) no other practitioner or designee authorized to access the registry, pursuant to public health law section 3343-a, is reasonably available; and

(c) the quantity of controlled substance prescribed does not exceed a five-day supply if the controlled substance were used in accordance with the directions for use;

(viii) a practitioner acting in circumstances under which consultation of the registry would, as determined by the practitioner, result in a patient's inability to obtain a prescription in a timely manner, thereby adversely impacting the medical condition of such patient, provided that the quantity of the controlled substance does not exceed a five-day supply if the controlled substance were used in accordance with the directions for use;

(ix) a situation where the registry is not operational as determined by the department or where it cannot be accessed by the practitioner due to a temporary technological or electrical failure as defined in Section 80.64 of this Part. In the instance of a temporary technological or electrical failure, a practitioner shall, without undue delay, seek to correct any cause for the failure that is reasonably within his or her control; or

(x) a practitioner to whom the commissioner has granted a waiver from the requirement to consult the registry. A waiver may be issued by the commissioner based upon a showing by a practitioner that his or her ability to consult the registry in accordance with this section is unduly burdened by:

(a) technological limitations that are not reasonably within the control of the practitioner; or

(b) other exceptional circumstance demonstrated by the practitioner.

The practitioner's showing shall include a sworn statement of facts detailing the circumstances in support of a waiver, and should be accompanied by any and all other information which would be relevant to the commissioner's determination. As part of the application for a waiver, the practitioner shall also provide any information which would tend to negate the need for a waiver. A waiver shall be granted by the commissioner for a specified period of time, but in no event for more than one year. Subsequent waivers shall be applied for in the same manner and shall be subject to the same requirements as the original waiver. A practitioner who has been granted a waiver shall notify the

department in writing within five business days upon gaining the capability to consult the prescription monitoring program registry. Without regard to the original expiration date, the waiver granted to the practitioner shall terminate within a reasonable period of time as determined by the department, allowing for the practitioner to make accommodations to begin consulting the prescription monitoring program registry.

(3) A practitioner may authorize a designee to consult the prescription monitoring program registry on his or her behalf, provided that the ultimate decision as to whether or not to prescribe or dispense a controlled substance remains with the practitioner and is reasonably informed by the relevant controlled substance history information obtained from the registry. A practitioner may only appoint a designee if:

(i) such designee is located in the state of New York when accessing the prescription monitoring program registry;

(ii) the designee is employed by the same professional practice or is under contract with such practice. For purposes of this subparagraph, professional practice shall include, but not be limited to, an institutional dispenser where the designating practitioner is employed, under contract, or otherwise has privileges or authorization to practice;

(iii) the practitioner takes reasonable steps to ensure or has actual knowledge that such designee is sufficiently competent in the use of the registry and that such designee is aware of and conforms to all relevant federal and state privacy statutes;

(iv) the practitioner remains responsible for ensuring that access to the registry by the designee is limited to authorized purposes and occurs in a manner that protects the confidentiality of the information obtained from the registry, and the practitioner remains responsible for any breach of confidentiality; and

(v) the practitioner selects and maintains all active designees authorized to access the prescription monitoring program registry in a format acceptable to the department. Upon a designee's relinquishment or termination of employment or authorization as a designee, a designating practitioner shall immediately notify the department, in a fashion deemed appropriate by the commissioner, of the revocation of the designee's authorization to access the prescription monitoring program registry on the designating practitioner's behalf.

(4) A pharmacist may consult the prescription monitoring program registry in order to review the controlled substance history of an individual for whom one or more prescriptions for controlled substances is presented to such pharmacist. A pharmacist may designate another pharmacist or a pharmacy intern as defined by section sixty-eight hundred six of the education law to consult the prescription monitoring program registry on the pharmacist's behalf, provided that:

(i) such designee is located in the state of New York when accessing the prescription monitoring program registry and is employed by the same pharmacy or is under contract with such pharmacy; and

(ii) the designating pharmacist selects and maintains all active designees authorized to access the prescription monitoring program registry in a format acceptable to the department. Upon relinquishment or termination of employment or authorization as a designee, a designating pharmacist shall immediately notify the department, in a fashion deemed appropriate by the

commissioner, of the revocation of the designee's authorization to access the prescription monitoring program registry on the designating pharmacist's behalf.

(d)(1) No controlled substance prescription shall be issued prior to the examination of the patient by the practitioner except as otherwise permitted by this subdivision.

(2) Once the initial examination has been completed, the frequency and necessity for future examinations prior to prescribing, either for the same acute or chronic condition, will be made by the practitioner utilizing generally accepted medical standards, including taking into account the drug to be prescribed and the patient's condition, history and disposition toward the use of controlled substances.

(3) In the temporary absence of the initial prescriber, an authorized practitioner may issue a controlled substance prescription for a patient as part of a continuing therapy if the practitioner: (i) had direct access to the patient's medical records and such records warrant continued controlled substance prescribing, or (ii) had direct and adequate consultation with the initial prescriber, who assures the necessity of continued controlled substance prescribing and with which the practitioner concurs. If the patient record is not available, the practitioner shall document the activity for his or her own record and shall transmit to the initial prescriber the prescription information. The initial prescriber shall include the prescription information in the patient's record.

(4) A practitioner may prescribe a controlled substance to his or her patient after review of the patient's record if the record contains the result of an examination performed by a consulting physician or hospital and such record warrants the prescribing.

(5) If a patient develops a new condition that would warrant the issuance of a prescription for a controlled substance, a practitioner may issue such prescription prior to performing an examination if: (i) the prescribing practitioner has a previously established practitioner/patient relationship with the patient; and (ii) an emergency exists; and (iii) the prescription does not exceed a 5 day supply as determined by the directions for use. An emergency means that the immediate administration of the drug is necessary for the proper treatment of the patient and that no alternative treatment is available. If the practitioner prescribes such substance orally, the practitioner must comply with the requirements of section 80.68 and section 80.70 of this Part.

Volume: A-1a



Final Report

Evaluation of the Electronic Prescribing of Controlled Substances Pilot

Submitted To:

California HealthCare Foundation

Submitted By:

Weslie Kary, MPP, MPH

Laurel Koester, MPH

Jennifer Stephens, MPH

Final Report: Evaluation of the Electronic Prescribing of Controlled Substances Pilot

November 2013

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EXECUTIVE SUMMARY

Introduction. In November 2012, two Federally Qualified Health Centers in California began prescribing controlled substances electronically in compliance with the Drug Enforcement Administration's (DEA) Interim Final Rule (IFR) number 21 CFR Parts 1300, 1304, 1306, and 1311. Over the 9-month pilot, the two sites completed the IFR's required steps to: implement certified functionality for the electronic prescribing of controlled substances (EPCS) within their electronic health record (EHR), identify-proof each of their prescribers (DEA-registered physicians and other providers); issue two-factor authentication credentials and train each prescriber on their use; and establish access to EPCS for each prescriber within the EHR. Several pharmacies with stores near the prescriber organizations also activated EPCS-certified pharmacy management software, allowing them to accept and fulfill the electronic prescriptions for controlled substances. An external project manager facilitated conversations and shared learning between the two prescriber organizations and communications with local and national representatives of the participating pharmacies. This evaluation chronicles the experiences of the pilot participants as they activated EPCS, identifying the impact of EPCS on prescriber and pharmacist workflows, the benefits of EPCS to the participants and the implementation challenges faced by pilot participants.

Pilot outcomes. Both sites succeeded in installing the EPCS software upgrade, in registering their individual prescribers and completing at least some EPCS transactions at EPCS-certified pharmacies. Mid-pilot, both sites experienced a system problem that brought EPCS down completely for their prescribers. Prescriber Organization 2 (PO2) was able to recover rapidly; this site also demonstrated a consistent upward trend in the percent of controlled substance (CS) prescriptions transmitted electronically. At PO2, EPCS usage peaked at 37% of CS prescriptions sent electronically across all local pharmacies; it sent about 70% of CS prescriptions electronically when considering only the pharmacies able to accept these scripts. Prescriber Organization One (PO1) struggled to get traction with EPCS, demonstrating some early acceptance by the prescribers, but then experiencing a rapid and consistent drop in usage. Only 44 of the 95 prescribers it registered ever sent a CS prescription electronically. Also, PO1 had much more difficulty recovering system functionality following the EPCS outage than PO2 experienced. In aggregate EPCS was down for two months at PO1; the outage spelled the effective end of its prescribers' use of EPCS.

EPCS benefits. All participants in the pilot accrued benefit from EPCS. Prescribers, staff and pharmacists interviewed for the evaluation described the EPCS workflows as "easy" and as requiring little extra effort over regular e-prescribing. Many welcomed the additional security they believe EPCS provides over current paper processes. Many appreciated the administrative efficiencies of EPCS over the current manual processes. Processes eliminated by EPCS included sending a prescription to a printer secured in a centralized locked location, distributing refill prescriptions securely (locked box, patient identification, charting pick-up), and the rekeying of paper prescription information at the pharmacy. Many believed that EPCS could improve patient safety in the same way that e-prescribing operates to reduce errors associated with paper prescriptions for other medications. Some called out the enhanced ability to trace

prescriptions for controlled substances and to include information about electronically prescribed controlled substances in internal patient acuity analyses and quality improvement initiatives.

Facilitators. Physicians working in an environment with a robust e-prescribing process may already be asking for relief from burdensome exception processing for CS prescriptions and eager to give EPCS a try. Prescribers' concerns about the security of paper prescriptions also pre-dispose them to appreciate the secure prescription transmissions offered by EPCS. Physician goodwill can be easily dissipated by negative experiences with the technology itself however. PO2 undertook specific actions to ensure that errors did not dilute physician demand for the technology, for example, running error reports up to four times per day and taking immediate steps to resolve errors with both local and national pharmacy representatives. Leadership commitment and applying the resources needed to ensure the system works smoothly for the physicians every time also appeared to be important facilitators of PO2's successful implementation. Similarly, a strong effort by PO2 to open lines of communication with the pharmacies and to coordinate business practices helped facilitate the rapid error resolution needed to keep prescribers engaged.

Barriers. The reliability of relatively new EPCS software proved to be a significant barrier to successful implementation. While the particular software glitch experienced by the two sites may not be repeated, the larger issue is how any negative experience with EPCS software may affect overall physician buy-in. The lack of critical mass of prescribers and pharmacies using the technology is an important current barrier to adoption as well. While the number of pharmacies that accept EPCS has grown rapidly, key independent pharmacies near the prescriber clinics were not able to participate in this pilot. At PO1, an in-house pharmacy—one that a significant portion of its patient population was required to use—could not obtain certification within the pilot period. The number of popular pharmacies that are EPCS certified defines the upper limit of electronic CS prescriptions that prescribers can send without requiring patients to change pharmacies, and forces the prescribers to maintain paper and fax processes even after embracing EPCS. For their part, the independent pharmacies may have little incentive to implement EPCS until many more physicians have adopted the technology and begun to encourage their patients to use certified pharmacies. Finally, the prescriber organizations found it difficult to interpret the IFR's requirements around identify-proofing and issuing prescriber authentication credentials, and the process of completing these steps was logistically challenging.

Conclusion. There is strong interest, high perceived value to users, technical capacity, societal benefit, and a business case to devote the resources needed to implement EPCS. Expansion is interdependent on prescribers and pharmacies; they must work collaboratively on implementation and incentives for expansion should address both sides of the EPCS equation. For pharmacies, addressing the cost of the DEA-required third party audits and uncertainty around the on-going costs of compliance might help induce smaller vendors working with independent pharmacies to bring the technology on board. Prescriber adoption might be encouraged by clarifying IFR requirements and by including CS prescriptions in meaningful use incentives. As for any new software, technology glitches are possible. With leadership commitment, adequate resources, and strong prescriber-pharmacy cooperation however, EPCS can work and work well.

I. INTRODUCTION

Numerous studies have shown benefits to electronic prescribing (e-prescribing), such as improved patient safety and efficiency.^{1,2,3,4,5} While adoption of e-prescribing technology continues to increase dramatically year over year, regulations imposed by the Drug Enforcement Administration (DEA) on the prescribing of controlled substances have required even those with robust e-prescribing protocols to maintain parallel paper and electronic faxing processes for controlled substance medications.

In 2010 the DEA published its Interim Final Ruling 21 CFR Parts 1300, 1304, 1306, and 1311 (the IFR). The IFR allows the electronic prescribing of controlled substances (EPCS) by DEA registrants (doctors, hospitals and other health professionals) when the software applications of both the e-prescribing organization and the recipient pharmacy are EPCS-certified pursuant to new security requirements.⁶ The IFR legalized EPCS nationally; however, each state must separately integrate EPCS into its own regulatory rubric for monitoring the prescribing of controlled substances. California approved the use of EPCS in accordance with the IFR in June 2010.⁷

Although the IFR was published in 2010, implementing EPCS functionality has required significant programming changes to pharmacy management systems, to EHR technology, and to intermediary systems. The IFR requires those programming changes to be certified by independent auditors or DEA-approved certification organizations before EHR software vendors may deploy new EPCS software. As a result of these requirements, national pharmacies and EHR vendors were just beginning to bring EPCS online in 2012. And, while pharmacies are now implementing EPCS in large numbers—more than 40% of California pharmacies can now accept EPCS prescriptions—prescriber adoption remains very low.⁸

In the fall of 2012, the California HealthCare Foundation (CHCF) provided grants to incentivize prescriber organizations—in this case, two Federally Qualified Health Centers (FQHCs) with a robust e-prescribing culture—to choose the path of early EPCS adoption. For example, the grants helped the clinics purchase the technology needed to support the issuance of two-factor authentication credentials to prescribers that is required for EPCS.

By capturing both the successes and challenges of each of these pilot sites and their local pharmacy counterparts as they implemented EPCS, this evaluation seeks to inform the field on the benefits of EPCS, factors that may facilitate a successful EPCS roll-out, and potential barriers to success that organizations considering EPCS implementation should address in their planning processes.

II. THE EPCS FRAMEWORK

The purpose of the DEA's IFR is to ensure that electronic communications of prescriptions for controlled substances are both secure and auditable to reduce the risk for drug diversion and fraud. To accomplish these goals, the IFR establishes numerous new security requirements that apply to prescribers, pharmacies and to the several systems that support the exchange of information that comprises e-prescribing. An audit trail is created within prescriber and pharmacy applications "to document those instances in which a controlled substance prescription is received, annotated, modified

or deleted.”⁹ Modifications to both the EHR and the pharmacy’s management software must be independently certified as compliant before its users can activate the EPCS functionality.

Prescriber organizations choosing to activate EPCS must also undertake certain required functions, including new reporting in the event of a security breach along with a registration process for its prescribers (described below).¹⁰ Similarly, pharmacies must activate EPCS at their individual store locations, training their pharmacists and staff in how to use EPCS in compliance with both state and federal regulations regarding the dispensing of controlled substances.

Figure 1 provides a high-level overview of the security features that EPCS adds to standard e-prescribing.

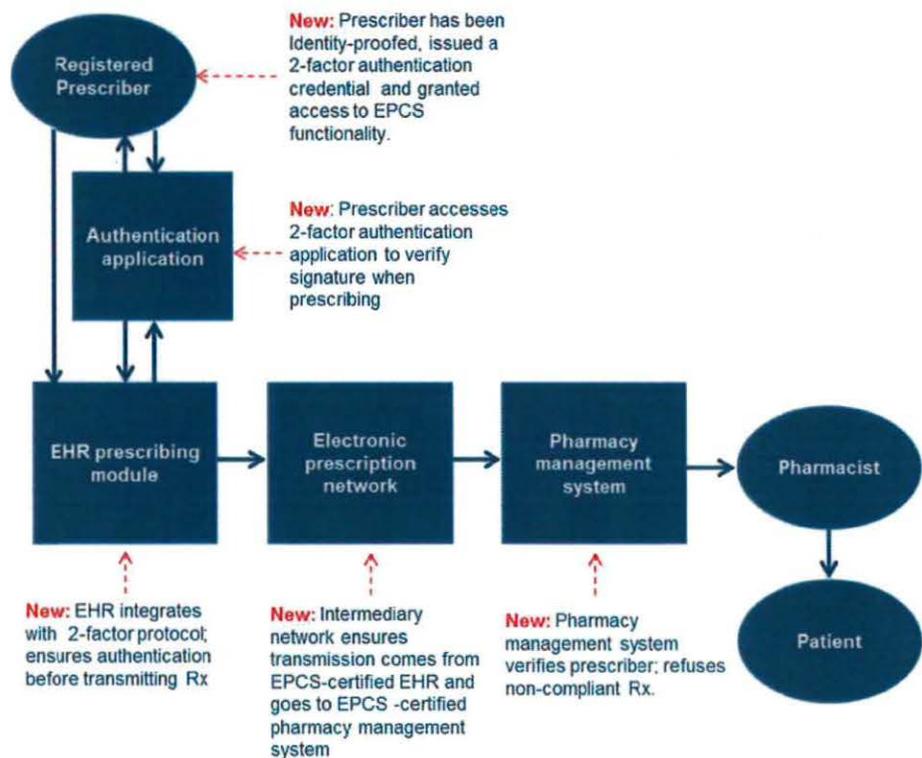
Prescriber registration. Before ever writing an electronic prescription for a controlled substance, the prescriber (who must be a DEA registrant) undergoes a set of processes this evaluation terms *registration*. Registration comprises: (1) identity proofing; (2) issuing a two-factor authentication credential; and (3) setting system controls to provide EPCS access to the prescriber.

Two-factor authentication.

“Two factor authentication” means that the prescriber must provide two of three required authentication factors when signing a CS prescription. The prescriber enters something she knows (e.g., a password to use the EPCS software), then accesses an external authentication application to provide something she has (e.g., a “one time only” code generated by the credential) or something she is (e.g., a fingerprint or voice recognition). A key modification to the EHR is its integration with the authentication application to validate the prescriber-entered authentication factors.

Electronic transmissions. The EHR recognizes whether the pharmacy chosen by the prescriber uses an EPCS-certified pharmacy management system and rejects attempts to transmit an EPCS prescription to a non-certified pharmacy. Once transmitted, the prescription flows through the intermediary e-prescribing network, which ensures that each prescription meets its pre-established EPCS transmission

Figure 1: Overview of EPCS security features



standards, including the requirement that both the transmitting and receiving systems be EPCS-certified. The pharmacy management system applies additional checks and flags scripts that do not arrive with an appropriate digital signature. Finally, the pharmacist has the option to reject an electronically prescribed CS prescription for non-compliance with state or federal regulation (e.g. an electronic refill for a Class II medication).

III. ABOUT THE EPCS PROJECT

A. SCOPE AND TIMELINE

The EPCS project officially began in November 2012 with a kick-off meeting bringing together the project leaders from the two pilot sites, the external project manager, the evaluation team and CHCF leadership. The two prescriber organizations each registered a few prescribers in December 2012 and had sent some initial prescriptions at the point of the first evaluation team site visits in that same month. The prescriber organizations completed the majority of their prescriber registrations over the first quarter of 2013 and encouraged their prescribers to begin sending CS prescriptions immediately. Both sites continue to use their EPCS functionality, although the official “pilot period” ended in July of 2013. Table 1 describes the pilot and evaluation timeline.

Table 1: Pilot and evaluation timeline

	Sep-Oct 12	Nov-12	Dec-12	Jan-13	Feb-13	Mar-13	Apr-13	May-13	Jun-13	Jul-13	Aug-13	Sep-13	Oct-13	Nov-13
Sites implement EHR upgrade	◆													
Pilot kickoff meeting		◆												
First prescribers activated			◆											
Sites send 1 st EPCS scripts			◆											
Pre evaluation site visits			◆											
Most prescribers activated							◆							
Interim evaluation interviews							◆							
Pilot period officially closes										◆				
Post evaluation site visits											◆	◆		
Evaluation complete														◆

B. PILOT PARTICIPANTS

The two pilot participants, hereafter Prescriber Organization One and Prescriber Organization Two, differ significantly in size and demographics. Prescriber Organization One (PO1) is located in urban Southern California, operates 23 clinic locations and has over 100 physicians who prescribe controlled substances. Prescriber Organization Two (PO2) operates six clinic sites with 39 employed physicians in a largely rural setting in Northern California.

Both prescriber organizations use the same electronic health record application, one of the first to achieve EPCS certification. Both pilot sites already had plans to implement a new version of their EHR that included the EPCS functionality and took the additional step of activating EPCS as part of this upgrade. The organizations expressed similar motives for choosing to activate EPCS within the context of this pilot, including a desire to create administrative efficiencies for prescribers, reduce medication errors associated with illegible or misinterpreted handwritten notes for regulated substances, and improve internal data for medication reconciliation and quality improvement initiatives.

Each pilot site identified pharmacy partners with whom they would implement EPCS. PO1 had planned to work with an external firm that manages on-site pharmacies at four of their clinic locations; unfortunately that firm’s pharmacy management software vendor was not able to provide EPCS-certification in time for the pharmacies to participate. PO2 had planned to work with two independent local pharmacies; only one ultimately was able to participate but that organization brought 10 pharmacy sites to the pilot. Both PO1 and PO2 worked with the local stores of two national pharmacy retailers from the beginning of the pilot; a third national pharmacy also activated EPCS in its California stores early in the pilot period. A few other local pharmacies in PO1’s region also began accepting EPCS. In effect, both prescriber sites could send prescriptions to any pharmacy that showed as EPCS certified within the EPCS module of their EHR. Table 2 provides additional information about the two pilot sites.

Table 2. Prescriber organization environment

	Prescriber Organization 1	Prescriber Organization 2
Size/environment	<ul style="list-style-type: none"> • 23 clinics in two urban counties • 119 medical staff providers and 68 per diem providers 	<ul style="list-style-type: none"> • 6 clinics in one largely rural county • 39 full-time providers and 16 contracted specialists
Demographics	125,000 medically underserved patients; primarily Hispanic but ethnic mix is changing.	36,000 low income patients; 3,650 homeless patients, 200 HIV-positive patients. Pre-dominantly white (81%) or Hispanic (9%).
Project leaders	Chief Medical Informatics Officer; IT Leader and Internal Consultant (also Project Manager).	Chief Executive Officer; Chief Information Officer (also Project Director); Chief Medical Officer; and Division Manager local pharmacy.
E-prescribing history	Implemented EHR in 2009; Meaningful Use Stage 1.	E-prescribing for 5 years. ~20% above Meaningful Use Stage 1.
Two-factor authentication approach	EHR password and one-time only code generated by token.	EHR password and one-time only code generated by smartphone application.

IV. PILOT OUTCOMES

In regular project status reports, the pilot participants self-reported their outcomes with EPCS in terms of the number of prescribers they registered, the number of those prescribers who used EPCS, their approach to addressing the EPCS outage that both experienced in May 2013, and the volume of CS prescriptions that they transmitted electronically. EPCS volume for the two prescriber organizations was also reported by the local stores of one national pharmacy retailer cooperating with the pilot. PO2 also provided information about their EPCS error rates over time. Evaluation interviews captured the actual changes in workflow imposed by EPCS at the prescriber organizations and pharmacies. This section summarizes these recorded outcomes.

A. EPCS ROLL-OUT

Both prescriber organizations rolled out EPCS successfully; pharmacies were able to accept the prescriptions.

At the time of the kick-off meeting in November, both prescriber organizations had completed the upgrade of their EHRs as required to activate EPCS. The prescriber organizations each registered a few providers with high volumes of CS scripts in December. Both had planned to quickly register successive waves of prescribers beginning in January. Both organizations found the requirements of the IFR around registration difficult to interpret however, and their original plan for registering prescribers was logistically challenging to implement. While both organizations immediately fell behind on their provider registration schedule, by early spring each had succeeded in registering the majority of their prescribers and each had prescribers who were actively using the EPCS functionality.

National pharmacy retailers and an independent, family-owned group of pharmacies were all able to receive and fulfill the prescriptions they received without major difficulty.

Table 3. Prescriber organization registration results

	Prescriber Organization 1	Prescriber Organization 2
Planned prescriber registrations	119	39
Number of actual prescriber registrations	95 (80%); 44 prescribers have used token at least once.	39 (100%)

B. EPCS RELIABILITY

Both prescriber organizations experienced a serious EPCS outage; only one recovered fully.

Both sites experienced a failure or “EPCS outage” in early May of 2013, when their EHR suddenly stopped accepting provider authentication credentials. The problem resulted from the expiration of an

embedded security certificate within the EHR. The EHR vendor issued a Hot Fix (a patch for operational software) in May 2013 to correct the problem with the expired security certificate, and PO2 was able to recover functionality in about one week.

PO1 was not able to install the patch until they had first implemented a number of earlier modifications issued by the vendor. PO1 sought a solution that would install only the security certificate correction to minimize the IT resource drain but the vendor was not able to supply a limited fix. In late June 2013, PO1 decided to implement all required modifications to reboot EPCS. Unfortunately, these changes did not resolve the issue for PO1 prescribers, who continued to report that the system would not accept their credentials. Research showed the new problem was related to a conflict with security protocols within the PO1 network. This problem was resolved in early July. In aggregate, at PO1 the EPCS functionality was out of commission from May 6-July 9, 2013.

C. EPCS VOLUME

PO2 achieved significant EPCS volume; PO1 had limited success.

PO2 rapidly expanded their EPCS volume over the course of the pilot period. PO1 struggled to convince their prescribers to use the functionality and their difficulty restoring the EPCS functionality following the outage substantially diminished prescriber use of EPCS within the pilot period.

At pharmacies that had activated EPCS, PO2 was sending 65-75% of their prescriptions for controlled substances electronically by the end of the pilot period. While this volume had begun to approach their e-prescribing rate for non-controlled substances (85%), they still faced the constraint that about 50% of their prescriptions were sent to pharmacies that had not yet activated EPCS. Looking across all pharmacies, PO2 achieved a peak EPCS rate of 37% of all CS prescriptions written by their prescribers.

PO1 had only just begun using the EPCS functionality again at the time of the post-pilot interviews. According the final progress report submitted by PO1, only 14 prescribers have used EPCS since the functionality was restored in July. PO1 self-reported a peak of 3.32% of controlled substances prescribed electronically across all pharmacies.

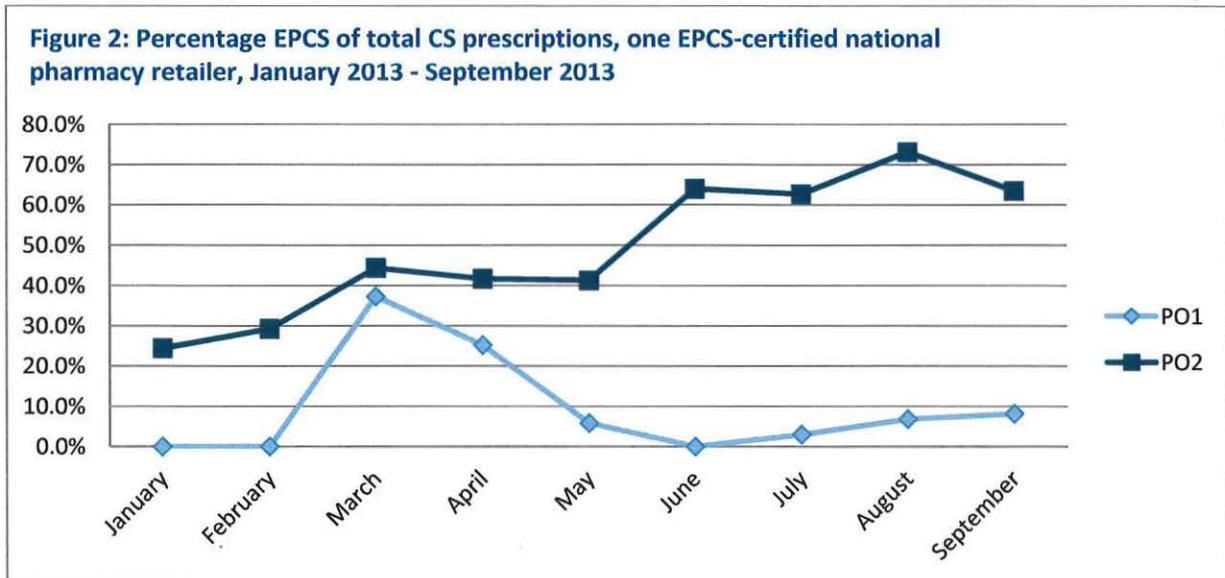
Table 4. Prescriber organization volume results

	Prescriber Organization 1	Prescriber Organization 2
Number activated pharmacies	>350 area locations of 3 national pharmacies across the two counties served, plus a few other local pharmacies	19 total: 10 locations of independent local pharmacy; all area locations of 3 national pharmacies
Pre-pilot % of CS volume at activated pharmacies	Not reported.	~50%

Table 4. Prescriber organization volume results

	Prescriber Organization 1	Prescriber Organization 2
Highest self-reported EPCS as % of total CS (all pharmacies)	<3.5 % (July 2013)	37% (August 2013)
Highest volume EPCS as % total CS (one certified national pharmacy)	8% (September 2013)	73% (August 2013)
Error rates for EPCS	Not reported	~3.5% first month, 1.35% overall

Figure 2 displays data provided by one national pharmacy that reported EPCS volume at their stores near PO1 and PO2 locations. While these data are from only one of the participating national pharmacies, they provide an interesting view of how EPCS volume varied over the course of the pilot for the two prescriber organizations, when considering only EPCS-certified pharmacies. Note that the sites registered physicians in waves; some of the increases displayed in the graph can be explained by the sites having added registered prescribers. The dip in May (for PO2) and the nadir in May and June (for PO1) correspond to the periods when EPCS was out of commission at their respective sites.



D. IMPACT ON PRESCRIBER AND PHARMACY WORKFLOWS

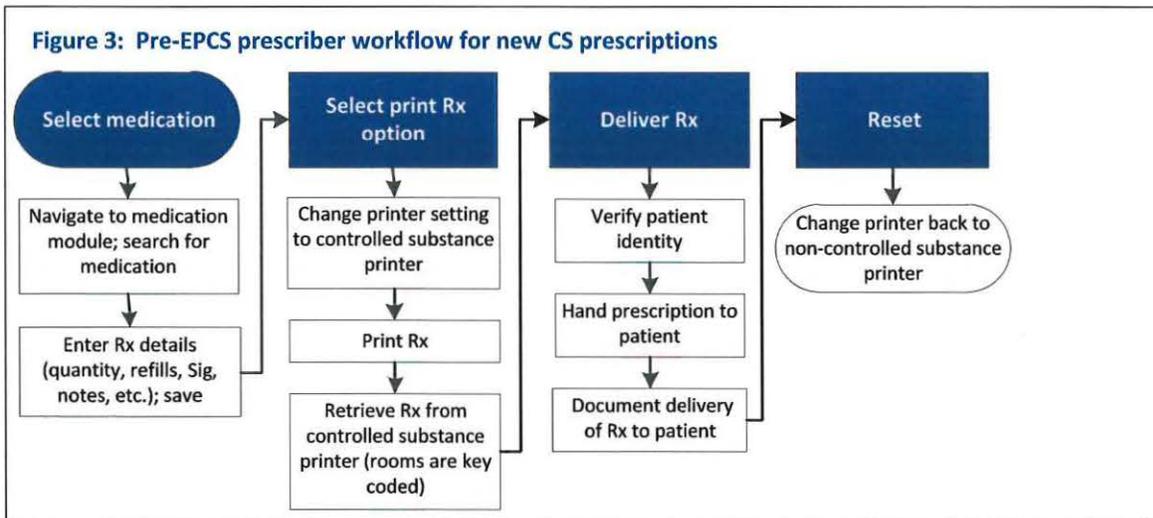
For new prescriptions, post-EPCS processes were nearly the same as for other e-prescribing.

The pre- and post-EPCS processes for new and refill prescriptions were very similar for the two sites, given that both sites operate under California regulation and both use the same vendor for their EHR. This section highlights key impacts of EPCS on workflows at the prescriber sites and local pharmacies.

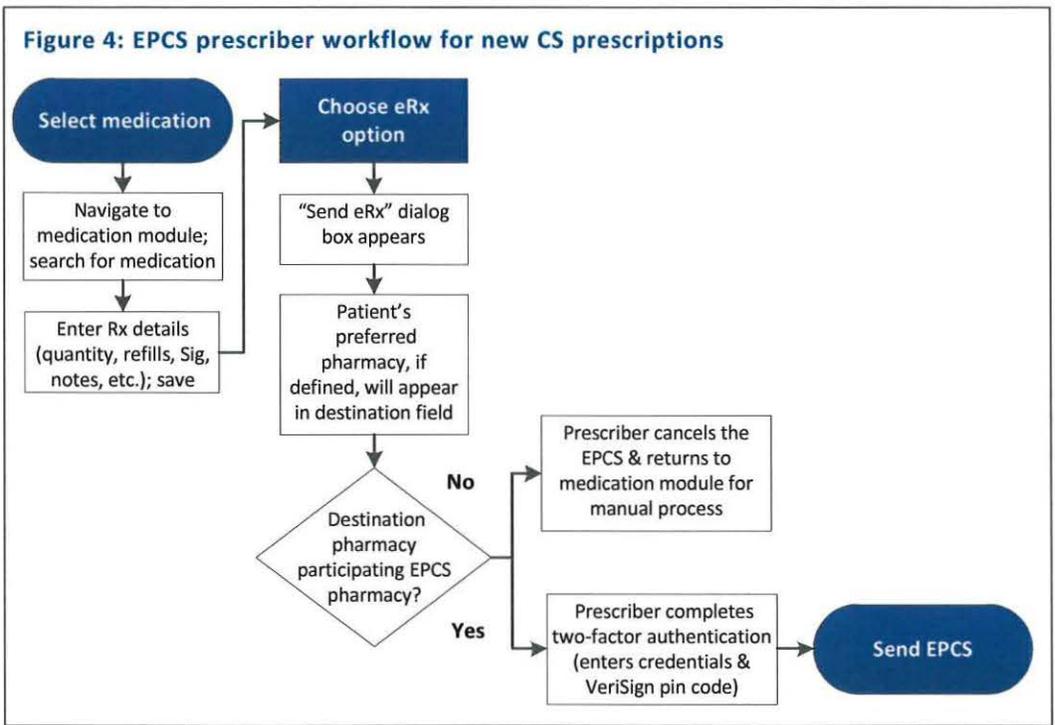
EPCS eliminates secure printer, secure paper and “wet signature” steps for prescribers. In the absence of EPCS, prescribers must use DEA-certified prescription paper for controlled substances. This paper includes features that can help a pharmacist distinguish a legitimate prescription from a fraudulent one; for example, a reflective watermark that shows as “VOID” when copied and a prescription logo that disappears or changes colors when breathed on or used. Prescriber sites typically stock this paper in a separate printer in a secure location; for example in a separate room with a keypad entry lock. Prescribers may send the prescription to print and pick it up themselves to sign and then hand to the patient, or may have procedures in which a medical assistant retrieves the prescription and brings it to the physician for signature before giving it to the patient.

To manage security when the patient is not handed a prescription directly by the physician, the clinics store printed and signed prescriptions (primarily refills) in a locked box. Staff members perform additional patient identification checks before giving the prescription to the patient and also note in the patient’s medical record when the prescription has been delivered and to whom.

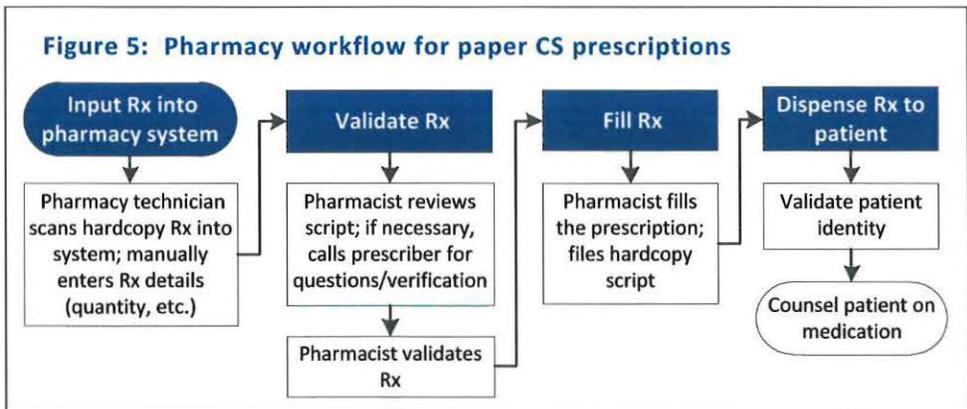
Figure 3 displays PO2’s description of the steps for filling a new prescription for a controlled substance without EPCS.



As shown in Figure 4, EPCS eliminates the printing and manual distribution steps for prescriptions that may be sent electronically—that is, those going to an EPCS-certified pharmacy. In comparison to the standard e-prescribing steps (not shown), EPCS adds two steps, selecting an EPCS-certified pharmacy and completing the two-factor authentication protocol before transmission.



Pharmacies also eliminate manual processes. Pharmacies receiving paper prescriptions first apply manual security protocols designed to help identify signs of fraudulent scripts. Examples include: verifying the features embedded in the water-marked paper; verifying a patient’s information against the information on the prescription; and looking out for certain combinations of medications that may flag prescription drug abuse. Then, they must type the prescription into their pharmacy management system. Figure 5 displays the typical workflow for a pharmacy receiving a paper or faxed controlled substance prescription according to interviews with pharmacists near both PO1 and PO2.



How pharmacists receive an EPCS prescription varies slightly based on their individual pharmacy software. In general, the prescriptions arrive in almost exactly the same format as other e-prescriptions and no longer require any manual entry before dispensing the medication.

Two pharmacists described security features within the pharmacy's certified system that detect whether a physician properly signed the script with their digital signature and is authorized to send controlled substance scripts electronically; if the requirements are not met, the system will instruct the pharmacist to generate a printout, after which the prescription deletes from the system.

"But if it doesn't have the digital signature, it self-deletes from my computer. It will actually make it through typing, the tech will type it, it'll show up on my computer, I will review it and then it'll pop up with a box that says this does not have a digital signature and it will delete and it will print out. So if somebody tries to send us one and they are not authorized to do so, on their end it deletes itself. My computer somehow knows."

(Pharmacist, PO2)

EPCS simplifies refill processes; but special issues also affect refills.

In the absence of EPCS functionality, front-line staff members typically handle the first step of processing the refill request, abstracting information from the chart and typing it manually into a prescription refill template. They then send a task with the template to the prescribing physician. The prescriber must accept the task, open the template, and approve or deny the request. If the request is approved, the written prescription must be printed securely and then faxed to the pharmacy or printed and given back to staff to call the patient for pickup. If the request is denied, support staff will notify the pharmacy, typically by phone.

"Every little thing, even if it's an easy step, it's still time consuming. You've got to go into the chart. You've got to verify everything. You've got to get up, unlock the drawer, get it out, go to the patient, get ID, go back and document it."

(Front-line staff member, PO2)

Front-line staff store written refill prescriptions in a locked drawer for patient pickup. Patients need to come to the clinic for the prescription, sign in, and wait their turn to talk to staff. Staff members check the patient ID and note in the chart who picked up the prescription.

With EPCS, refill requests for Class III, IV, and IV substances come directly into the provider's task queue, eliminating the front-end step of manually creating the refill request and

also the back-end process to securely distribute the refill prescriptions.

A practice PO2 had adopted to expedite refills for CS prescriptions before EPCS caused problems for them after implementing EPCS. To avoid working from faxed requests from the pharmacies, PO2 had requested that pharmacies send electronic refill requests for all controlled substances (Class II-V). The physicians receive these requests as refill tasks in their respective work queues. Before EPCS, the standard process was for the physician to immediately decline the electronic request but use this task as the reminder to speak to the patient if denying the refill or to create a paper prescription to fax or hand to the patient if approving it. Implementing EPCS meant the physician could now accept the electronic requests for Class III-V substances but not for Class II medications because no refills—paper or electronic—are allowed for Class II drugs. Once physicians began responding to refill requests electronically for Class III-V medications however, they sometimes attempted to authorize electronic refill requests for Class II substances as well. These requests would then be denied at the pharmacy. One pharmacist remarked that he disliked PO2's process and thought it should be discontinued. Even

though the refill request is appropriately denied, it still counts as an error and requires a call back to obtain the new prescription for the patient.

Some interviewees also described a limitation of electronic prescribing related to storing “pending” refill prescriptions. Before EPCS, a physician wishing to prescribe three months of a medication with a 30-day prescription limit might write three paper prescriptions simultaneously and give the future prescriptions to the staff to store for pick-up when each new prescription is due. When prescribers tried this same approach for electronic prescriptions they found that some of the pharmacy systems are able to store future prescriptions while others cannot.

V. EVALUATION FINDINGS

A. EPCS BENEFITS

When the technology works as planned, prescribers and pharmacists alike found that EPCS offers significant benefits.

Participants reported high satisfaction and positive impacts on productivity. Staff and providers commented that they and their teams were satisfied with EPCS. While PO1 prescribers had concerns about the technology problems and long delays to get to smooth operations, for the most part they still believed that EPCS was more efficient than manual processes.

PO2 prescribers and staff cited the ease and efficiency of the system and reported that improvements in workflow contributed to staff satisfaction. Several providers and pharmacists reported the integration of EPCS with the electronic prescribing system made it easy for them to learn and use. Participants did not formally measure changes in productivity as a result of EPCS. Most believed however that EPCS had enhanced productivity through: saving physician time to print and retrieve prescriptions; allowing physicians to prescribe from anywhere; reducing pharmacy time to enter a prescription; and avoiding clarification callbacks. Several physicians and pharmacists commented that EPCS

EPCS Benefits

EPCS pilot participants—including physicians, pharmacists and their parent organizations—described many benefits from adopting EPCS.

Benefits for physicians and clinic staff

- ✓ Easy to use; prescribe from any secure computer (not tied to secure printer).
- ✓ Saves physician and staff time on both new and refill prescriptions.
- ✓ Reduces use of expensive watermarked prescription paper.
- ✓ Direct communication channel between prescriber and pharmacy improves ability to track prescriptions and eases prescriber concerns about security.
- ✓ Provides robust data on CS prescribing patterns for quality improvement.

Benefits for pharmacies

- ✓ Easy to use; close to regular e-prescribing.
- ✓ Saves time by eliminating rekeying of Rx information.
- ✓ More accurate prescriptions, potentially improving patient safety.
- ✓ Stronger security reduces the opportunity for fraudulent prescriptions to escape detection.

allowed them to spend more time seeing or counseling patients. Prescribers and front-line staff reported that EPCS reduced their work handling refill pick-ups and pharmacy call-backs.

Improved patient safety. Participants across all roles—managers, providers, pharmacists, and front-line staff—believed that electronic prescribing would avoid errors that might harm patients, for example, those caused by illegible prescriptions.

Potential cost savings. Many participants cited cost savings stemming from eliminating the use of costly watermarked prescription paper and time spent by staff on controlled substance prescriptions. One senior manager stated there was an \$8,000-10,000 savings just from reduction in the use of the secure prescription paper, but most could only assume that EPCS reduced costs.

“I hate printing ... because I’m always nervous, like are these people legit, or is it just a drug seeker? I don’t know, and sometimes it’s a gamble, especially because I’m not the primary so I don’t know these people well enough. I hate ... printing prescriptions, and oh and on our prescriptions actually if you flip it over it has everybody’s DEA number, so when you pass that out, I mean it’s like a gold ticket to somebody that knows how to use that stuff.”

(Prescriber, PO1)

Stronger security. Nearly half of respondents across sites reported that improving security for prescribing controlled substances was a primary driver behind implementing EPCS. Participant concerns with fraudulent or tampered written prescriptions were common in pre-EPCS interviews; post-pilot, few noted security concerns or worries about using EPCS. One prescriber mentioned that EPCS caused leadership to revisit how to handle sensitive prescribing issues around drug-seeking patients and communicating with the primary provider. With EPCS, an on-call provider could choose whether or not to prescribe a controlled substance to a patient just as before (i.e., paper or electronic fax), or exercise the option to delegate the CS prescribing decision to the primary care physician.

Increased ability to track prescriptions and analyze physician prescribing habits. A few physicians called out the ability to track where the prescription was sent and whether it was picked up. Representatives from both sites valued the potential for new EPCS data on physician prescribing habits to enhance quality improvement initiatives.

B. IMPACT ON WORKFLOW

EPCS imposed only minor modifications to prescriber and pharmacist workflows (compared to standard e-prescribing) and those modifications were well-received.

Concerns about provider reaction to the two-factor identification process are largely unwarranted. Early in the project, some senior leaders expressed concerns that the physicians would not like the two-factor authentication process. As has been reported in other studies however, prescribers in this pilot seemed unfazed by the need to carry a token (PO1) or use their smartphone application (PO2) to obtain the one-time only code they used to sign electronic CS prescriptions.¹¹ Prescribers saw the additional security as adding value, given their worries about the security of current paper processes.

Pharmacists, physicians and staff called post-EPCS workflows “easy.” Prescribers noted the new processes were extremely similar to existing e-prescribing processes, adding only the steps to obtain and enter the PIN. The physicians appreciated that EPCS freed them to write a prescription from anywhere, not just when they were down the hall from a secure printer. One spoke in the pre-

“Like what if it’s Friday night and I remember that I didn’t do a morphine script? I really have to drive in the following morning, take my kids, because I have to take my kids, take my kids into urgent care ... sign in, print it out [on the urgent care printer], then sign it, then tell the urgent care person that it’s there. I mean, what a waste of time and energy for a stupid piece of paper. Come on. We got computers. So that’s why I want this e-prescribing thing immediately.”

(Prescriber, PO2)

Behind the scenes, prescriber organizations and pharmacies will need new processes and policies.

Prescriber organizations needed to determine: how to register and train new physicians; how to address lost tokens or phones; and whether and how to educate or encourage patients to use EPCS-certified pharmacies. Senior leaders at PO1 mentioned they had concerns with new liabilities imposed by EPCS, including how to ensure compliance with new reporting requirements related to security breaches, as they debated whether to participate in the pilot. Pharmacies must also prepare their pharmacists to accept EPCS, and must develop procedures to ensure substitute or “floater” pharmacists are made aware of the availability of EPCS when they take a shift at an EPCS-certified store.

interviews about how he hated having to physically go to the clinic to access the secured printer and special paper in the evening or on the weekend because he had forgotten an urgent prescription. Post-pilot, he particularly appreciated the ability to prescribe from home.

Front-line staff at PO2 valued how EPCS diminished the effort to distribute paper refills for controlled substances—a process that involved several extra steps and many phone calls from patients about whether the refill was ready.

“It’s actually smoother because we don’t have the 45 minutes of the angry patient having to wait to pick up the prescription.”

“Or them calling, is my prescription ready to be picked up yet?”

“[Or asking] did the doctor print it out yet?”

“That happens a lot. That is very good. That happens a lot. I’ll get 3 or 4 calls a day with that on the hard copies.”

(Three front-line staff members, PO2)

C. FACILITATORS

Facilitators for successful EPCS implementation include physician demand, leadership commitment and prescriber-pharmacy partnerships.

Physician demand and a strong e-prescribing culture. At both sites, prescribers had previously expressed a desire to enhance security over the prescribing of controlled substances. Given the strong e-prescribing history at both organizations, physicians also looked forward to relief from the administrative burden of manual processes for ordering controlled substances.

PO2 took active steps to nurture physician acceptance and usage through immediate error resolution—including monitoring errors up to four times per day at the start of the pilot—and through regular interactions with the physicians to celebrate milestones and communicate timelines for fixing any problems. The close relationships that PO2 developed with the local pharmacies and with their national representatives during the pilot also helped to facilitate immediate error resolution. For example, when faced with the problem of a substitute (or floater) pharmacist denying EPCS prescriptions because he was unfamiliar with the new processes, PO2 could pick up the phone and have a pharmacy manager or national pharmacy representative immediately contact the pharmacist to say it was okay to accept the prescription.

Leadership support and adequate internal resources to address problems before they negatively affect user experience of EPCS. EPCS is not yet at a point where implementation is routine. Leadership commitment must include the internal resources needed to address unexpected issues. PO1's outage was much longer and deeper than that of PO2, in part because they had not anticipated the need to implement a large backlog of noncritical system fixes before rebooting EPCS.

Implementation as a prescriber organization-pharmacy partnership. EPCS is not an initiative that is implemented solely within any one organization. A successfully filled prescription for a controlled

Tactics for Success

There's more to EPCS implementation than ensuring the technology works reliably. The evaluation identified several tactics that might improve the likelihood of successfully implementing EPCS.

- ✓ Nurture physician and staff demand. Current processes are a pain-point for prescribers and staff alike. Identify those feeling the most pain for early adoption; let them spread the positive word.
- ✓ Develop the pharmacy relationships before you begin. Find partners that want to work with you. Put their problem solvers on speed dial and let them know how they can quickly reach you to resolve their issues.
- ✓ Consciously create positive first experiences for prescribers. Jump on errors and other problems. Let the physician know when the problem will be resolved and then deliver.
- ✓ Pave the way for patients to demand EPCS from their physicians:
 - Highlight service in patient newsletters.
 - Develop handouts for physicians and staff to explain EPCS and identify EPCS certified pharmacies.
 - Train staff to explain EPCS in response to refill requests. If prepared, this group can sincerely promote the convenience of EPCS refills.

substance represents a complex interplay of manual and electronic processes, the transfer of information across several independent systems, coordinated business processes between prescribers and pharmacies and a common interpretation of the mix of state and federal regulations surrounding controlled substances. PO2 included the Division Manager of a large local pharmacy on the pilot implementation team and worked closely with the manageable number (19) of pharmacy partners to install EPCS—a set of integrated systems and processes—as an integrated team. Both the pharmacies and the clinic found value in the new or stronger relationships that resulted from their joint effort and in working collaboratively with the local pharmacies to resolve early issues with EPCS.

“...as soon as we went live, [the project director] sent us an email and we did a lot of test claims to make sure we were receiving them and it was fine...We’ve had a lot of communication keeping each other informed as to what is going [on]...I think that has been very helpful.”

Pharmacist, PO2

The pharmacy with which PO1 had the closest existing relationship—their in-house group—was unable to participate in the pilot. While PO1 had contacts at the regional level for each of the national pharmacies, they did not try the one-to-one communications and testing strategies with individual stores that PO2 employed with apparent success. These tactics might have proven more difficult to implement in a large urban area; however, they might also have facilitated quick responses to any process or communication blips between the pharmacies and PO1 prescribers and thus helped to ensure that physicians’ critical first experiences with EPCS were positive.

D. BARRIERS

Key barriers to wide-spread use of EPCS include: lack of critical mass; cost of pharmacy entry; reliability of new technology; and challenging prescriber registration processes.

Lack of critical mass. In both pre- and post-interviews, pharmacists wished more physicians would use EPCS and physicians wished more pharmacies were certified so EPCS could become the norm rather than an exception process. The maximum potential EPCS volume at each of the pilot sites was significantly constrained by the inability of key pharmacies to participate in the pilot. At PO1, an in-house pharmacy—one that a significant portion of its patient population was required to use—could not obtain certification within the pilot period. At PO2, a pharmacy located onsite—and one to which prescribers felt patients were particularly loyal—was similarly unable to participate. Each of these pharmacies asked their pharmacy system vendor to quickly complete EPCS certification and participate in the pilot, but these overtures were rebuffed. While the critical mass issue will likely resolve itself over time, the current state remains a significant barrier to the rapid expansion of EPCS and to realizing the benefits it promises to provide.

Cost as a barrier to pharmacy entry. Several interviewees cited cost as a barrier to entry for the pharmacies. While the DEA’s economic impact report for EPCS assumed a cost of about \$15,000 per audit for both practices and pharmacies, participants interviewed were hearing anecdotally that actual costs were much higher—from \$30,000 to \$100,000 and up.¹² Since audit costs are borne by the

pharmacy system vendors, each vendor makes its own decision as to how to allocate the expense across their customer base. For large national pharmacies with in-house systems, the cost of the audit is a cost for the pharmacy system, spread over a great number of stores nationally. A smaller vendor might have more difficulty recovering costs from its customer base; on the other hand, one of the independent pharmacies participating in the pilot reported that their vendor had not assessed any specific expense for the EPCS functionality. This issue intersects with the critical mass barrier described above. That is, more physicians and physician organizations need to implement EPCS before the pharmacy management system vendors that supply smaller pharmacies will perceive a clear mandate to initiate the effort and expense of EPCS certification.

Reliability issues. EPCS technology is new and relies on multiple systems interfacing around complex security requirements. Glitches can occur and starts and stops may damage physician receptivity. Both sites experienced a problem where prescribers were suddenly unable to e-prescribe, receiving a message that the system would not accept their credentials. In addition, one of the pilot sites discovered a serious problem with all incoming refill requests—including non-EPCS refills. This problem was not captured by vendor monitoring reports, pointing out the need for strong internal testing and monitoring for the unexpected. Staff members at PO1 reported ongoing problems following the EPCS outage. One, they discovered an issue involving proxy settings of their internal system that was blocking EPCS prescriptions and had to be reprogrammed. Two, a couple providers reported problems with the functionality of their tokens that PO1 was in the process of addressing at the time of the post-pilot interviews; these negative experiences affected prescriber ongoing willingness to use EPCS.

“... it was a small group of us, maybe 5 or 6 of us trying it first and then it was supposed to get bigger and eventually it got bigger but then, you know... if you get burned, so to speak a couple times, you just stop using it. So like Dr. --- hasn't, I told him, hey, it should be working, try it. So he finally tried it again yesterday after a month or whatever and his still didn't work. So he's like, really?”

(IT staff member, PO1)

Challenge of initial registration effort. Both sites found it challenging to interpret the registration requirements, that is, the required steps to identify-proof prescribers, issue two-factor authentication credentials and to set system access controls to allow prescriber access to the EPCS functionality. Both sites found that the registration effort went more slowly than expected. Their initial plan to register prescribers en masse at clinical meetings did not work well. Attendance was low and the physicians did not like waiting in line for others to be credentialed. Both sites subsequently decided to send the two registrars to the clinicians at their respective locations and to register them individually according to a schedule. Registration was combined with training on how to use EPCS, including how to obtain the one-time only code. The registrars estimated the combined process took about 15 minutes to complete.

Along the way, PO2 discovered that both registrars did not need to meet in person with each physician prescriber. The project director met with each physician to authenticate the physician's network user ID, to load and authenticate the device, and to provide the training. Later, the IT representative and the second registrar would meet separately to complete the final step—authenticating the user in the EHR.

This approach saved significant time for the DEA-licensed registrar, a senior physician leader, and PO2 shared it with PO1. Even after making the change however, PO1 continued to find that their original team of two registrars was insufficient to register so many prescribers. They added a second registration team late in the pilot.

Substitute or “floater” pharmacists were not ready for EPCS. Both sites experienced problems where a substitute pharmacist coming in to cover a shift would be unaware of EPCS and begin denying electronic prescriptions for controlled substances. The sites reported that the problem occurred most frequently at the national pharmacy retailers, pointing to a need for these pharmacies to develop procedures for just in time communications about EPCS and training for their contingent workforce.

Many prescribers are reluctant to ask patients to change pharmacies. While a few physicians reported that they actively encouraged their patients to use EPCS-certified pharmacies, several commented that they were unwilling to mention EPCS to their patients. This reluctance may derive from several factors; one that was mentioned was a desire not to interfere with the patient’s ability to price-shop prescriptions or to choose a more conveniently-located pharmacy. This barrier may become less salient as patients become more familiar with the availability of EPCS and the conveniences it offers them.

E. EPCS AND PATIENTS

Prescriber and staff opinions on patient reaction to EPCS were mixed.

The evaluation did not include any direct contact or interviews with patients, however the evaluation queried participants about patient reactions to EPCS they had observed and how their organizations were handling the question of whether to encourage patients to choose an EPCS-certified pharmacy.

Participant perspectives on the impact of EPCS on patient experience were mixed. Clinic staff generally believed that patients had not been significantly impacted by EPCS or that patients took the change for granted because they were used to other electronic prescriptions. Several pilot participants noted that the patients who had previously complained about the distance from the clinic to their home or the wait time for refills were most likely to comment about EPCS benefits.

Encouraging patients to choose EPCS pharmacies was neither the policy nor the norm, but some physicians did so.

“I think the patients like it, the ones that are using it. I think they enjoy not having to come back here and stand in line and wait and pick their prescription up and then go to the pharmacy...We hear about I can’t come in because I don’t have gas or I don’t have a ride or my caregiver can’t get there and I’m due today...”

(Front-line staff member, PO2)

Neither PO1 nor PO2 established a specific policy to encourage patients to use EPCS-certified pharmacies. At PO1, a senior leader said that at the beginning of EPCS they actively told patients they could send their prescriptions electronically, but some patients were vocal about wanting to use their same pharmacy (that may not be EPCS-certified).

“In the beginning we were putting [on] a little pressure. You know, why don’t you go next door and get it, but now we are not. We just, you want to use this pharmacy, fine. If that pharmacy doesn’t do it, then we’ll [give you paper]. And the computer knows. The system knows if that pharmacy allows [EPCS] or not ... we saw so much pushback from the patient that they want to use only one pharmacy or their pharmacy that we said ... continue. You know, even asking, it doesn’t make sense.”

(Senior leader, PO1)

physicians there reported that they now inform patients that they have the ability to send controlled substance scripts electronically and that only some pharmacies accept controlled medications in this fashion. Two front-line staff members at PO2 concurred that some physicians now encourage EPCS. They’ve been asked by the physicians they support to educate patients about the EPCS option; one of the physicians had developed a handout for the staff member to provide to the patient after the physician had verbally advised the patient about the EPCS process. She added that many patients have become familiar with the ability to send their prescriptions via EPCS and are now using pharmacies with EPCS capability; others continue to ask for paper prescriptions.

While PO2 physicians appeared farther along with the idea of suggesting a patient choose an EPCS-certified pharmacy, the practice was not unknown at PO1. A PO1 staff member also remarked that the physician she supports explains EPCS to his patients; her role is to reinforce the explanation.

The project director at PO2 noted that some physicians were apprehensive about directing patients to use EPCS-certified pharmacies. To address this discomfort, PO2 published information about EPCS and the participating pharmacies in their patient newsletter. The organization’s role was to inform the patients of the option; the patients retained the choice of pharmacy. Physicians determined individually whether to suggest EPCS.

Prescribers were free to communicate the potential advantages to the patient if they desired, and it appeared that a good number of physicians were taking this step. PO2 physicians seemed to be more comfortable making a suggestion to the patient, perhaps because EPCS was more firmly established there by the end of the pilot. A few

“Like if they call and ask for a refill, I know through Dr. ---, he’s asked us to always ask them do you want ... this on a paper script or would you like me to send it via the computer to one of these three pharmacies? And like I said, educate them that that’s a possibility.”

(Front-line staff member, PO2)

VI. POLICY IMPLICATIONS

Participants called current lack of critical mass the most significant barrier to widespread EPCS adoption. Because many physicians are reluctant to suggest patients change pharmacies, the independent pharmacies most often used by clinic patients must participate to achieve high EPCS volumes. To encourage pharmacy adoption, policymakers might take steps to address the frequency and cost of the required third-party audits. Greater clarity on the type of system changes that would require an EPCS re-audit might allay pharmacy vendor concerns about ongoing compliance costs.

Physician organizations are only just beginning to adopt EPCS and may need stronger incentives since the market share incentive that encourages pharmacy adoption does not apply. Previous research suggested that physician adoption of regular e-prescribing was accelerated in response to federal incentive programs under the Medicare Improvements for Patients and Providers Act.¹³ For EPCS, policymakers might consider adding EPCS to federal meaningful use incentives, for example by including CS prescriptions in the calculation for the e-prescribing measure.

VII. AREAS FOR ADDITIONAL RESEARCH

Although many interviewed participants believed that EPCS has the potential to improve care quality and patient experience while simultaneously producing efficiency gains, additional research is needed to test these perceptions. Studies might address:

- Whether perceived improvements in prescriber and staff workflows translate into measurable changes in staff productivity and savings that exceed the costs of implementation.
- The impact on patient experience. The evaluation did not include direct feedback from patients on their experience with EPCS. Participants had mixed views on how EPCS impacted patient experience. Further research might address whether EPCS—which should increase patient convenience—has any unintended consequences on their experience of care.
- The relative security of EPCS over current manual processes. Nearly all interviewed participants felt that EPCS is more secure than current processes, and since a desire for increased security is a key driver of physician demand, research confirming this belief might incentivize physician adoption.
- The possibility that EPCS might improve care coordination. One prescriber suggested this intriguing idea, noting that EPCS allows an on-call provider to delegate the decision to prescribe a controlled substance to the primary care physician. Research into the impact of EPCS on prescribing habits and the use of EPCS data in internal analyses might answer these and other care quality questions.

VIII. CONCLUSION

EPCS is an innovation that appears here to stay. There is strong interest, high perceived value to users, technical capacity, societal benefit, and a business case to devote the resources needed to implement this functionality. Expansion is interdependent on prescriber and pharmacy adoption; society will not realize the full potential of EPCS until both groups decide jointly to make the effort and work cooperatively on implementation. Incentives to accelerate wide-spread adoption should address both physician groups (e.g., include EPCS in meaningful use standards) and pharmacies (e.g., address the timing and cost of third party audits).

EPCS also presents implementation challenges that must be carefully addressed. The failure to devote adequate attention or resources to both systemic problems and episodic errors may erode physician support and cause the effort—which should enhance physician and staff satisfaction—to create physician resistance instead. With leadership support, adequate resources, and strong prescriber-pharmacy cooperation, EPCS can work and work well.

“You know, as a culture here we have embraced technology and this is such, this component of our practice is such a big one, a large one, that it just seemed it was ripe for solution, and why not us? You know, why not us? We have good partners, we have good technology, we have great leadership, we have a medical staff buy-in.... So that, I mean, all those conditions, all right. I think it's a culture issue for us. I think it was a leadership issue for us.”

(Senior leader/project director, PO2)

APPENDIX A: RESEARCH METHODS

AIR used qualitative research methods to address the following research questions:

1. Did participants perceive operational efficiencies and benefits that exceeded burden as a result of implementing EPCS? What data are available to support these perceptions?
2. How were prescribing and pharmacy fulfillment workflows affected by the implementation of EPCS compliant with current national and state regulatory requirements? What facilitators and what barriers did each pilot site experience during implementation?
3. What lessons can provider organizations and pharmacies considering EPCS learn from these early adopters?
4. What are the implications of the implementation pilot for policymakers and regulators, such as the DEA and the California Board of Pharmacy? Can opportunities be identified to streamline requirements for EPCS while maintaining adequate security protections?

Research activities included pre- and post-pilot site visits with in-person interviews and observations, interim telephonic interviews with project leaders, and document collection. AIR's Institutional Review Board approved all data collection protocols, recruitment, and interview procedures before contact and data collection. In total, AIR conducted 55 individual and small group interviews with 42 key stakeholders involved in the EPCS pilot. Both in-person and telephonic interviews were transcribed verbatim and systematically coded in NVivo 10.0. Table A-1 categorizes participant interviews.

Table A-1. Interviewed participants by organizational role

Position in organization	PO1	PO2	Total
Senior leaders/project directors	3	2	5
Physicians	4	5	9
Front-line staff (nurse and nonclinical)	1	3	4
Pharmacists	8	5	13
Information technology staff	3	0	3
External individuals/vendors (both local and national)	--	--	8
Total participants	19	15	42
Total interviews	25	23	55

Quantitative data used in the report were self-reported or provided by the external project manager and have not been validated.

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ABOUT AMERICAN INSTITUTES FOR RESEARCH

Established in 1946, with headquarters in Washington, D.C., American Institutes for Research (AIR) is an independent, nonpartisan, not-for-profit organization that conducts behavioral and social science research and delivers technical assistance both domestically and internationally. As one of the largest behavioral and social science research organizations in the world, AIR is committed to empowering communities and institutions with innovative solutions to the most critical challenges in education, health, workforce, and international development.

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Liberia
Malawi
Pakistan
South Africa
Zambia



**Second Update Regarding Industry Progress in Implementing
Electronic Prescribing for Controlled Substances (EPCS)**

To: State Boards of Pharmacy
State Controlled Substance Agencies
State and National Pharmacy Organizations

From: Ken Whittemore, Jr., RPh, MBA
Senior VP, Professional & Regulatory Affairs

Date: December 16, 2014

It has been four years since the Drug Enforcement Administration (DEA) published its interim final rule (IFR) allowing electronic prescribing for controlled substances (EPCS). Over the past four years, Surescripts, as the primary network facilitating e-prescribing in the U.S., has worked with the pharmacy and prescriber application vendors that connect to its network to ensure that EPCS is implemented in the ambulatory healthcare setting in a way that is fully compliant with the DEA's EPCS rules.

Surescripts published an update similar to this two years ago and distributed it to the pharmacy community with the goal of answering the questions that were being asked most frequently about EPCS by a variety of stakeholders, both within and without the industry. Given that Surescripts continues to receive general and technical questions from the field with respect to the adoption and utilization of EPCS processes, this second update seems appropriate, and a question and answer format is being used again as a vehicle to share such information. We hope you find this information useful.

Question: How can prescribers and pharmacists confirm that EPCS is legal according to the DEA?

Answer: This might seem to be an unusual question, but Surescripts continues to receive reports of both pharmacists and prescribers not believing that EPCS is a legal practice. The best resource for confirming the legality of EPCS is the section of the DEA website that discusses the issue at: http://www.deadiversion.usdoj.gov/ecomm/e_rx/index.html

At this website, the following highly recommended FAQs can be found:

- General: http://www.deadiversion.usdoj.gov/ecomm/e_rx/faq/faq.htm
- Pharmacies: http://www.deadiversion.usdoj.gov/ecomm/e_rx/faq/pharmacies.htm
- Prescribers: http://www.deadiversion.usdoj.gov/ecomm/e_rx/faq/practitioners.htm

Of course, in addition to the DEA's rules, one must also comply with state rules when choosing to engage in EPCS communications. At this writing, 49 states and the District of Columbia allow EPCS, and the remaining state is in the process of adopting enabling legislation. It is assumed that the readers of this update will be aware of and will understand the rules regarding EPCS in their respective states.

Question: How can pharmacists be assured that EPCSs transmitted through the Surescripts network are compliant with DEA's EPCS rules?

Answer: Surescripts is committed to full compliance with the DEA's EPCS IFR. The Surescripts network adheres strictly to the sections within the DEA's EPCS rule that place requirements on intermediary networks. Surescripts also requires that pharmacy and prescriber application vendors that would like to connect to its network for EPCS purposes prove that they have successfully completed a Part 1311 EPCS audit as required by the DEA prior to being activated for EPCS transactions on the Surescripts network. This is accomplished by insisting that all such application vendors submit a copy of their successful EPCS audit reports to Surescripts, both at their initial activation and on a biennial basis as is required by the DEA. Further, it should be noted that the DEA's EPCS IFR makes very rigorous requirements on prescribers and their application vendors, which include prescriber identity proofing according to Federal security standards, issuance and use of highly secure two-factor authentication credentials to sign EPCSs, and extensive application audit trails. Finally, Surescripts requires that pharmacies and pharmacy system application vendors display an indication to pharmacists to confirm to them that the EPCS that they are viewing is in fact DEA EPCS IFR compliant.

Question: What must be done in order for a pharmacy practice management application vendor or prescriber electronic health record application vendor to be able to connect its users to the Surescripts network for EPCS purposes?

Answer: The first step is that the application vendor must study the extensive technical requirements made by the DEA in its EPCS IFR and then work through the software development process necessary to meet said requirements. It is Surescripts' experience that this effort typically takes a minimum of several months to complete.

Once the development process is concluded, the application vendor must:

- (1) Successfully complete the Surescripts EPCS certification process, which is in addition to the basic Surescripts certification that is required in order for an application vendor to connect to the network for general e-prescribing purposes,
- (2) Submit to Surescripts documentation satisfactory to Surescripts in form and substance confirming the successful completion of the application vendor's third-party audit or certification as required by the DEA in § CFR 1311.300 Application Provider Requirements--Third-party Audits or Certifications, and

(3) Fill out, sign, and submit to Surescripts a form attesting to the application vendor's compliance with all EPCS aspects of 21 CFR § 1300, 1304, 1306, and 1311 along with a copy of the application vendor's third-party audit or certification.

These procedures are designed to confirm and document that all application vendors connecting to the Surescripts network have met all of the applicable DEA EPCS IFR requirements, thereby ensuring that EPCS communications on the Surescripts network are legal. It is only upon complying with all of these requirements that a pharmacy or prescriber application vendor is permitted to connect its end users to the Surescripts network for EPCS purposes.

Question: Do pharmacy or prescriber applications need to be approved, audited or certified by the DEA prior to their use to receive or transmit EPCSs?

Answer: This is a commonly misunderstood aspect of the DEA's EPCS IFR. The answer is no, the DEA itself does not approve, audit or certify any pharmacy or prescriber applications for EPCS purposes. What the DEA does do in the EPCS IFR is identify the types of entities that the agency recognizes as being capable of conducting what are commonly referred to as Part 1311 EPCS audits. These audits are mandated by the DEA's EPCS IFR, and it is the responsibility of pharmacy and prescriber application vendors to identify and contract with such entities in order to have their EPCS audits performed.

Question: What entities are available in the industry to conduct the third-party Part 1311 EPCS audits required by the DEA's EPCS IFR?

Answer: In Surescripts' experience, the types of entities that are allowed to conduct third-party Part 1311 EPCS audits is probably the least understood aspect of the DEA's EPCS IFR. To review, here is an excerpt from the DEA's EPCS IFR that specifies what types of entities are recognized as being able to conduct such audits:

- (b) The third-party audit must be conducted by one of the following:
 - (1) A person qualified to conduct a SysTrust, WebTrust, or SAS 70 audit.
 - (2) A Certified Information System Auditor who performs compliance audits as a regular ongoing business activity.
- (c) An audit for installed applications must address processing integrity and determine that the application meets the requirements of this part.
- (d) An audit for application service providers must address processing integrity and physical security and determine that the application meets the requirements of this part.
- (e) If a certifying organization whose certification process has been approved by DEA verifies and certifies that an electronic prescription or pharmacy application meets the requirements of this part, certification by that organization may be used as an alternative to the audit requirements of paragraphs (b) through (d) of this section

Surescripts does not recommend any entities to its network participants as being able to conduct Part 1311 EPCS audits. This said, Surescripts has been informed by its network participants that they have used many different entities for such audits. The following entities have been reported to Surescripts as belonging to the first two DEA EPCS IFR categories mentioned in sections (b)(1) and (b)(2) above, and they have therefore been employed by pharmacy and prescriber application vendors to conduct such audits:

- A-align CPAs
- Assurance Concepts
- BDO USA, LLP
- Brightline
- Chief Security Officers, LLC
- Coalfire Systems, Inc.
- ComplySmart, LLC
- Deloitte & Touche, LLP
- Electronic Healthcare Network Accreditation Commission (EHNAC)
- KPMG
- McGladrey, LLP
- NetSPI
- Paladion Inc.
- Price Waterhouse Coopers
- Roosa CPA, LLC
- Schneider Downs & Company, Inc.
- SunGard Availability Service
- Weaver & Tidwell, LLP

In addition, since the publication of the agency's EPCS IFR, the DEA has identified six entities pursuant to the third EPCS IFR category, which is in section (e) above. These entities have all applied directly to the DEA to be recognized as being able to conduct Part 1311 EPCS audits, and they all have been approved to do so:

- ComplySmart, LLC
- Drummond Group Inc
- EHNAC (approved for this category by the DEA on 12/03/2014)
- Global Sage Group, LLC
- iBeta, LLC
- InfoGard Laboratories

It is important to note that the DEA does not list entities in the first two categories on its website, but the agency does list entities in the third category on its website as industry stakeholders otherwise would not know who they are.

To reiterate, Surescripts has chosen not to recommend or endorse any of these specific entities over another, and the first list should not be considered to be comprehensive. It is simply meant to share examples of the types of entities that are offering Part 1311 EPCS audit services in the industry. Surescripts does, however, recommend that application vendors interview several potential Part 1311 EPCS auditors prior to engagement, because it has been reported to Surescripts that services offered and fees charged by these entities vary dramatically.

Question: Does Surescripts publish the names of pharmacy and prescriber application vendors that have completed the necessary processes and have been allowed to connect to the Surescripts network for EPCS purposes?

Answer: Yes, Surescripts posts the names of application vendors that have been certified and audited as being able to engage in EPCS transactions at the following links on its website:

- Pharmacies and pharmacy application vendors: <http://surescripts.com/epcscertified>
- Prescriber application vendors: <http://surescripts.com/epcscertifiedehr>

In addition to these resources, if individual pharmacists or prescribers want to confirm that their own applications have been audited and found to be in compliance with the DEA's EPCS IFR, all they need do is ask their application vendor for a copy of its audit report. The DEA's EPCS IFR requires application vendors to give documentation of their Part 1311 EPCS audit reports to their current and potential customers upon request.

Question: To what extent have DEA-compliant EPCSs been transmitted across the Surescripts network?

Answer: Since the first legal EPCS transmission took place on the Surescripts network in August 2011, approximately 1.8 million new EPCSs and 60,000 refill responses have traversed the Surescripts network. (Note that refill responses must meet DEA EPCS IFR requirements and are treated as new prescriptions by pharmacies.)

Question: In which states have EPCS transactions been transmitted and received via the Surescripts network since August 2011?

Answer: EPCS transactions have been transmitted by prescribers and received by pharmacies in all states except Montana.

Question: Is Surescripts doing anything to facilitate the EPCS process that is not required of it by the DEA in its EPCS IFR?

Answer: Yes, Surescripts is offering the following value-added services and/or implementing the following additional requirements that are not included in the DEA's EPCS IFR:

- As mentioned above, Surescripts requires all application vendors to prove that they have successfully completed their Part 1311 EPCS audits as required by the DEA prior to being activated for EPCS transactions on the Surescripts network.
- Pharmacy directories in prescriber applications are required to indicate which pharmacies are enabled to receive EPCSs, and prescribers are only able to send EPCSs to those pharmacies.
- Prescriber directories in pharmacy applications are required to indicate which prescribers are using applications that have been certified and audited for EPCS purposes.
- As an added security feature, Surescripts is digitally signing all EPCSs that include the "Signature Indicator" flag so as to augment transaction traceability.
- Surescripts is monitoring compliance with EPCS rules, e.g., reminding network participants that EPCS procedures must be followed for state controlled drugs and that schedule II drugs should not be electronically prescribed in states in which it is not yet permitted.
- In instances in which an EPCS crosses a state line, Surescripts requires that both the transmitting prescriber and the receiving pharmacy be in compliance with both the DEA's EPCS IFR and the controlled substance rules of the state in which the prescriber or pharmacy is located. For example, Surescripts does not allow a prescriber in a state in which EPCS is legal to transmit an EPCS to a pharmacy in a state in which EPCS is not yet permitted.

Question: To whom should additional questions about the implementation of EPCS on the Surescripts network be posed?

Answer: More information about EPCS is available on the Surescripts website at: <http://www.surescripts.com/epcs>. Individuals who have additional questions about EPCS processes not answered in this memo or on the Surescripts website can send an email to ken.whittemore@surescripts.com and said questions will be triaged and replied to in a timely fashion.

###

Attachment 11

For Entities Considering Whether to Register As Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft 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*.

For questions regarding this draft document contact Sara Rothman (CDER) at 301-796-3110.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)**

**February 2015
Procedural**

For Entities Considering Whether to Register As Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

Additional copies are available from:

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Center for Drug Evaluation and Research

Food and Drug Administration

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Silver Spring, MD 20993-0002

Phone: 8855-543-3784 or 301-796-3400; Fax: 301-431-6353

Email: druginfo@fda.hhs.gov

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)**

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1 **For Entities Considering Whether to Register As Outsourcing**
2 **Facilities Under Section 503B of the Federal Food, Drug, and**
3 **Cosmetic Act**
4 **Guidance¹**
5

6
7 This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's or the
8 Agency's) current thinking on this topic. It does not create or confer any rights for or on any person and
9 does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies
10 the requirements of the applicable statutes and regulations. If you want to discuss an alternative
11 approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the
12 appropriate FDA staff, call the appropriate number listed on the title page of this guidance.
13

14
15 **I. INTRODUCTION**
16

17 This guidance is intended for entities considering whether to register with the Food and Drug
18 Administration (FDA or Agency) as an outsourcing facility under section 503B of the Federal
19 Food, Drug, and Cosmetic Act (FD&C Act).²
20

21 FDA has received questions about whether entities engaged in various types of activities (e.g., a
22 facility that is compounding only non-sterile drugs or only repackaging biological products)
23 should register as an outsourcing facility. Because entities that register as outsourcing facilities
24 in fiscal year (FY) 2015 (beginning October 1, 2014) must pay a registration fee and FDA has
25 determined that fees paid pursuant to sections 503B and 744K of the FD&C Act will not be
26 refunded, FDA is issuing this guidance to answer some of these questions and to provide
27 potential registrants additional information about the regulatory impact of registering as an
28 outsourcing facility.
29

30 Separate FDA guidance documents contain details on the process for registering as an
31 outsourcing facility³ and explain how outsourcing facilities should report the products they
32 compound to FDA.⁴

¹ This guidance has been prepared by multiple offices in the Center for Drug Evaluation and Research (CDER) in cooperation with the Center for Biologics Evaluation and Research (CBER), the Center for Veterinary Medicine (CVM), and the Office of Regulatory Affairs (ORA) at the Food and Drug Administration.

² A new section 503B was added to the FD&C Act by the Drug Quality and Security Act (DQSA). See Pub. L. No. 113-54, § 102(a), 127 Stat. 587, 587-588 (2013).

³ See draft guidance for industry *Registration for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act*.

All FDA guidances are available on the FDA guidance Webpage at
<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

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33
34 FDA’s guidance documents, including this guidance, do not establish legally enforceable
35 responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should
36 be viewed only as recommendations, unless specific regulatory or statutory requirements are
37 cited. The use of the word *should* in Agency guidances means that something is suggested or
38 recommended, but not required.

39 40 **II. BACKGROUND**

41
42 The Drug Quality and Security Act, signed into law on November 27, 2013, creates a new
43 section 503B of the FD&C Act. Section 503B(d)(4) defines an outsourcing facility as

44
45 a facility at one geographic location or address that— (i) is engaged in the
46 compounding of sterile drugs; (ii) has elected to register as an outsourcing
47 facility; and (iii) complies with all of the requirements of this section.

48 Section 503B(d)(4) further states that an outsourcing facility is not required to be a licensed
49 pharmacy and may or may not obtain prescriptions for identified individual patients.⁵ Section
50 503B(d)(5) defines *sterile drug* as a “drug that is intended for parenteral administration, an
51 ophthalmic or oral inhalation drug in aqueous format, or a drug that is required to be sterile under
52 Federal or State law.”

53 A human drug product compounded by or under the direct supervision of a licensed pharmacist
54 in a registered outsourcing facility can *qualify for exemptions* from the drug approval
55 requirements in section 505 of the FD&C Act (21 U.S.C. 355), the requirement to be labeled
56 with adequate directions for use in section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)), and
57 the track and trace requirements in section 582 of the FD&C Act (21 U.S.C. 360eee-1).
58 However to qualify, each of the following conditions must be met.

- 59 1. The outsourcing facility must be in compliance with the registration and reporting
60 requirements of section 503B(b). This includes submitting twice yearly reports regarding
61 the drugs compounded by the outsourcing facility and submitting adverse event reports in
62 accordance with section 503B(b)(5).^{6,7}

⁴ See draft guidance for industry *Interim Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act*.

⁵ Although an outsourcing facility may send prescription drugs to healthcare facilities without obtaining prescriptions for identified individual patients, drugs produced by outsourcing facilities remain subject to the requirements in section 503(b) of the FD&C Act. Therefore, an outsourcing facility cannot dispense a prescription drug to a patient without a prescription.

⁶ See section 301(ccc)(3) of the FD&C Act, which makes it a prohibited act for an entity that is registered in accordance with section 503B(b) to fail to report drugs or adverse events as required.

⁷ See sections 503B(a)(1) and (b).

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- 63 2. If the outsourcing facility compounds drugs using one or more bulk drug substances, the
64 bulk drug substances must meet certain requirements.⁸
- 65 3. If the outsourcing facility compounds using ingredients other than bulk drug substances,
66 those ingredients must meet certain requirements.⁹
- 67 4. The outsourcing facility must not compound drugs that appear on a list published by FDA
68 of drugs that have been withdrawn or removed from the market because the drugs or
69 components of such drugs have been found to be unsafe or not effective.^{10,11}
- 70 5. The outsourcing facility must not compound drugs that are essentially a copy of one or
71 more approved drugs.¹²
- 72 6. The outsourcing facility must not compound drugs that appear on a list published by FDA
73 of drugs that present demonstrable difficulties for compounding.¹³
- 74 7. If the outsourcing facility compounds from a drug that is the subject of a risk evaluation
75 and mitigation strategy (REMS) approved with elements to assure safe use pursuant to
76 section 505-1, or from a bulk drug substance that is a component of such drug, the
77 outsourcing facility must demonstrate to FDA before beginning to compound that it will
78 use controls comparable to the controls applicable under the REMS.¹⁴
- 79 8. The outsourcing facility's compounded drugs will not be sold or transferred by an entity
80 other than that outsourcing facility.¹⁵
- 81 9. The outsourcing facility has paid all applicable establishment and reinspection fees owed
82 under section 744(k).^{16,17}
- 83 10. The outsourcing facility must include on the labels and labeling of its compounded drug
84 products the information required under section 503B(a)(10).¹⁸

⁸ See section 503B(a)(2).

⁹ See section 503B(a)(3).

¹⁰ See section 503B(a)(4).

¹¹ The list of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective (the withdrawn-or-removed list) can be found at 21 CFR 216.24. On July 2, 2014, FDA published a proposed rule that would update that list (Additions and Modifications to the List of Drug Products That Have Been Withdrawn or Removed from the Market for Reasons of Safety or Effectiveness, 79 FR 37,687). In the preamble to the proposed rule, FDA explained that FDA is proposing to revise and update the withdrawn-or-removed list at 21 CFR 216.24 for purposes of both sections 503A and 503B. Until the final rule revising and updating the withdrawn-or-removed list is published, drugs included on the existing list at 21 CFR 216.24 may not be compounded under section 503B.

¹² See section 503B(a)(5).

¹³ See section 503B(a)(6).

¹⁴ See section 503B(a)(7).

¹⁵ See section 503B(a)(8).

¹⁶ See section 503B(a)(9).

¹⁷ See also sections 744J and 744K of the FD&C Act, and guidance for industry Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act.

¹⁸ See section 503B(a)(10).

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85 11. The outsourcing facility must compound all drugs in accordance with section 503B.¹⁹

86

87 Because drugs compounded by outsourcing facilities are not exempt from section 501(a)(2)(B)
88 of the FD&C Act, outsourcing facilities are subject to current good manufacturing practice
89 (CGMP) requirements, among other requirements under the FD&C Act.^{20,21} In addition,
90 outsourcing facilities will be inspected by FDA on a risk-based schedule.²²

91 III. GUIDANCE

92 If you register a facility as an outsourcing facility, you are indicating your intent for the facility's
93 compounded drugs to be regulated under section 503B of the FD&C Act. Under section
94 503B(a)(11), a compounded drug can only qualify for the exemptions from sections 502(f)(1),
95 505, and 582 of the FD&C Act if *all* of the facility's compounded drugs are compounded in
96 accordance with section 503B. As stated above, drugs compounded in accordance with section
97 503B are not exempt from CGMP requirements, and outsourcing facilities will be inspected by
98 FDA on a risk-based schedule.

99

100 If you do not intend to compound *all* drugs at your facility in accordance with section 503B and
101 comply with CGMP requirements, you should not register as an outsourcing facility under
102 section 503B.²³ In addition, entities considering registering as outsourcing facilities should
103 consider the following:

104

- 105 • To meet the definition of an *outsourcing facility*, the facility must be engaged in the
106 compounding²⁴ of sterile human drugs.²⁵
- 107 • The definition of *compounding* in section 503B(d)(1) does not include repackaging.
- 108 • For purposes of section 503B, a drug, including a sterile drug, does not include a
109 biological product subject to licensure under section 351 of the Public Health Service Act
110 (PHS Act), or an animal drug subject to approval under section 512 of the FD&C Act.²⁶

111

¹⁹ See section 503B(a)(11).

²⁰ FDA has issued a draft guidance for industry *Current Good Manufacturing Practice—Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act*. Once finalized, that guidance will represent the Agency's thinking on this topic.

²¹ See section 503B(a).

²² See section 503B(b)(4).

²³ If an entity is not registered as an outsourcing facility under section 503B, its drugs could qualify for the exemptions from sections 505, 502(f)(1), and 501(a)(2)(B) of the FD&C Act, if they meet all of the conditions of section 503A. Otherwise, the drugs would be subject to all of the requirements in the FD&C Act applicable to drugs made by conventional manufacturers.

²⁴ Section 503B(d)(1) defines the term *compounding*, for purposes of that section, to include the combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering of a drug or bulk drug substance to create a drug.

²⁵ See section 503B(d)(4).

²⁶ In addition, for purposes of section 503A of the FD&C Act, the term *drug* does not include a biological product subject to licensure under section 351 of the PHS Act.

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112 Therefore, you should ***not*** register a facility as an outsourcing facility if the ***only*** activities
113 conducted at the facility are repackaging, compounding non-sterile or animal drugs, or mixing,
114 diluting, or repackaging biological products subject to licensure under section 351 of the PHS
115 Act because ***none of the products produced at the facility would qualify for the exemptions***
116 ***provided in section 503B.***

117
118 In addition, by registering as an outsourcing facility, an entity is electing to have its compounded
119 drugs regulated under section 503B of the FD&C Act, not section 503A. Drugs compounded at
120 an outsourcing facility are not eligible for the exemptions provided in section 503A, even if the
121 conditions in that section are met with respect to the particular drug.

122
123 FDA is issuing separate draft guidances on (1) mixing, diluting, and repackaging biological
124 products outside the scope of an approved biologics license application and (2) repackaging
125 certain human drug products by pharmacies and outsourcing facilities. These guidance
126 documents will describe FDA’s compliance policies with respect to biological products that are
127 mixed, diluted, or repackaged outside the scope of an approved biologics license application
128 (BLA) and repackaged human drugs.

129
130 If a facility compounds sterile human drugs and otherwise meets the definition of an outsourcing
131 facility, any non-sterile human drugs compounded by the facility would also be eligible for the
132 exemptions from sections 505, 502(f)(1), and 582 if the drugs are compounded in accordance
133 with the provisions of section 503B. However, if a facility that meets the definition of an
134 outsourcing facility repackages certain human drugs, or mixes, dilutes, or repackages biological
135 products outside the scope of an approved BLA, FDA does not intend to take action against
136 those products for violations of certain provisions of the FD&C Act or the PHS Act, if
137 applicable, provided those products satisfy the conditions described in the two guidances on
138 biological products and repackaging, referenced above.

Attachment 12

Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft 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*.

For questions regarding this draft document contact Gail Bormel, CDER Office of Unapproved Drugs and Labeling Compliance (OUDLC), at 301-796-3110.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Office of Compliance/OUDLC**

**February 2015
Compliance**

Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities

Guidance for Industry

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<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
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1 **Repackaging of Certain Human Drug Products by Pharmacies and**
2 **Outsourcing Facilities¹**
3 **Guidance for Industry²**
4

5
6 This draft guidance, when finalized, will represent the Food and Drug Administration’s (FDA’s) current
7 thinking on this topic. It does not create or confer any rights for or on any person and does not operate to
8 bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of
9 the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA
10 staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call
11 the appropriate number listed on the title page of this guidance.
12

13
14
15 **I. INTRODUCTION AND SCOPE**
16

17 This guidance sets forth the Food and Drug Administration’s (“FDA” or “the Agency”) policy
18 regarding repackaging by state-licensed pharmacies, Federal facilities, and facilities that register
19 with FDA as outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic
20 Act (FD&C Act or the Act). This guidance describes the conditions under which FDA does not
21 intend to take action for violations of sections 505, 502(f)(1), and where specified, section
22 501(a)(2)(B) of the Act, when a state-licensed pharmacy, a Federal facility, or an outsourcing
23 facility repackages human prescription drug products.
24

25 This guidance **does not address** the following:

- 26 • Biological products that are subject to licensure under section 351 of the Public Health
27 Service (PHS) Act. The repackaging of biological products subject to licensure under
28 section 351 is addressed in a separate draft guidance document.³

¹ “Outsourcing facility” refers to a facility that meets the definition of an outsourcing facility under section 503B(d)(4) of the Federal Food, Drug, and Cosmetic Act.

² This guidance has been prepared by multiple offices in the Center for Drug Evaluation and Research (CDER) and in consultation with the Office of Regulatory Affairs at the Food and Drug Administration.

³ FDA has issued a draft guidance, titled *Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application*. Once finalized, that guidance will represent FDA’s thinking on this topic.

All FDA guidances are available on the Agency’s guidance website at <http://www.fda.gov/ForIndustry/FDABasicsforIndustry/ucm234622.htm>. FDA updates guidances regularly. To ensure that you have the most recent version, please check this web page.

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- 29 • Repackaging drug products for use in animals. FDA will consider addressing this issue
30 in a separate guidance document.
- 31 • Repackaging by entities that are not state-licensed pharmacies, Federal facilities, or
32 outsourcing facilities. See additional information in section III.A. of this draft guidance
33 document.
- 34 • Removing a drug product from the original container at the point of care for immediate
35 administration to a single patient after receipt of a patient-specific prescription or order
36 for that patient (e.g., drawing up a syringe to administer directly to the patient). FDA
37 does not consider this to be “repackaging,” for purposes of this guidance document.
- 38 • Upon receipt of an individual patient-specific prescription, a licensed pharmacy removing
39 from one container the quantity of solid oral dosage form drug products necessary to fill
40 the prescription and placing it in a smaller container to dispense directly to its customer.

41
42 FDA’s guidance documents, including this guidance, do not establish legally enforceable
43 responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should
44 be viewed only as recommendations, unless specific regulatory or statutory requirements are
45 cited. The use of the word *should* in Agency guidances means that something is suggested or
46 recommended, but not required.

47

II. BACKGROUND

48

A. Repackaging, Generally

49

50
51
52 FDA regards repackaging as the act of taking a finished drug product from the container in
53 which it was distributed by the original manufacturer and placing it into a different container
54 without further manipulation of the drug. Repackaging also includes the act of placing the
55 contents of multiple containers (e.g., vials) of the same finished drug product into one container,
56 as long as the container does not include other ingredients. If a drug is manipulated in any other
57 way, including if the drug is reconstituted, diluted, mixed, or combined with another ingredient,
58 that act is not considered repackaging.

59

60 Repackaging is performed by a range of entities, including facilities that specialize in
61 repackaging drug products, and pharmacies, including pharmacies in hospitals and health
62 systems. FDA is aware that repackaging is done for a variety of reasons including: to meet the
63 needs of specific groups of patients (e.g., pediatric patients or ophthalmic patients who require
64 smaller doses of approved sterile drug products that may not be available commercially); to
65 reduce medication errors associated with drawing up a dose from a vial at the point of patient
66 care; to reduce the availability of drug products of abuse when controlled substances are left over
67 in a vial after a dose is drawn out; to provide a particular sized container to fit into a particular
68 device to administer the drug (such as a particular pain medication pump); for convenience for
69 the practitioner administering an injection to a patient; and in some cases to reduce cost. Some
70 repackagers repack both sterile and non-sterile drug products. For example, tablets and
71 capsules are repackaged from large containers into smaller containers or blister packs, and
72 creams and lotions are sometimes purchased in bulk and repackaged into smaller tubes or
73 containers.

74

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75 As part of the drug application review and approval process, FDA evaluates the container closure
76 system and the packaging into which the drug will be placed, as well as the conditions under
77 which the drug will be packaged. The container closure system and packaging can affect the
78 quality of the drug product when it is on the market. In particular, during the approval process
79 FDA reviews whether the container closure system and the packaging are appropriate for
80 maintaining the stability of the drug product through its expiration date, as long as the container
81 and package are not breached, and the drug is stored according to the conditions specified in the
82 application. For drug products required to be sterile, FDA also considers whether the container
83 closure system and packaging are adequate to ensure that the drug product will remain sterile
84 until its expiration date, as long as the container closure is not breached and the drug product is
85 stored appropriately.

86
87 When a drug product is repackaged, its characteristics may change in ways that have not been
88 evaluated during the FDA approval process and that could affect the safety and efficacy of the
89 drug product. Improper repackaging of drug products can cause serious adverse events. Of
90 particular concern is repackaging of sterile drug products, which are susceptible to contamination
91 and degradation. For example, failure to properly manipulate sterile drug products under
92 appropriate aseptic conditions could introduce contaminants that could cause serious patient
93 injury or death. Repackaging practices that conflict with approved product labeling could result
94 in drug product degradation and adverse events associated with impurities in the product or lack
95 of efficacy because the active ingredient has deteriorated.

B. Regulatory Framework for Repackaging

96
97
98
99 Repackaged drug products are generally not exempt from any of the provisions of the FD&C Act
100 related to the production of drugs. For example, repackaged drug products are generally subject
101 to the premarket approval, misbranding, and adulteration provisions of the FD&C Act, including
102 section 505 (concerning new drug applications),⁴ section 502(f)(1) (concerning labeling with
103 adequate directions for use), and section 501(a)(2)(B) (concerning current good manufacturing
104 practice (CGMP)).

105
106 Drugs that are repackaged are not subject to sections 503A and 503B of the FD&C Act.⁵
107 Therefore, drug products repackaged by state-licensed pharmacies, Federal facilities, or
108 outsourcing facilities are not eligible for the exemptions provided under those sections. In this

⁴ But see *U.S. v. Kaybel*, 430 F.2d 1346 (3d Cir. 1970) (holding that repackaging of approved Enovid (estrogen) tablets from large bottles into small bottles did not require pre-approval under section 505 of the FD&C Act).

⁵ Section 503A of the FD&C Act exempts compounded drug products from sections 505, 502(f)(1), and 501(a)(2)(B) of the FD&C Act provided certain conditions are met, including that the drug product is compounded pursuant to a prescription for an individually identified patient from a licensed practitioner. The Drug Quality and Security Act added a new section 503B to the FD&C Act. Under section 503B(b), a compounder can register as an outsourcing facility with FDA. Drug products compounded under the direct supervision of a licensed pharmacist in an outsourcing facility can qualify for exemptions from the FDA approval requirements in section 505 of the FD&C Act and the requirement to label drug products with adequate directions for use under section 502(f)(1) of the FD&C Act if the conditions in section 503B are met. Drug products compounded in outsourcing facilities are not exempt from the CGMP requirements of section 501(a)(2)(B).

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109 guidance, FDA describes the conditions under which it does not intend to take action regarding
110 violations of certain requirements of the FD&C Act, in the context of drug repackaging.

111

C. Hospital and Health System⁶ Repackaging of Drugs In Shortage For Use in the Health System (Section 506F of the FD&C Act)

114

115 The Food and Drug Administration Safety and Innovation Act (FDASIA), signed into law in
116 July, 2012, added section 506F to the FD&C Act. This section exempts certain hospitals within
117 a health system from registration requirements in section 510 of the Act provided certain
118 conditions are met, including that the drugs are, or have recently been, listed on FDA’s drug
119 shortage list⁷ and are repackaged for the health system. Section 506F of the FD&C Act defines
120 “repackaging,” for purposes of that section only, as “divid[ing] the volume of a drug into smaller
121 amounts in order to—(A) extend the supply of a drug in response to the placement of the drug on
122 a drug shortage list under section 506E; and (B) facilitate access to the drug by hospitals within
123 the same health system.”

124

125 Section 506F of the FD&C Act has a termination clause that states “This section [506F] shall not
126 apply on or after the date on which the Secretary issues final guidance that clarifies the policy of
127 the Food and Drug Administration regarding hospital pharmacies repackaging and safely
128 transferring repackaged drugs to other hospitals within the same health system during a drug
129 shortage.”⁸ These issues are addressed and clarified by this guidance and the guidance on
130 *Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved*
131 *Biologics License Application*. Therefore, when these guidances become final, section 506F of
132 the FD&C Act will no longer apply.

133

III. POLICY

134

A. General Policy

135

136 As discussed above, repackaged drug products are generally subject to the adulteration,
137 misbranding, and approval provisions of the FD&C Act.⁹ FDA does not intend to take action for
138 violations of sections 505 and 502(f)(1) if a state-licensed pharmacy, a Federal facility, or an
139
140

⁶ For purposes of this guidance, the term “*health system*” refers to a collection of hospitals that are owned and operated by the same entity and that share access to databases with drug order information for their patients.

⁷ See section 506F(b) (providing that the exemption may be available if, among other factors, the drug is repackaged (1) during any period in which the drug is listed on the drug shortage list under section 506E; or (2) during the 60-day period following any period described in paragraph (1)).

⁸ See section 506F(d) of the FD&C Act.

⁹ As described in section II.B., repackaged drug products are generally not exempt from any of the provisions of the FD&C Act related to the production of drugs. Therefore, drug products that do not meet the conditions in this guidance, including drug products repackaged by entities that are not state-licensed pharmacies, Federal facilities, or outsourcing facilities, generally must comply with requirements in the FD&C Act and FDA regulations applicable to drug products including, but not limited to, CGMP and new drug approval requirements.

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141 outsourcing facility repackages drug products in accordance with the conditions described below,
142 and any applicable requirements.¹⁰ In addition, FDA does not intend to take action for violations
143 of section 501(a)(2)(B) of the FD&C Act if the drug product is repackaged by a state-licensed
144 pharmacy or a Federal facility in accordance with the conditions described below, and any
145 applicable requirements.

146

147 The conditions referred to in the preceding paragraph are as follows:

148

149 1. The drug that is being repackaged is a prescription drug product approved under
150 section 505 of the FD&C Act, except as provided in section III.B of this guidance
151 regarding repackaging unapproved drug products that appear on FDA's drug shortage
152 list under section 506E.

153

154 2. The drug product is repackaged in a state-licensed pharmacy, a Federal facility, or an
155 outsourcing facility.

156

157 3. If the drug product is repackaged in a state-licensed pharmacy or a Federal facility
158 (but not an outsourcing facility), it is repackaged and distributed¹¹ after (a) the receipt
159 of a valid prescription for an identified, individual patient directly from the
160 prescribing practitioner, patient, or patient's agent; or (b) a written order in a patient's
161 chart in a health care setting, unless it is repackaged (but not distributed) in advance
162 of receipt of such a prescription or a written order in a patient's chart in a quantity
163 that does not exceed the amount of drug product that the state-licensed pharmacy or
164 the Federal facility repackaged pursuant to patient-specific prescriptions or written
165 orders in a previous, consecutive 14-day period, and based on a history of receipt of
166 prescriptions or written orders over a consecutive 14-day period for such repackaged
167 drug products.

168

169 4. The drug product is repackaged by or under the direct supervision of a licensed
170 pharmacist.

171

172 5. Except as provided below for a single-dose vial, the drug product is repackaged in a
173 way that does not conflict with approved drug product labeling.¹²

174

175 For a single-dose vial that is repackaged into multiple units, the drug product is
176 repackaged in a way that does not conflict with the approved labeling, except for the

¹⁰ Applicable requirements include, for example, the requirement that manufacturers not adulterate a drug product by preparing, packing, or holding the drug product under insanitary conditions. See section 501(a)(2)(A) of the FD&C Act.

¹¹ Distribution means that the repackaged drug product has left the facility in which it was repackaged.

¹² For example, if the approved labeling contains instructions for handling or storage of the product, the repackaging is done in accordance with those instructions. Otherwise, it would be considered to be in conflict with the approved labeling.

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177 statements designating the product as a single dose or single use product, and related
178 language (e.g., discard remaining contents).¹³

- 179
- 180 6. The repackaged drug product is assigned a beyond-use-date (BUD)¹⁴ as described below:
- 181
- 182 a. **FDA-approved drug product with a specified in-use time:** If the drug product
183 being repackaged is an FDA-approved drug product that specifies in the labeling a
184 time within which the opened product is to be used (an “in-use” time), the repackaged
185 drug product is assigned a BUD (1) that is established in accordance with the in-use
186 time on the drug product being repackaged; or (2) that is the expiration date on the
187 drug product being repackaged, whichever is shorter.¹⁵
- 188
- 189 b. **FDA-approved drug product without an in-use time or unapproved drug**
190 **product:** If the drug product being repackaged is an FDA-approved drug product
191 whose labeling does not specify an in-use time, or if it is an unapproved drug product
192 on the FDA drug shortage list (which does not have an in-use time reviewed by FDA
193 as part of the drug approval process), the repackaged drug product is assigned a BUD
194 (1) that is established in accordance with the time described in (i) or (ii) below, as
195 applicable, or (2) that is the expiration date on the drug product being repackaged,
196 whichever is shorter.¹⁶
- 197
- 198 i. **Sterile Drug Products:** The repackaged drug product is assigned a BUD no
199 longer than the following, even if the time until the expiration date on the drug
200 product being repackaged is longer:
- 201
- 202 1. **If repackaged in a state-licensed pharmacy or Federal facility,** the
203 repackaged drug product is assigned a BUD that is¹⁷:

¹³ This condition would not be satisfied if a drug product repackaged from a single-dose vial is repackaged in a way that conflicts with other language in the approved labeling (e.g., regarding storage conditions).

¹⁴ Unless otherwise indicated, the BUD timeframes in this condition begin from the time in which the container of the original drug product to be repackaged is punctured or otherwise opened.

¹⁵ For example, if an approved drug product that includes a 3-day in-use time and an expiration date of January 15, 2015 on the label is repackaged on January 1, 2015, the applicable BUD for the repackaged drug product would be January 4, 2015, because the labeled in-use time of 3 days is shorter than the time until the labeled expiration date of the drug product (14 days). If the drug product is repackaged on January 14, 2015, the applicable BUD for the repackaged drug product would be January 15, 2015, because the time until the labeled expiration date of the approved drug product is 1 day, which is shorter than the labeled 3-day in-use time.

¹⁶ In other words, if the FDA-approved drug product does not have an in-use time, or the drug product being repackaged is an unapproved drug product, the times in (i) and (ii) are the default BUDs, unless the expiration date on the drug product being repackaged is shorter, in which case the BUD would be the same as the expiration date.

¹⁷ These BUDs are consistent with the BUDs established by USP Chapter <797> for “medium-risk” compounded sterile preparations. Although USP <797> addresses *compounded* sterile preparations, many of the same principles for conditions and practices to assure sterility and stability of compounded drug products, such as the requirement to maintain a sterile environment, engage in appropriate sterile processing techniques, and put appropriate BUDs on the product, also apply to repackaged sterile drug products to help ensure their quality is not compromised during

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- ≤ 30 hours if stored at USP controlled room temperature;
 - ≤ 9 days if stored in a refrigerator; or
 - ≤ 45 days if stored in a solid frozen state between -25°C and -10°C
2. **If repackaged in an outsourcing facility**, the outsourcing facility conducts a sterility test in accordance with CGMP requirements¹⁸ (e.g., using the sterility test described in USP Chapter <71>) and receives passing results before release, and the repackaged drug product is assigned a BUD that is¹⁹:
- Not more than 14 days beyond completion of the sterility test or 28 days from the time of repackaging, whichever is shorter, if stored at USP controlled room temperature or in a refrigerator; or
 - Not more than 45 days beyond completion of the sterility test or 59 days from the time of repackaging, whichever is shorter, if stored in a solid frozen state between -25°C and -10°C²⁰
- ii. **Non-sterile Drug Products:** The BUD for the repackaged drug product is no longer than the expiration date on the original drug product being repackaged.
7. Except with regard to BUDs, which are addressed in condition 6, above:
- a. If the drug product is repackaged in a state-licensed pharmacy or a Federal facility:
 - i. If it is a non-sterile drug product, it is repackaged in accordance with USP Chapter <795>; or

and after the repackaging operation. The BUDs for medium-risk compounded preparations in USP <797> are appropriate for sterile drug products that do not include an “in-use” time and are repackaged by a state-licensed pharmacy or Federal facility because the two activities present comparable risks.

¹⁸ See 21 CFR part 211.

¹⁹ These longer BUDs reflect that outsourcing facilities must comply with CGMP requirements and are subject to FDA inspections on a risk-based schedule. Conditions maintained to comply with CGMP requirements provide greater assurance of the quality of manufacturing operations and the products that are produced at the facility. FDA has issued a draft guidance entitled, *Current Good Manufacturing Practice — Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act* (“Interim CGMP Guidance”). (See <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM403496.pdf>) The Interim CGMP Guidance, when finalized, will describe FDA’s expectations regarding outsourcing facilities and the CGMP requirements in 21 CFR parts 210 and 211 until more specific CGMP regulations for outsourcing facilities are promulgated. The BUDs set forth for sterile drug products repackaged by outsourcing facilities in this condition are consistent with the BUDs listed in the Interim CGMP Guidance that are applicable to sterile drug products compounded at outsourcing facilities.

²⁰ The 28-day and 59-day timeframes provide for the 14 days it takes to receive results from the sterility test conducted under USP Chapter <71>.

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- 229 ii. If it is sterile drug product, it is repackaged in accordance with USP
230 Chapter <797>, e.g., a sterile drug product is repackaged in an area
231 with air quality that meets or exceeds ISO Class 5 standards (see USP
232 Chapter <797>, Table 1).
- 233 b. If the drug product is repackaged in an outsourcing facility, repackaging is
234 conducted in accordance with CGMP requirements.
- 235
- 236 8. The drug product that is being repackaged does not appear on a list of drug products
237 that have been withdrawn or removed from the market because they have been found
238 to be unsafe or ineffective. For purposes of this provision, repackagers should refer
239 to the list of drug products in 21 CFR 216.24, developed for use with sections 503A
240 and 503B.
- 241
- 242 9. The drug product is not sold or transferred by an entity other than the entity that
243 repackaged such drug product. For purposes of this condition, a sale or transfer does
244 not include administration of a repackaged drug product in a health care setting.
- 245
- 246 10. The repackaged drug product is distributed only in states in which the facility
247 repackaging the drug product meets all applicable state requirements.
- 248
- 249 11. If the drug product is repackaged by an outsourcing facility:
- 250
- 251 a. The label on the immediate container (primary packaging, e.g., the syringe) of
252 the repackaged product includes the following:
- 253 i. The statement “This drug product was repackaged by [name of
254 outsourcing facility]”
- 255 ii. The address and phone number of the outsourcing facility that
256 repackaged the drug product
- 257 iii. The established name of the original, approved drug product that
258 was repackaged
- 259 iv. The lot or batch number of the repackaged drug product
- 260 v. The dosage form and strength of the repackaged drug product
- 261 vi. A statement of either the quantity or volume of the repackaged
262 drug product, whichever is appropriate
- 263 vii. The date the drug product was repackaged
- 264 viii. The BUD of the repackaged drug product
- 265 ix. Storage and handling instructions for the repackaged drug
266 product
- 267 x. The National Drug Code (NDC) number of the repackaged drug
268 product, if available²¹
- 269 xi. The statement “Not for resale,” and, if the drug product is
270 distributed by an outsourcing facility other than pursuant to a

²¹ The NDC number of the original approved drug product should not be placed on the repackaged drug product.

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- 271 prescription for an individual identified patient, the statement
272 “Office Use Only”
- 273 xii. If included on the label of the FDA-approved drug product from
274 which the drug product is being repackaged, a list of the active
275 and inactive ingredients, unless such information is included on
276 the label for the container from which the individual units are
277 removed, as described below in 11.b.i.
- 278
- 279 b. The label on the container from which the individual units are removed for
280 administration (secondary packaging, e.g., the bag, box, or other package in
281 which the repackaged products are distributed) includes:
- 282 i. The active and inactive ingredients, if the immediate drug
283 product label is too small to include this information
- 284 ii. Directions for use, including, as appropriate, dosage and
285 administration, and the following information to facilitate
286 adverse event reporting: www.fda.gov/medwatch and 1-800-
287 FDA-1088.
- 288
- 289 c. Each repackaged drug product is also accompanied by a copy of the
290 prescribing information that accompanied the original drug product that was
291 repackaged.
- 292
- 293 d. The drug product is included on a report submitted to FDA each June and
294 December identifying the drug products made by the outsourcing facility
295 during the previous 6-month period, and providing the active ingredient(s);
296 source of the active ingredient(s); NDC number of the source ingredient(s), if
297 available; strength of the active ingredient(s) per unit; the dosage form and
298 route of administration; the package description; the number of individual
299 units produced; and the NDC number of the final product, if assigned.²²
- 300
- 301 e. The outsourcing facility reports serious adverse events to FDA that may be
302 associated with its repackaged drug products.
- 303

B. Repackaging Drugs on FDA’s Drug Shortage List

306 This guidance addresses repackaging of prescription drug products, including drug products on
307 FDA’s drug shortage list, by a state-licensed pharmacy, Federal facility, or outsourcing facility,
308 including within a hospital or health system. This guidance also specifically addresses the
309 repackaging of single-dose vials, a practice that is sometimes used to extend the supply of a drug

²² FDA has issued a draft guidance for industry, *Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act*, which prescribes how human drug compounding facilities are to submit drug product reports to FDA. Once finalized, that guidance will represent the Agency’s current thinking on that topic. Although that guidance addresses reporting of compounded human drug products, outsourcing facilities should follow the same procedure to electronically report the drug products they repackaged.

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310 product that is on the FDA drug shortage list. In addition, the first condition described in section
311 III.A.1 of this guidance provides that the drug product being repackaged is a prescription drug
312 product approved by FDA under section 505 of the FD&C Act. However, with respect to an
313 unapproved drug product that appears on FDA’s drug shortage list, FDA also does not intend to
314 take action for violations of sections 505, 502(f)(1), and, as specified above, section
315 501(a)(2)(B), provided that the state-licensed pharmacy, the Federal facility, or the outsourcing
316 facility (including within a hospital or health system) meets all of the conditions of this guidance,
317 and the repackaged drug product is distributed during any period in which the drug product is
318 listed on the drug shortage list under section 506E of the FD&C Act or during the 30 days
319 following such period. As stated above, this guidance and the guidance on *Mixing, Diluting, or*
320 *Repackaging Biological Products Outside the Scope of an Approved Biologics License*
321 *Application* clarify the Agency’s policy regarding hospital pharmacies repackaging and safely
322 transferring repackaged drug products to other hospitals within the same health system during a
323 drug shortage. Therefore, when these guidances become final, section 506F of the FD&C Act
324 will no longer apply.

Attachment 13

Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management, 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*.

For questions regarding this draft document contact Leah Christl (CDER) at 301-796-0869 or the Office of Communication, Outreach, and Development (CBER) at 800-835-4709 or 240-402-7800.

**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)**

**February 2015
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Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application

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
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Email: druginfo@fda.hhs.gov

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>

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<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/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)

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1 **Mixing, Diluting, or Repackaging Biological Products Outside the**
2 **Scope of an Approved Biologics License Application**
3 **Guidance for Industry¹**
4

5
6 This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's or the
7 Agency's) current thinking on this topic. It does not create or confer any rights for or on any person and
8 does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies
9 the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach,
10 contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate
11 FDA staff, call the appropriate number listed on the title page of this guidance.
12

13
14 **I. INTRODUCTION AND SCOPE**
15

16 This guidance sets forth FDA's policy regarding the mixing,² diluting, and repackaging³ of
17 certain types of biological products that have been licensed under section 351 of the Public
18 Health Service Act (PHS Act) when such activities are not within the scope of the product's
19 approved biologics license application (BLA) as described in the approved labeling for the
20 product.⁴ This guidance describes the conditions under which FDA does not intend to take action
21 for violations of sections 351 of the PHS Act and sections 502(f)(1) and where specified, section
22 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), when a state-licensed
23 pharmacy, a Federal facility, or an outsourcing facility⁵ dilutes, mixes or repackages certain
24 biological products without obtaining an approved BLA.

¹ This guidance has been prepared by multiple offices in the Center for Drug Evaluation and Research (CDER), in cooperation with the Center for Biologics Evaluation and Research (CBER), and the Office of Regulatory Affairs at the Food and Drug Administration.

² For purposes of this guidance, mixing means combining an FDA-licensed biological product with one or more ingredients. Not covered by this guidance is diluting or mixing a biological product at the point of care for immediate administration to a single patient after receipt of a patient specific prescription or order for that patient (e.g., diluting or mixing into a syringe to administer directly to the patient).

³ For purposes of this guidance, repackaging means taking a licensed biological product from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the product. As used in this guidance, the terms mixing, diluting, and repackaging describe distinct sets of activities with respect to a biological product.

⁴ This guidance does not apply to blood and blood components for transfusion, vaccines, cell therapy products, and gene therapy products

⁵ "Outsourcing facility" refers to a facility that meets the definition of an outsourcing facility under section 503B(d)(4) of the FD&C Act. See FDA's draft guidance, "Guidance for Entities Considering Whether to Register As Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act."

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25 This guidance **does not address** the following:

- 26 • Biological products not subject to licensure under section 351 of the PHS Act (i.e.,
27 biological products for which a marketing application could properly be submitted under
28 section 505 of the FD&C Act (see section 7002(e) of the Affordable Care Act)). The
29 repackaging of biological products not subject to licensure under section 351 is addressed
30 in a separate draft guidance document.⁶
- 31 • Products intended for use in animals. FDA will consider addressing this issue in a
32 separate guidance document.
- 33 • Mixing, diluting, or repackaging biological products (other than allergenic extracts) by
34 entities that are not state-licensed pharmacies, Federal facilities, or outsourcing facilities;
35 and preparation of allergenic extracts by entities that are not state-licensed pharmacies,
36 Federal facilities, outsourcing facilities, or physicians (See additional information in
37 section III.A. of this draft guidance document).
- 38 • Removing a biological product from the original container at the point of care for
39 immediate administration to a single patient after receipt of a patient-specific prescription
40 or order for that patient (e.g., drawing up a syringe to administer directly to the patient).
41 FDA does not consider this to be “repackaging,” for purposes of this guidance document.
- 42 • Upon receipt of a patient-specific prescription, a licensed pharmacy removing from one
43 container the quantity of solid oral dosage form biological products necessary to fill the
44 prescription and placing it in a smaller container to dispense directly to its customer.
- 45 • Mixing, diluting, or repackaging a licensed biological product when the product is being
46 mixed, diluted, or repackaged in accordance with the approved BLA as described in the
47 approved labeling for the product. FDA considers this to be an approved manipulation of
48 the product.
- 49 • Mixing, diluting, or repackaging of blood and blood components for transfusion,⁷
50 vaccines, cell therapy products, or gene therapy products (see footnote 4). The guidance
51 does not alter FDA’s existing approach to regulating the collection and processing of
52 blood and blood components. In addition, FDA intends to consider regulatory action if
53 licensed vaccines, cell therapy products, and gene therapy products are subject to
54 additional manufacturing, including mixing, diluting, or repackaging, in ways not
55 specified in the product’s approved BLA as described in the approved labeling for the
56 product.

57
58 As stated above, this guidance does not address the mixing, diluting, or repackaging of a
59 biological product for which a marketing application could properly be submitted under section
60 505 of the FD&C Act (see section 7002(e) of the Affordable Care Act). Accordingly, the term

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⁶ The repackaging of biological products approved under section 505 is addressed in a separate draft Guidance, “*Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities*.”

⁷ The guidance does apply to licensed biological products that are plasma derived products, including recombinant and transgenic versions of plasma derivatives, mixed, diluted, or repackaged outside the scope of an approved BLA.

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61 “*biological product*” as used in this guidance does not include products for which a marketing
62 application can be or has been submitted under section 505 of the FD&C Act.

63
64 Section II of this guidance provides background on biological products and the legal framework
65 for FDA’s regulation of these products, and explains that sections 503A and 503B of the FD&C
66 Act do not provide exemptions for mixing, diluting, or repackaging of biological products.
67 Section III describes FDA’s policy on mixing, diluting, or repackaging of certain licensed
68 biological products that is not within the scope of the product’s approved BLA as described in
69 the approved labeling for the product.

70
71 FDA’s guidance documents, including this guidance, do not establish legally enforceable
72 responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should
73 be viewed only as recommendations, unless specific regulatory or statutory requirements are
74 cited. The use of the word *should* in Agency guidances means that something is suggested or
75 recommended, but not required.

76 77 II. BACKGROUND

78 79 A. Biological Products

80
81 The term “biological product” is defined in section 351(i)(1) of the PHS Act to mean:

82
83 a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or
84 derivative, allergenic product, protein (except any chemically synthesized
85 polypeptide), or analogous product, or arsphenamine or derivative of
86 arsphenamine (or any other trivalent organic arsenic compound), applicable to
87 the prevention, treatment, or cure of a disease or condition of human beings.

88
89 Biological products can be complex chains or combinations of sugars, amino acids, or nucleic
90 acids, or living entities such as cells and cellular therapies. Biological products include
91 therapeutic proteins, monoclonal antibodies, allergenic extracts, blood and blood derivatives, cell
92 therapy products, and gene therapy products, preventive vaccines, and therapeutic vaccines.
93 Generally, biological products have a complex set of structural features (e.g., amino acid
94 sequence, glycosylation, folding) essential to their intended effect, and are very sensitive to
95 changes to their manufacturing process, including, but not limited to, any manipulation outside
96 of their approved container-closure systems. In addition, many biological products are
97 particularly sensitive to storage and handling conditions and can break down or aggregate if
98 exposed to heat and/or light, if dropped, or if shaken during storage and handling. Accordingly,
99 diluting or mixing a biological product with other components, or repackaging a biological
100 product by removing it from its approved container-closure system and transferring it to another
101 container-closure system, is, in the absence of manufacturing controls, highly likely to affect the
102 safety and/or effectiveness of the biological product.

103
104 Nevertheless, certain licensed biological products may need to be mixed or diluted in a way not
105 described in the approved labeling for the product to meet the needs of a specific patient. For
106 example, for some biological products there is no licensed pediatric strength and/or dosage form,
107 so the product must be diluted for use in pediatric patients. In addition, there may be certain

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108 circumstances where a person would repackage a licensed biological product by removing it
109 from its original container and placing it into a different container(s), in a manner that is not
110 within the scope of the approved BLA as described in the approved labeling for the product.
111 Like other drugs, biological products are sometimes repackaged for various reasons including for
112 pediatric or ophthalmic use. For example, a pediatric dialysis unit may repackage a larger
113 quantity of a product into smaller aliquots so that the optimal dose may be administered to each
114 pediatric dialysis patient being treated at that particular time.
115

116 Repackaging a drug or biological product could change its characteristics in ways that have not
117 been evaluated during the approval process and that could affect the safety and effectiveness of
118 the product. Improper repackaging of drug and biological products can cause serious adverse
119 events. Of particular concern is the repackaging of sterile drugs, which are susceptible to
120 contamination and degradation. For example, failure to properly repackage a sterile drug under
121 appropriate aseptic conditions could introduce contaminants that could cause serious patient
122 injury or death. Repackaging practices that conflict with approved product labeling have led to
123 product degradation resulting in adverse events associated with impurities in the product or lack
124 of efficacy because the active ingredient has deteriorated. These risks are often even more acute
125 for biological products due to their complex composition and sensitivity to variations in storage
126 and handling conditions.
127

128 Cell and gene therapy products often contain viable cells or intact/active viral vectors. The
129 manufacturing process for these products is complex and includes multiple controls to assure the
130 purity or potency of the product and its safety and effectiveness. Many cell therapy products are
131 cryopreserved, and the procedures for thawing and handling in preparation for administration
132 described in the approved labeling must be followed to maintain the safety and effectiveness of
133 the product. In addition, because these products are frequently implanted or administered
134 intravenously and are not typically amenable to terminal sterilization, their microbiological
135 safety is dependent largely on facility design, aseptic technique, and manufacturing protocols
136 that are best controlled by robust quality systems.
137

138 Vaccines are manufactured using biological systems and supplied by manufacturers in single
139 dose or multi-dose presentations. Unlike most other drugs and biological products, vaccines are
140 administered to healthy individuals, including infants, to prevent disease. Vaccines may contain
141 live attenuated organisms, inactivated organisms, or components of bacteria or viruses such as
142 polysaccharides, inactivated toxins, or purified proteins. The manufacturing process for
143 vaccines is complex and includes multiple controls to assure safety and effectiveness. Each
144 single dose of a vaccine is formulated to deliver the correct quantity of active ingredient(s) to the
145 recipient.
146

147 The policies in this guidance do not cover cell therapy products, gene therapy products, and
148 vaccines. Because of the particularly sensitive nature of these products as described above, these
149 categories of products must be prepared, and if applicable to that product's use, repackaged,
150 under an approved BLA, in accordance with section 351 of the PHS Act.
151

152 The policies in this guidance also do not cover or alter FDA's existing approach to regulating the
153 collection and processing of blood and blood components for transfusion. These activities are

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154 currently conducted in FDA licensed or registered blood collection establishments and in
155 hospital-based transfusion services regulated in part by the Centers for Medicare and Medicaid
156 Services under the Clinical Laboratory Improvement Amendments of 1988. In all instances,
157 blood collection and processing is already subject to current good manufacturing practices
158 (CGMP) under the existing statutory and regulatory framework for blood and blood components
159 and will not be subject to the policies described here.

160

B. Legal Framework for FDA’s Regulation of Biological Products

162

163 Section 351(a)(1) of the PHS Act prohibits the introduction into interstate commerce of any
164 biological product unless “a biologics license...is in effect for the biological product.” For FDA
165 to approve a BLA, the BLA must contain data to demonstrate that the biological product is safe,
166 pure, and potent and that the facility in which the biological product will be manufactured,
167 processed, packed, or held meets standards designed to ensure that the biological product
168 continues to be safe, pure, and potent. Because manufacturing controls are so important to
169 ensuring the safety and effectiveness of biological products, FDA licensing of a biological
170 product is based, in part, on an extensive review of chemistry and manufacturing controls data
171 submitted by the applicant. This includes a thorough evaluation of the raw materials, drug
172 substance, and drug product to ensure consistency in manufacturing and continued safety and
173 effectiveness. In addition, other data are submitted and reviewed (e.g., stability and
174 compatibility testing results) to establish the storage and handling conditions appropriate to
175 ensure the safety, purity, and potency of the biological product.

176

177 A biological product that is mixed, diluted, or repackaged outside the scope of an approved BLA
178 is an *unlicensed biological product* under section 351 of the PHS Act. For example, if a licensed
179 biological product is diluted or mixed with components other than those described in the
180 approved labeling for the product, or if it is removed from its original container-closure system
181 and placed in a new container-closure system that is not described in the approved labeling for
182 the product, these additional manufacturing steps would create a new, unlicensed biological
183 product. To be legally marketed, the new biological product would have to be licensed on the
184 basis of an approved BLA that includes, among other things, chemistry and manufacturing
185 controls data.

186

C. Sections 503A and 503B of the FD&C Act Do Not Exempt Biological Products from the Premarket Approval Requirements of the PHS Act or from Provisions of the FD&C Act

189

191 Section 503A of the FD&C Act exempts compounded drugs from sections 505 (concerning new
192 drug approval of human drugs products), 502(f)(1) (concerning labeling of drug products with
193 adequate directions for use), and 501(a)(2)(B) of the FD&C Act (concerning CGMP) provided
194 that certain conditions are met, including that the drug is compounded pursuant to a prescription
195 for an individually-identified patient from a licensed practitioner.

196

197 The Drug Quality and Security Act added a new section 503B to the FD&C Act. Under section
198 503B(b) of the FD&C Act, a compounder can register as an outsourcing facility with FDA.
199 Drug products compounded under the direct supervision of a licensed pharmacist in an

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200 outsourcing facility can qualify for exemptions from the FDA approval requirements in section
201 505 of the FD&C Act and the requirement to label drug products with adequate directions for use
202 under section 502(f)(1) of the FD&C Act if the conditions in section 503B are met. Drugs
203 compounded in outsourcing facilities are not exempt from the CGMP requirements of section
204 501(a)(2)(B).

205
206 Although sections 503A and 503B provide an exemption for certain compounded drugs from the
207 requirement to obtain premarket approval under section 505 of the FD&C Act, they do not
208 provide an exemption from the requirement to obtain premarket approval under section 351 of
209 the PHS Act. Manufacturers of biological products must obtain an approved license under
210 section 351(a) or (k) of the PHS Act. Thus, for purposes of sections 503A and 503B, a *drug*
211 does not include any biological product that is subject to licensure under section 351 of the PHS
212 Act. Accordingly, such biological products are not eligible for the exemptions for compounded
213 drugs under sections 503A and 503B of the FD&C Act. In other words, the FD&C Act does not
214 provide a legal pathway for marketing biological products that have been prepared outside the
215 scope of an approved BLA.

D. Hospital and Health System⁸ Repackaging of Drugs In Shortage For Use in the Health System (Section 506F of the FD&C Act)

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219
220 The Food and Drug Administration Safety and Innovation Act (FDASIA), signed into law in
221 July, 2012, added section 506F to the FD&C Act. This section exempts certain hospitals within
222 a health system from registration requirements in section 510 of the Act provided certain
223 conditions are met, including that the drugs (including biological products) are, or have recently
224 been, listed on FDA’s drug shortage list⁹ and are repackaged for the health system. Section 506F
225 of the FD&C Act defines “repackaging,” for purposes of that section only, as “divid[ing] the
226 volume of a drug into smaller amounts in order to—(A) extend the supply of a drug in response
227 to the placement of the drug on a drug shortage list under section 506E; and (B) facilitate access
228 to the drug by hospitals within the same health system.”

229
230 Section 506F of the FD&C Act has a termination clause that states “This section [506F] shall not
231 apply on or after the date on which the Secretary issues a final guidance that clarifies the policy
232 of the Food and Drug Administration regarding hospital pharmacies repackaging and safely
233 transferring repackaged drugs [including drugs that are licensed biological products] to other
234 hospitals within the same health system during a drug shortage.”¹⁰ These issues are addressed
235 and clarified by this guidance, and the guidance on *Repackaging of Certain Human Drug*
236 *Products by Pharmacies and Outsourcing Facilities*. Therefore, when these guidances become
237 final, section 506F of the FD&C Act will no longer apply.

⁸ For purposes of this guidance, the term “*health system*” refers to a collection of hospitals that are owned and operated by the same entity and that share access to databases with drug order information for their patients.

⁹ See section 506F(b) (providing that the exemption may be available if, among other factors, the drug is repackaged (1) during any period in which the drug is listed on the drug shortage list under section 506E; or (2) during the 60-day period following any period described in paragraph (1)).

¹⁰ See section 506F(d) of the FD&C Act.

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III. POLICY

Because biological products sometimes need to be mixed, diluted, or repackaged in ways not addressed in labeling approved for the product under section 351 of the PHS Act, but do not qualify for the exemptions in sections 503A or 503B of the FD&C Act, FDA has developed this guidance to explain the conditions under which FDA does not intend to take action when certain biological products are mixed, diluted, or repackaged in a manner not described in their approved labeling.

A. General Conditions

This guidance addresses the mixing, diluting, or repackaging of a licensed biological product, not a biological product licensed for further manufacturing use only, or a bulk drug substance. The policies expressed in this guidance do not extend to any person or entity that mixes, dilutes, or repackages a biological product from any other starting material. Consistent with section 351 of the PHS Act, a manufacturer seeking to mix, dilute, or repackage a biological product licensed for further manufacturing use only, or a bulk drug substance, must first submit a BLA and obtain a license for the product.

Furthermore, the policies expressed in this guidance apply only to the mixing, diluting, or repackaging of certain licensed biological products, in accordance with the conditions specified in sections III.B and III.C of this guidance. Except as described in sections III.B and III.C, the agency will consider regulatory action if a licensed biological product is subject to additional manufacturing, including mixing, diluting, or repackaging, outside of the conditions specified in the approved labeling for the licensed product.

As described in section B, a biological product that is mixed, diluted, or repackaged outside the scope of an approved BLA is an unlicensed biological product under section 351 of the PHS Act. To be legally marketed, the new biological product would have to be licensed on the basis of an approved BLA, have labeling with adequate directions for use, and be made in accordance with biological product standards and CGMP requirements. Therefore, biological products that do not meet the conditions in this guidance, including 1) biological products that are mixed, diluted, or repackaged by entities that are not state-licensed pharmacies, Federal facilities, or outsourcing facilities or 2) prescription sets of allergenic extracts that are not prepared by state-licensed pharmacies, Federal facilities, outsourcing facilities, or licensed physicians, must comply with requirements in the PHS Act, FD&C Act, and FDA regulations applicable to biological products manufactured by “conventional” manufacturers, including, but not limited to, biological product license requirements, and compliance with applicable standards and CGMP requirements.

B. Mixing, Diluting, or Repackaging Licensed Biological Products

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280 FDA does not intend to take action for violations of sections 351 of the PHS Act or 502(f)(1) of
281 the FD&C Act if a state-licensed pharmacy, a Federal facility, or an outsourcing facility¹¹ mixes,
282 dilutes, or repackages a biological product in accordance with the conditions described below,
283 and any applicable requirements.¹² In addition, FDA does not intend to take action for violations
284 of section 501(a)(2)(B) of the FD&C Act when a state-licensed pharmacy or a Federal facility
285 mixes, dilutes, or repackages a biological product in accordance with the conditions described
286 below, and any applicable requirements. Outsourcing facilities remain subject to applicable
287 CGMP requirements.

288

289 The conditions referred to in the preceding paragraph are as follows:

290

- 291 1. The biological product that is mixed, diluted, or repackaged is an FDA-licensed biological
292 product, not a biological product licensed for further manufacturing use only or a bulk drug
293 substance.
- 294 2. The biological product is mixed, diluted, or repackaged in a state-licensed pharmacy, a
295 Federal facility, or an outsourcing facility.
- 296 3. If the biological product is mixed, diluted, or repackaged in a state-licensed pharmacy or a
297 Federal facility (but not an outsourcing facility), it is mixed, diluted, or repackaged after (a)
298 the receipt of a valid prescription for an identified, individual patient directly from the
299 prescribing practitioner, patient, or patient's agent; or (b) a written order in a patient's chart
300 in a healthcare setting,¹³ unless it is mixed, diluted, or repackaged (but not distributed) in
301 advance of receipt of such a prescription or a written order in a patient's chart in a quantity
302 that does not exceed the expected demand for the biological product within the beyond use
303 date (BUD) on the product, based on a history of receipt of prescriptions or orders for such a
304 biological product for that time period.
- 305 4. The biological product is mixed, diluted, or repackaged by or under the direct supervision of
306 a licensed pharmacist.
- 307
- 308
- 309

¹¹ As we discuss in section II of this guidance, biological products licensed under section 351 of the PHS Act are not eligible for the statutory exemptions offered by sections 503A or 503B of the FD&C Act, and if a facility registers as an outsourcing facility but only mixes, dilutes, or repackages such biological products, none of the products made at the facility will be eligible for the exemptions under section 503B. However, this guidance describes the conditions under which FDA does not intend to take action for violations of section 351 of the PHS Act and sections 501(a)(2)(B) and 502(f)(1) of the FD&C Act if such biological products are mixed, diluted, or repackaged at a state-licensed pharmacy, a Federal facility, or an outsourcing facility that compounds drug products in accordance with section 503B.

¹² Applicable requirements include, for example, the requirement that manufacturers not adulterate a biological product by preparing, packing, or holding the drug under insanitary conditions. See section 501(a)(2)(A) of the FD&C Act.

¹³ Drugs produced by outsourcing facilities, including drugs that are also biological products, remain subject to the requirements in section 503(b) of the FD&C Act. Therefore, a prescription drug, including a biological product, cannot be dispensed to a patient without a prescription.

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311 5. Except as provided below for a single dose vial, the biological product is mixed, diluted, or
312 repackaged in a way that does not conflict with the approved labeling for the licensed
313 biological product.¹⁴

314

315 For a biological product packaged in a single dose vial that is mixed, diluted, or repackaged
316 into multiple units, the biological product is mixed, diluted, or repackaged in a way that does
317 not conflict with the approved labeling, except for the statements designating the product as a
318 single dose or single use product, and related language (e.g., discard remaining contents).¹⁵

319

320 6. As described in section II of this guidance, biological products are very susceptible to
321 product quality concerns when mixed, diluted, or repackaged. For example, because
322 biological products provide a rich media for microbial growth, they are particularly
323 susceptible to microbial proliferation over time, if contaminated. Therefore, the mixed,
324 diluted, or repackaged biological product is given a BUD that is not longer than the
325 applicable BUD¹⁶ below:

326

327 a. If the biological product is mixed, diluted, or repackaged by a state-licensed
328 pharmacy or a Federal facility, it is given a BUD that

329 - is not longer than 4 hours, or is equal to the time within which the opened product
330 is to be used as specified in the approved labeling, whichever is shorter;¹⁷ or

331 - is up to 24 hours if microbial challenge studies performed on the formulation of
332 the diluted, mixed, or repackaged biological product in the type of container in
333 which it will be packaged demonstrate that microbial growth will not progress to
334 an unacceptable level within the period of the BUD. (See Appendix 1 for a
335 description of microbial challenge study design.)

336 b. If the biological product is mixed or diluted by an outsourcing facility, it is given a
337 BUD that

¹⁴ For example, if the approved labeling for the licensed biological product contains instructions for handling or storage of the product, the mixing, diluting, or repackaging is done in accordance with those instructions. Otherwise, it would be considered to be in conflict with the approved labeling for the licensed biological product.

¹⁵ For example, Avastin (bevacizumab) is packaged in a single dose vial. This condition could be satisfied even if Avastin is repackaged into multiple single dose syringes despite the fact that the label of the approved product states, “Single-use vial...Discard unused portion.” However, this condition would not be satisfied if Avastin is mixed, diluted, or repackaged in a manner that conflicts with other language in the approved labeling (e.g., regarding the appropriate diluent and storage conditions).

¹⁶ The BUD timeframes in this condition begin from the time in which the container of the original biological product to be repackaged or to be used for mixing or diluting is punctured or otherwise opened (“opened product”).

¹⁷ The 4 hour BUD timeframe in this guidance is consistent with the labeling of many licensed biological products, which require the disposal of any product not used within 4 hours after the product has been reconstituted or the container has been entered. Where another timeframe is provided in the labeling, it is based on data generated under specific conditions by the product’s manufacturer and submitted with the BLA. Such data are not available for products mixed, diluted, or repackaged outside the scope of a BLA, as described in this guidance.

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- 338 - is not longer than 4 hours, or is equal to the time within which the opened product
339 is to be used as specified on the approved labeling, whichever is shorter; or
- 340 - is up to 24 hours if microbial challenge studies performed on the formulation of
341 the mixed or diluted biological product in the type of container in which it will be
342 packaged demonstrate that microbial growth will not progress to an unacceptable
343 level within the period of the BUD. (See Appendix 1 for a description of
344 microbial challenge study design.)
- 345 c. If the biological product is repackaged by an outsourcing facility, it is given a BUD
346 that
- 347 - is not longer than 4 hours, or is equal to the time within which the opened product
348 is to be used as specified on the approved labeling, whichever is shorter; or
- 349 - is up to 24 hours if microbial challenge studies performed on the formulation of
350 the repackaged biological product in the type of container in which it will be
351 packaged demonstrate that microbial growth will not progress to an unacceptable
352 level within the period of the BUD. (See Appendix 1 for a description of
353 microbial challenge study design); or
- 354 - does not exceed 5 days or the expiration date of the biological product being
355 repackaged, whichever is shorter, provided that the outsourcing facility conducts
356 adequate compatibility studies on the container-closure system (e.g., the syringe)
357 of the repackaged biological product to demonstrate compatibility and ensure
358 product integrity. (See Title 21, section 211.94 of the Code of Federal
359 Regulations for regulations on drug product containers and closures).¹⁸
- 360 7. If the biological product is mixed, diluted, or repackaged in a state-licensed pharmacy or a
361 Federal facility, it is done in accordance with the United States Pharmacopeia (USP) Chapter
362 <797>, except the BUD is as specified in condition 6; if the biological product is mixed,
363 diluted, or repackaged in an outsourcing facility, it is done in accordance with CGMP
364 requirements, except the BUD is as specified in condition 6.
- 365
- 366 8. The biological product is not sold or transferred by an entity other than the entity that mixed,
367 diluted, or repackaged the biological product. For purposes of this condition, a sale or
368 transfer does not include administration of a biological product in a health care setting.
369

¹⁸ This longer BUD reflects that outsourcing facilities must comply with CGMP requirements and are subject to FDA inspections on a risk-based schedule. Conditions maintained to comply with CGMP requirements provide greater assurance of the quality of manufacturing operations and the products that are produced at the facility. This longer BUD is not provided for mixed or diluted biological products because these activities are more likely to alter the characteristics of the biological product in ways that could harm patients, even if performed under CGMP conditions. To provide a sufficient basis for FDA to conclude that a longer BUD on a mixed or diluted product was justified, an outsourcing facility would need to submit a BLA that included data on the impacts of diluting or mixing the specific product.

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- 370 9. The mixed, diluted, or repackaged biological product is distributed only in states in which the
371 facility mixing, diluting, or repackaging the biological product meets any applicable state
372 requirements.
373
- 374 10. If the biological product is mixed, diluted, or repackaged by an outsourcing facility:
375
- 376 a. The label on the immediate container (primary packaging, e.g., the syringe) of the
377 mixed, diluted, or repackaged biological product includes the following:
- 378 i. The statement “This biological product was mixed/diluted by [name of
379 outsourcing facility],” or “This product was repackaged by [name of
380 outsourcing facility]”, whichever statement is appropriate
- 381 ii. The address and phone number of the outsourcing facility that mixed, diluted,
382 or repackaged the biological product
- 383 iii. The proper name of the original biological product that was mixed, diluted, or
384 repackaged
- 385 iv. The lot or batch number assigned by the outsourcing facility for the mixed,
386 diluted, or repackaged biological product
- 387 v. The dosage form and strength of the mixed, diluted, or repackaged biological
388 product
- 389 vi. A statement of either the quantity or the volume of the mixed, diluted, or
390 repackaged biological product, whichever is appropriate
- 391 vii. The date the biological product was mixed, diluted, or repackaged
- 392 viii. The BUD of the mixed, diluted, or repackaged biological product
- 393 ix. Storage and handling instructions for the mixed, diluted, or repackaged
394 biological product
- 395 x. The National Drug Code (NDC) number of the mixed, diluted, or repackaged
396 biological product, if available¹⁹
- 397 xi. The statement “Not for resale,” and, if the biological product is distributed by
398 an outsourcing facility other than pursuant to a prescription for an individual
399 identified patient, the statement “Office Use Only”
- 400 xii. If included on the label of the FDA-licensed biological product from which
401 the biological product is being mixed, diluted, or repackaged, a list of the
402 active and inactive ingredients, unless such information is included on the
403 label for the container from which the individual units are removed, as
404 described below in 10.b.i; and if the biological product is mixed or diluted, the
405 label of the mixed or diluted product includes any ingredients that appear in
406 the mixed or diluted product in addition to those ingredients that are on the
407 original FDA-licensed biological product.
408
- 409 b. The label on the container from which the individual units are removed for
410 administration (secondary packaging, e.g., the bag, box, or other package in which the
411 mixed, diluted, or repackaged biological products are distributed) includes:

¹⁹ The NDC number of the original licensed biological product should not be placed on the mixed, diluted, or repackaged biological product.

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- 412 i. The active and inactive ingredients, if the immediate product label is too small
413 to include this information
414 ii. Directions for use, including, as appropriate, dosage and administration, and
415 the following information to facilitate adverse event reporting:
416 www.fda.gov/medwatch and 1-800-FDA-1088.
417
418 c. Each mixed, diluted, or repackaged biological product is also accompanied by a copy
419 of the prescribing information that accompanied the original FDA-licensed biological
420 product that was mixed, diluted, or repackaged.
421
422 d. The mixed, diluted, or repackaged biological product is included on a report
423 submitted to FDA each June and December identifying the drug products made by the
424 outsourcing facility during the previous 6-month period, including: a notation that this
425 is a mixed, diluted, or repackaged biological product; the active ingredient; the source
426 of the active ingredient; NDC number of the source ingredient, if available; strength
427 of the active ingredient per unit; the dosage form and route of administration; the
428 package description; the number of individual units mixed, diluted, or repackaged²⁰;
429 and the NDC number of the final product, if assigned.²¹
430
431 e. The outsourcing facility reports serious adverse events to FDA that may be associated
432 with its mixed, diluted, or repackaged biological products.
433

C. Licensed Allergenic Extracts

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435
436 FDA recognizes that there are circumstances in which licensed allergenic extracts would be
437 mixed and diluted to provide subcutaneous immunotherapy to an individual patient, even though
438 these allergenic extract combinations are not specified in the approved BLAs for the licensed
439 biological products. Such combinations are commonly referred to as prescription sets.²² For the
440 purpose of this guidance a *prescription set* is defined as a vial or set of vials of premixed licensed
441 standardized and non-standardized allergenic extracts for subcutaneous immunotherapy diluted
442 with an appropriate diluent prepared according to instructions from a prescription or order by a
443 licensed physician for an individual patient.

²⁰ Currently, FDA's electronic drug reporting system is not configured to accept additional information that is specific to biological products, such as license number. In the future, FDA intends to modify the system to accept this information.

²¹ FDA has issued a draft guidance for industry, *Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act*, which prescribes how human drug compounding facilities are to submit drug product reports to FDA. Although this guidance addresses reporting of compounded human drug products, outsourcing facilities should follow the same procedure to electronically report the biological products they mixed, diluted, or repackaged.

²² Under 21 CFR 610.17, licensed biological products must not be combined with other licensed biological products; either therapeutic, prophylactic or diagnostic, except as covered by a license obtained for the combined product. All mixes of allergenic extracts that are not prescription sets must be the subject of an approved BLA, or have in effect an investigational new drug application.

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444
445 FDA does not intend to take action for violations of section 351 of the PHS Act or section
446 502(f)(1) of the FD&C Act if a physician, state-licensed pharmacy, a Federal facility, or
447 outsourcing facility prepares prescription sets of allergenic extracts in accordance with the
448 conditions described below, and any applicable requirements.²³

449
450 In addition, with respect to a prescription set prepared in accordance with the following
451 conditions and any applicable requirements, FDA does not intend to take action for violations of
452 section 501(a)(2)(B) of the FD&C Act when the prescription set is prepared by a physician,
453 state-licensed pharmacy, or a Federal facility in accordance with the conditions described below;
454 outsourcing facilities remain subject to applicable CGMP requirements.

455
456 The conditions referred to in the preceding paragraph are as follows:

- 457
- 458 1. The prescription set is prepared from FDA-licensed allergenic extracts and appropriate
459 diluents.
 - 460
 - 461 2. The prescription set is prepared in a in a physician's office, state-licensed pharmacy, a
462 Federal facility, or outsourcing facility.
 - 463
 - 464 3. If the prescription sets are prepared in a physician's office, state-licensed pharmacy, or a
465 Federal facility (but not an outsourcing facility), each set is prepared after (a) the receipt of a
466 valid prescription for an identified, individual patient directly from the prescribing
467 practitioner, patient, or patient's agent; or (b) a written order in a patient's chart, unless it is
468 prepared in advance of receipt of such a prescription or a written order in a quantity that does
469 not exceed the expected demand for that prescription set within the BUD for the product,
470 based on a history of receipt of prescriptions or orders for such a prescription set for that
471 time period. If the prescription sets are prepared in an outsourcing facility, those sets are
472 prepared either after, or in anticipation of, receiving valid prescriptions for an identified,
473 individual patient or a written order in a patient's chart.
 - 474
 - 475 4. The prescription set is distributed to a physician or to a health system for use within the
476 health system only after the receipt of a valid prescription for an identified, individual patient
477 or a written order in a patient's chart.
 - 478
 - 479 5. The prescription set is prepared in a way that does not conflict with approved labeling of the
480 licensed biological products that are part of the prescription set.²⁴
 - 481
 - 482 6. The BUD for the prescription set is no later than the earliest expiration date of any allergenic
483 extract or any diluent that is part of the prescription set.
- 484

²³ See note 12.

²⁴ See note 15.

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- 485 7. If the prescription set is prepared in a state-licensed pharmacy or a Federal facility, or in a
486 physician’s office, it is prepared in accordance with USP Chapter <797>, except the BUD is
487 as specified in condition 6; if the prescription set is prepared in an outsourcing facility, it is
488 prepared in accordance with applicable CGMP requirements, except the BUD is as specified
489 in condition 6.
490
- 491 8. The prepared prescription set is not sold or transferred by an entity other than the entity that
492 prepared the prescription set. For purposes of this condition, a sale or transfer does not
493 include administration of a prescription set in a health care setting.
494
- 495 9. The prescription set is distributed²⁵ only in states in which the facility preparing the
496 prescription set meets any applicable state requirements.
497
- 498 10. If the prescription set is prepared by an outsourcing facility:
499
- 500 a. The label on the immediate container(s) (primary packaging) of the prescription set
501 includes the following:
 - 502 i. The patient’s name as identified on the prescription
 - 503 ii. The statement “This prescription set was prepared by [name of outsourcing
504 facility]”
 - 505 iii. The address, and phone number of the outsourcing facility that prepared the
506 prescription set
 - 507 iv. The identity of each allergenic extract in the prescription set, and the quantity
508 of each
 - 509 v. The dilution of each dilution vial
 - 510 vi. The lot or batch number of the prescription set
 - 511 vii. The date the prescription set was prepared
 - 512 viii. The BUD of the prescription set
 - 513 ix. Storage and handling instructions for the prescription set
 - 514 x. The statement “Not for resale”
515
 - 516 b. The label of the container from which the individual units of the prescription set are
517 removed for administration (secondary packaging) includes the following information
518 to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088.
519
 - 520 c. Each prescription set also is accompanied by instructions for use and the FDA
521 approved package insert for each allergenic extract.
522
 - 523 d. The prescription set is included in a report submitted to FDA each June and
524 December identifying the drug products made by the outsourcing facility during the
525 previous 6-month period, including: a notation that this is a biological product; the
526 active ingredient(s); source of the active ingredient(s); NDC number of the source
527 ingredient(s), if available; strength of the active ingredient(s) per unit; the dosage

²⁵ *Distribution* means that the prepared prescription set has left the facility in which it was prepared.

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- 528 form and route of administration; the package description; the number of individual
529 units produced; and the NDC number of the final product, if assigned.²⁶
530
531 e. The outsourcing facility reports serious adverse events to FDA that may be associated
532 with its prescription sets.
533

²⁶ FDA has issued a draft guidance for industry, *Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act*, which prescribes how human drug compounding facilities are to submit drug product reports to FDA. Once finalized, that guidance will represent the Agency’s thinking on that topic. Although this guidance addresses reporting of compounded human drug products, outsourcing facilities should follow the same procedure to electronically report the prescription sets they prepared.

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APPENDIX 1 — MICROBIAL CHALLENGE STUDY DESIGN

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The following design recommendations for product growth promotion studies should be followed to extend the BUD to up to 24 hours for a mixed, diluted, or repackaged biological product as referenced in Section II. B.

Microbial challenge studies are designed to demonstrate that the product in question does not support adventitious microbial growth under the proposed storage conditions. Each facility would conduct a microbial challenge study at least once for each mixed, diluted, or repackaged biological product, to demonstrate that the microbial quality of the biological product mixed, diluted, or repackaged by that facility can be ensured. The microbial challenge study should be repeated if the formulation or the container-closure system is changed. The studies should be accurately documented and records maintained for inspection.

The challenge microbes should include the panel provided in USP<51> Antimicrobial Effectiveness Testing.²⁷ These strains represent the species *Escherichia coli*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Candida albicans* and *Aspergillus brasiliensis* (formerly *Aspergillus niger*). It should also incorporate typical skin microflora and nosocomial agents to simulate the types of flora that may contaminate a drug product in a healthcare setting. Finally, the challenge should include strains of the tribe *Klebsielleae*, as they have been shown to proliferate in infusion products.²⁸

Individual containers of the mixed, diluted, or repackaged biological product should be inoculated with each challenge organism, with each container receiving one type of organism. The inoculum size should be small but also measurable and repeatable. For example, if a membrane filtration method is used to quantify the number of organisms, an inoculum size of fewer than 100 CFU/mL is appropriate.

Following inoculation of the final product with the challenge organisms, the test units should be stored at the temperature(s) described in the biological product's labeling. Samples should be removed periodically throughout the duration of the study for determination of microbial count for up to 72 hours (3 times the maximum BUD). To support a BUD of 24 hours, each challenge organism should demonstrate no increase from the initial count (where *no increase* is defined as not more than 0.5 log₁₀ unit higher than the initial inoculum at any time point up to 72 hours) and no evidence of growth. As explained in the example below, data from a study of 72 hours' duration should be examined for trending and to establish a maximum storage time of up to 24 hours at a specified temperature.

Example: Determination of Microbial Growth

²⁷ USP51/NF26. United States Pharmacopeial Convention, 2008.

²⁸ See, Mahl, M.C., et al. Nitrogen Fixation by Members of the Tribe *Klebsielleae*, *J. Bacteriol.*, 1965, 89(6): 1482; Maki, D., et al., Infection Control in Intravenous Therapy, *Annals of Internal Medicine*, 1973, 79: 867.

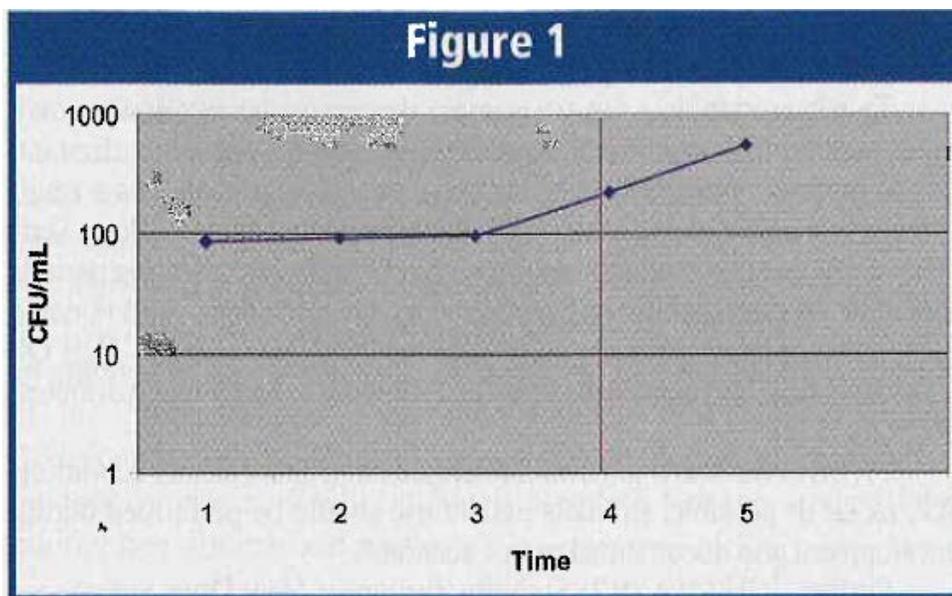
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574 The following table represents data from a hypothetical microbial challenge experiment where
575 the inoculum is less than 100 CFU/mL, and the requested maximum hold time is equivalent to
576 Time Point 4.
577

Time	Microbial Count (CFU/mL)	Log of Microbial Count
1	88	1.9
2	95	2
3	98	2
4	220	2.3
5	552	2.7

578
579
580 These data reflect *no increase* from the initial count through Time Point 4. However, as
581 illustrated in Figure 1 below, the semi-logarithmic graph of CFU/mL vs. Time shows clear
582 evidence of growth of the challenge organism at Time Point 4.
583



584
585
586 Thus, a maximum hold time equivalent to that of Time Point 4 would pose potential risk to the
587 microbiological quality of the hypothetical mixed, diluted, or repackaged biological product, and
588 the acceptable BUD would be set at one-third of Time Point 3. It is also important to note that, if
589 the experiment were concluded at Time Point 4, the ability to predict the trend of the data would
590 be lost. As presented in the graphic, the growth trend appears to signal the start of log-phase
591 growth, which could occur earlier or later with different strains of a given species. Such growth
592 would produce exponential increases in the microbial population that pose significant risk to
593 patients. This concern is the reason for periodic sampling when determining microbial
594 concentration.

Attachment 14

Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft 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*.

For questions regarding this draft document contact H. Joy Sharp at 301-796-3647 or Joy.Sharp@fda.hhs.gov.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)**

**February 2015
Drug Safety**

Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act

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
Phone: 855-543-3784 or 301-796-3400; Fax: 301-431-6353
Email: druginfo@fda.hhs.gov*

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)**

**February 2015
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1 **Adverse Event Reporting for Outsourcing Facilities**
2 **Under Section 503B of the Federal Food, Drug, and Cosmetic Act**
3 **Guidance for Industry¹**
4
5
6

7
8 This draft guidance, when finalized, will represent the Food and Drug Administration’s (FDA’s or the
9 Agency’s) current thinking on this topic. It does not create or confer any rights for or on any person and
10 does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies
11 the requirements of the applicable statutes and regulations. If you want to discuss an alternative
12 approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the
13 appropriate FDA staff, call the appropriate number listed on the title page of this guidance.
14

15
16
17
18 **I. INTRODUCTION**
19

20 This guidance is intended for firms that have registered with the Food and Drug Administration
21 (FDA) under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) as human
22 drug compounding outsourcing facilities (outsourcing facilities). Under section 503B(b)(5) of
23 the FD&C Act, an outsourcing facility must submit adverse event reports to FDA “in accordance
24 with the content and format requirements established through guidance or regulation under
25 section 310.305 of title 21, Code of Federal Regulations (or any successor regulations).”² This
26 guidance explains FDA’s current thinking on adverse event reporting for outsourcing facilities.
27

28 FDA’s guidance documents, including this guidance, do not establish legally enforceable
29 responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should
30 be viewed only as recommendations, unless specific regulatory or statutory requirements are
31 cited. The use of the word *should* in Agency guidances means that something is suggested or
32 recommended, but not required.
33

34 **II. BACKGROUND**
35

36 **A. Statutory and Regulatory Framework**
37

¹ This guidance has been prepared by multiple offices in the Center for Drug Evaluation and Research (CDER) in cooperation with the Office of Regulatory Affairs (ORA) at the Food and Drug Administration.

² 21 U.S.C. 353b(b)(5).

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38 On November 27, 2013, the Drug Quality and Security Act (DQSA) was signed into law. Title I
39 of the DQSA contains important provisions related to the oversight of human drug
40 compounding.³ The DQSA added section 503B to the FD&C Act. Under section 503B(b), a
41 compounder can register as an *outsourcing facility* with FDA.⁴ Under section 503B(b)(5), an
42 outsourcing facility must submit adverse event reports to FDA “in accordance with the content
43 and format requirements established through guidance or regulation under section 310.305 of
44 title 21, Code of Federal Regulations (or any successor regulations).”⁵

45
46 Section 310.305 requires, among other things, that manufacturers, packers, and distributors of
47 marketed prescription drug products that are not the subject of an approved new drug application
48 or an abbreviated new drug application establish and maintain records and make reports to FDA
49 of all serious, unexpected adverse drug experiences⁶ associated with the use of their prescription
50 drug products. For purposes of reporting adverse drug experiences, the term *prescription drug*
51 *products* includes any compounded drug product subject to the prescription requirements in
52 section 503(b)(1) of the FD&C Act. The adverse event reporting requirements apply to
53 prescription drug products regardless of whether the outsourcing facility distributes them
54 pursuant to prescriptions.⁷

55
56 In addition, on June 10, 2014, FDA issued a final rule requiring, among other things, that
57 postmarketing safety reports required under 21 CFR 310.305, 314.80, 314.98, and 600.80 be
58 submitted to FDA in an electronic format the Agency can process, review, and archive. The final
59 rule also adds 21 CFR 329.100 to address electronic submission of safety reports required by
60 section 760 of the FD&C Act regarding serious adverse event reporting for nonprescription
61 drugs.⁸ These requirements are effective as of June 10, 2015.⁹

62
63 Under section 503B, outsourcing facilities are required to submit adverse event reports to FDA,
64 in accordance with content and format requirements established through guidance or regulation
65 under 21 CFR 310.305 (or any successor regulations).

³ See text of Compounding Quality Act at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm376732.htm>.

⁴ 21 U.S.C. 353b(b).

⁵ Id. at 353b(b)(5).

⁶ This guidance uses the terms *adverse drug experience* and *adverse event* interchangeably.

⁷ Section 503B(d)(4)(C) of the FD&C Act provides that outsourcing facilities may or may not obtain prescriptions for identified individual patients. Although outsourcing facilities may send prescription drugs to healthcare facilities without obtaining prescriptions for identified individual patients, drugs produced by outsourcing facilities remain subject to the requirements in section 503(b) of the FD&C Act. Therefore, an outsourcing facility cannot dispense a prescription drug to a patient without a prescription.

⁸ 21 U.S.C. 379aa.

⁹ See 79 FR 33072. FDA intends to issue guidance reflecting the requirements of the final rule before they become effective.

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66
67 Failure to report adverse events by an entity that is registered in accordance with section 503B(b)
68 is a prohibited act under section 301(ccc)(3) of the FD&C Act.¹⁰ Violations relating to this
69 provision are subject to regulatory and enforcement action.

70
71 **B. Section 310.305**

72
73 Section 310.305(b) defines a *serious adverse drug experience* to mean:

74
75 Any adverse drug experience occurring at any dose that results in any of the
76 following outcomes:

- 77 • Death,
- 78 • A life-threatening adverse drug experience,
- 79 • Inpatient hospitalization or prolongation of existing hospitalization,
- 80 • A persistent or significant disability/incapacity, or
- 81 • A congenital anomaly/birth defect

82
83 Important medical events that may not result in death, be life-threatening, or
84 require hospitalization may be considered a serious adverse drug experience
85 when, based upon appropriate medical judgment, they may jeopardize the
86 patient or subject and may require medical or surgical intervention to prevent
87 one of the outcomes listed in this definition. Examples of such medical
88 events include

- 89 • allergic bronchospasm requiring intensive treatment in an emergency
90 room or at home,
- 91 • blood dyscrasias or convulsions that do not result in inpatient
92 hospitalization, or
- 93 • the development of drug dependency or drug abuse.

94
95 Section 310.305(b) defines an *unexpected adverse drug experience* as any adverse drug
96 experience that is not listed in the current labeling for the drug product. This includes events that
97 may be symptomatically and pathophysiologically related to an event listed in the labeling, but
98 differ from the event because of greater severity or specificity. The term *unexpected*, as used in
99 this definition, refers to an adverse drug experience that has not been previously observed (i.e.,
100 included in the labeling), rather than from the perspective of such experience not being
101 anticipated from the pharmacological properties of the pharmaceutical product.

102
103 The regulations require reporting of each adverse drug experience received or otherwise obtained
104 that is both serious and unexpected as soon as possible, but in no case later than 15 calendar days
105 of initial receipt of the information along with a copy of the drug product's current labeling.¹¹ In
106 addition, all serious, unexpected adverse drug experiences that are the subject of these reports

¹⁰ 21 U.S.C. 331(ccc)(3).

¹¹ See 21 CFR 310.305(c)(1)(i).

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107 shall be promptly investigated and a follow-up report must be submitted within 15 calendar days
108 of receipt of new information or as requested by FDA.¹²

109
110 FDA’s regulations also state that information on the names and addresses of individual patients
111 should **not** be included.¹³ A unique code number should therefore be assigned instead for each
112 individual patient and placed in section A1 of Form FDA 3500A (Patient Identifier).

113
114 The regulations require that firms maintain certain records relating to adverse drug experiences
115 required to be reported under section 310.305 for 10 years and provide FDA access to them.¹⁴

116 The regulations also provide a disclaimer that the report or information submitted (and any
117 release by FDA of that report or information) does not necessarily reflect a conclusion that the
118 report or information constitutes an admission that the drug caused or contributed to an adverse
119 effect.¹⁵

120

121 **III. Adverse Event Reporting by Outsourcing Facilities**

122

123 **A. What to Report**

124

125 Outsourcing facilities must report all serious, unexpected adverse drug experiences associated
126 with the use of their compounded prescription drug products.

127

128 In addition, FDA strongly recommends that outsourcing facilities report **all** serious adverse drug
129 experiences associated with their compounded prescription drug products. We believe reporting
130 **all** serious adverse events would provide important information about potential product quality
131 issues or public health risks associated with drug products compounded by outsourcing facilities.

132

133 **B. Threshold for Reporting**

134

135 As noted above, outsourcing facilities must submit to FDA reports of all serious, unexpected
136 adverse events associated with their compounded prescription drugs.¹⁶

137

138 When considering any adverse drug experience for submission to FDA in a report, after
139 receiving information about the adverse drug experience, an outsourcing facility should actively
140 investigate the following four data elements, which are described in greater detail later in this
141 section:

142

143 1. An identifiable patient

¹² See 21 CFR 310.305(c)(2).

¹³ See 21 CFR 310.305(e).

¹⁴ See 21 CFR 310.305(f).

¹⁵ See 21 CFR 310.305(g).

¹⁶ See 21 CFR 310.305(c).

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- 144 2. An identifiable reporter
145 3. A suspect drug
146 4. A serious adverse event

147

148 Although an outsourcing facility should actively seek to obtain each of these four data elements,
149 the facility must submit the report as a *15-day “Alert report”* to FDA as soon as possible, but no
150 later than 15 calendar days after first receiving information about the adverse event.¹⁷ **Reports**
151 **should be submitted as long as the outsourcing facility has information on at least the**
152 **suspect drug and the adverse event.**

153

154 The outsourcing facility must also promptly investigate adverse events that are the subject of a
155 15-day “Alert report”.¹⁸ If the outsourcing facility was not able to include all four of the data
156 elements in its initial report, it should exercise due diligence to obtain information about any of
157 the remaining elements. Additionally, the outsourcing facility should report new information it
158 obtains regarding data elements listed in its initial report when the information could assist FDA
159 in investigating an adverse event. If additional information is not obtainable, the outsourcing
160 facility should maintain records of the steps that were taken to attempt to seek the additional
161 information.¹⁹

162

163 An outsourcing facility must submit a follow-up report within 15 calendar days of receipt of new
164 information about the adverse event, or as requested by FDA.²⁰

165

166 1. *Identifiable Patient*

167

168 To have an identifiable patient, there should be enough information to indicate the existence of a
169 specific patient. One or more of the following would qualify a patient as identifiable:

170

- 171 • Age or age category (e.g., adolescent, adult, elderly)
- 172 • Gender
- 173 • Initials
- 174 • Date of birth
- 175 • Name
- 176 • Patient identification number

177

178 A report stating that “an elderly woman had anaphylaxis” or “a young man experienced
179 anaphylaxis” would be sufficient. If a report refers to groups of unknown size, such as “some”
180 or “a few” college students had anaphylaxis, the outsourcing facility should follow up to find out

¹⁷ See 21 CFR 310.305(c)(1)(i).

¹⁸ See 21 CFR 310.305(c)(2).

¹⁹ Id.

²⁰ Id.

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181 how many students were involved and submit a separate report to FDA for each student, because
182 each is considered to be an identifiable patient. The outsourcing facility should distinguish each
183 identifiable patient so that it is clear that each report is not a duplicate report of a single adverse
184 event.

185

186 Patients should not be identified by name or address when reporting to FDA. Instead, the
187 outsourcing facility should assign a unique code number for each patient.²¹

188

189 2. *Identifiable Reporter*

190

191 A reporter is a person who initially notifies the outsourcing facility about an adverse event. An
192 initial reporter can be a patient, consumer, family member, doctor, pharmacist, other health care
193 professional, or other individual. The outsourcing facility should obtain, if possible, sufficient
194 information to indicate that the reporter is an identifiable person who purports to have knowledge
195 about the patient, adverse event, and drug involved. One or more of the following would qualify
196 a reporter as identifiable:

197

- 198 • A personal identifier (e.g., name)
- 199 • A professional identifier (e.g., doctor, nurse, pharmacist)
- 200 • Contact information (e.g., e-mail address, phone number)

201

202 When possible, the outsourcing facility should attempt to obtain the initial reporter's contact
203 information so that the outsourcing facility and/or FDA can conduct follow-up investigations. If
204 an identifiable reporter provides contact information, but requests that the outsourcing facility
205 not forward this information to FDA, the outsourcing facility can submit a report to FDA without
206 specifically identifying the reporter by filling out the *initial reporter identity fields* on Form FDA
207 3500A with a statement such as "Requested Anonymity."

208

209 If an adverse event is reported anonymously to an outsourcing facility, the outsourcing facility
210 should note when submitting the report to FDA that the initial reporter is anonymous (section E1
211 of the Form FDA 3500A).

212

213 3. *Suspect Drug*

214

215 A *suspect drug product* is one that the initial reporter suspected was associated with the adverse
216 event.

217

218 For reporting purposes, an adverse event report should describe the known product attributes
219 (e.g., active ingredient(s), dosage form, strength, color, lot number). If an adverse event involves
220 multiple suspect drug products that are compounded by the same outsourcing facility, the
221 outsourcing facility should submit only one report that notes the drug product considered most

²¹ See 21 CFR 310.305(e).

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222 suspect by the reporter. If the reporter views each drug product as equally suspect, the
223 outsourcing facility should submit only one report that lists all of the drug products as suspect.
224 In all cases, including those where not all of the drug products were made by the outsourcing
225 facility, the report would include information on all suspect drug products.

226

227 4. *Serious Adverse Event*

228

229 As described above, outsourcing facilities must report an unexpected adverse event to FDA
230 that results in one or more of the following patient outcomes:

231

- 232 • Death,
- 233 • A life-threatening adverse drug experience,
- 234 • Inpatient hospitalization or prolongation of existing hospitalization,
- 235 • A persistent or significant disability or incapacity, or
- 236 • A congenital anomaly or birth defect.²²

237

238 Inpatient hospitalization includes initial admission to the hospital on an inpatient basis (even if
239 released the same day).

240

241 Important medical events that may not result in death, be life-threatening, or require
242 hospitalization may be considered a serious adverse drug experience if, when based upon
243 appropriate medical judgment, they may jeopardize the patient or subject and may require
244 medical or surgical intervention to prevent one of the outcomes listed above.

245

246 The outsourcing facility must report the adverse event to FDA if it is serious and unexpected.
247 For reporting purposes, an adverse event should be described in terms of signs (including
248 abnormal laboratory findings, if appropriate), symptoms, or disease diagnosis (including any
249 colloquial descriptions obtained), if available.

250

251 As part of the adverse event report, we encourage, as appropriate, attachment of the following:
252 (1) hospital discharge summaries, (2) autopsy reports/death certificates, (3) relevant laboratory
253 data, and (4) other critical clinical data. In the case of a death, outsourcing facilities should
254 also provide any available information on the event(s) that led to the death.

255

256 **C. How to Report Adverse Events**

257

258 Outsourcing facilities must report adverse events using Form FDA 3500A or an alternate method
259 in accordance with 21 CFR 310.305(d) and should submit the report to FDA as described here.
260 FDA is currently modifying its process to specifically identify reports from outsourcing facilities
261 and drug products compounded by outsourcing facilities. Until those actions are completed,
262 FDA will not be able to effectively accept adverse event reports from outsourcing facilities

²² See 21 CFR 310.305(b).

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263 through the electronic system, but FDA will issue additional guidance when the electronic
264 interface is ready to accept these reports.

265

266 1. *Obtaining Form FDA 3500A*

267

268 Outsourcing facilities can access paper copies of Form FDA 3500A as follows:

269

- 270 • Download and print the Form FDA 3500A and instructions from the Internet at
271 <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048334.pdf>
272
- 273 • Request a paper copy of Form FDA 3500A and instructions from CDER's Division of
274 Drug Information:

275

276 By e-mail: druginfo@fda.hhs.gov

277

278 By phone: 1-800-FDA-1088
279 1-888-INFO-FDA
280 1-888-463-6332 or (301) 796-3400

281

282 By mail: Division of Drug Information
283 10903 New Hampshire Avenue
284 WO51-2201
285 Silver Spring, MD 20993-0002

286

287 2. *How to Submit Adverse Event Reports*

288

289 Until FDA modifies its adverse event collection database to more effectively accommodate
290 direct electronic submissions from outsourcing facilities, adverse event reports and follow-up
291 reports for compounded drug products should be provided in hard copy.²³ In accordance with
292 section 310.305(c), outsourcing facilities must submit a copy of Form FDA 3500A to:

293

294 Central Document Room
295 Center for Drug Evaluation and Research
296 Food and Drug Administration
297 5901-B Ammendale Rd.
298 Beltsville, MD 20705-1266

299

300 3. *What Should Be Included*

301

²³ FDA is currently modifying its database to include fields specifically identifying reports from outsourcing facilities and drug products compounded by outsourcing facilities. As noted above, on June 10, 2014, FDA issued a final rule requiring that, among other things, postmarketing safety reports under 21 CFR 310.305 be submitted to FDA in electronic format (79 FR 33072). This rule is effective as of June 10, 2015.

Contains Nonbinding Recommendations

Draft — Not for Implementation

302 Outsourcing facilities must indicate whether the report is a 15-day Alert report or a 15-day Alert
303 report-follow-up²⁴ and should include the following header on the first page of a cover letter
304 accompanying each Form FDA 3500A:

305

306 *Adverse event report submitted by human drug compounding outsourcing facility (503B)*

307

308 If the compounded drug product contains multiple components (e.g., excipients, drug substances,
309 finished dosage forms), the outsourcing facility should list each component and its manufacturer,
310 if known, in section C10 of Form FDA 3500A. The outsourcing facility should also list in
311 section C10, in addition to the components of the compounded drug and each component's
312 manufacturer, any other medical product(s) the patient was taking at the time he or she
313 experienced the adverse event and the manufacturer of that product(s) (i.e., any concomitant
314 medical products).

315

316 As part of each adverse event report, outsourcing facilities must submit a copy of the current
317 labeling for the compounded drug product that is the subject of the report.²⁵

318

319 When submitting a follow-up report under 21 CFR 310.305(c)(2), the report should be assigned
320 the same manufacturer report number that appears in section G9 of the initially submitted Form
321 FDA 3500A.

322

D. Inspection of Adverse Event Reporting

323

324 Under section 503B(b)(4) of the FD&C Act, outsourcing facilities are subject to inspection
325 pursuant to section 704 of the FD&C Act and are not eligible for the exemption under section
326 704(a)(2)(A) of the FD&C Act.

327

328 As part of its inspections of outsourcing facilities, FDA may review adverse event information
329 received by the outsourcing facility.²⁶ FDA may also review whether the outsourcing facility has
330 developed and implemented written processes for the surveillance, receipt, evaluation, and
331

²⁴ 21 CFR 310.305(c)(4).

²⁵ See section 21 CFR 310.305(c)(1)(i).

²⁶ See section 21 CFR 310.305(f)(3).

Contains Nonbinding Recommendations

Draft — Not for Implementation

332 reporting of adverse events for the drug products it compounds as described in 21 CFR
333 310.305(a) and 211.198.²⁷

334

E. Recordkeeping

336

337 Under section 310.305, all entities subject to the regulation must maintain for 10 years the
338 records of all adverse events required to be reported under this section, including raw data and
339 any correspondence relating to the adverse event, and allow FDA access to review, copy, and
340 verify these records, in accordance with 21 CFR 310.305(f). In addition, the outsourcing facility
341 should maintain records of its efforts to obtain the four data elements discussed in section III.B.
342 for each individual case report.

²⁷ Outsourcing facilities are subject to current good manufacturing practice (CGMP) requirements. Pending the development of further regulations, FDA expects outsourcing facilities, among other things, to comply with the CGMP requirements in 21 CFR 211.198, which is a companion to 21 CFR 310.305. This section requires that “[w]ritten procedures describing the handling of all written and oral complaints regarding a drug product shall be established and followed,” and further requires that these procedures must include “provisions for review to determine whether the complaint represents a serious and unexpected adverse drug experience which is required to be reported to the Food and Drug Administration in accordance with [section] 310.305 ... of this chapter.” See FDA’s guidance for industry, *Current Good Manufacturing Practice—Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act*, available at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM403496.pdf>.

Attachment 15

DRAFT MEMORANDUM OF UNDERSTANDING ADDRESSING CERTAIN
DISTRIBUTIONS OF COMPOUNDED HUMAN DRUG PRODUCTS
BETWEEN THE STATE OF [insert STATE] AND
THE U.S. FOOD AND DRUG ADMINISTRATION

I. PURPOSE

This Memorandum of Understanding (MOU) establishes an agreement between the State of [insert State] and the U.S. Food and Drug Administration (FDA) regarding the distribution of inordinate amounts of compounded human drug products interstate and the appropriate investigation by the State of [insert State] of complaints relating to compounded human drug products distributed outside such State. This is the MOU provided for by section 503A(b)(3)(B)(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 353a), and does not apply to drugs that are compounded by registered outsourcing facilities.

II. BACKGROUND

- a. Section 503A of the FD&C Act describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist or licensed physician to be exempt from three sections of the FD&C Act requiring:
 1. Compliance with current good manufacturing practice (CGMP) (section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B));
 2. Labeling with adequate directions for use (section 502(f)(1) (21 U.S.C. 352(f)(1)); and
 3. FDA approval prior to marketing (section 505 (21 U.S.C. 355)).
- b. To qualify for these exemptions, among other things, a compounded human drug product must meet the condition in section 503A(b)(3)(B) of the FD&C Act, under which the drug product is compounded in a State that:
 1. Has entered into an MOU with FDA that addresses the distribution of inordinate amounts¹ of compounded human drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded human drug products distributed outside such State (section 503A(b)(3)(B)(i)); or

¹The definition of *inordinate amounts* in this MOU is separate and distinct from and should not be used in relation to the term *inordinate amounts* as it is used in section 503A(b)(1)(D) of the FD&C Act (pertaining to compounding a drug product that is essentially a copy of a commercially available drug product).

2. Has not entered into an MOU with FDA and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded human drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician (section 503A(b)(3)(B)(ii)).
- c. Section 503A(b)(3) of the FD&C Act directs FDA to develop a standard MOU for use by the States in complying with section 503A(b)(3)(B)(i). The content of this MOU conforms with the standard MOU developed by FDA for this purpose.

III. SUBSTANCE OF AGREEMENT

- a. Investigation of Complaints Relating to Compounded Human Drug Products Distributed Outside the State
 1. Appropriate agencies of the State of [insert State] will investigate complaints received relating to human drug products compounded by a pharmacist, pharmacy, or physician located in the State of [insert State] and distributed outside the State. Primary responsibility for investigating complaints involving human drug products compounded by a pharmacy or pharmacist will generally lie with the [insert State Board of Pharmacy or other appropriate State agency] and similar responsibility for human drug products compounded by a physician will generally lie with the [insert State Medical Licensing Board or other appropriate State agency], except where State laws otherwise require. The [insert State Board of Pharmacy or other appropriate State agency] and [insert State Medical Licensing Board or other appropriate State agency] will cooperate in investigating any complaints involving overlapping jurisdiction.
 2. Complaints relating to compounded human drug products distributed outside the State that will be investigated include reports received by the State concerning adverse drug experiences, or product quality issues that if left uncorrected could lead to potential public health risks or safety concerns. See Appendix A for definitions of *adverse drug experiences* and *product quality issues*.
 3. Any investigations performed by the State of [insert State] under this MOU will include, but are not limited to (1) determination of whether there is a potential public health risk or safety concern associated with the compounded human drug product; and (2) confirmation that any risk or safety concern associated with the product is adequately contained (i.e., there is no ongoing risk to the public).

4. Based on findings from an investigation of a complaint about compounded human drug products distributed outside the State, if the complaint is found to be valid, the State of [insert State], in accordance with State law, will take appropriate action to ensure that the relevant compounding pharmacist, pharmacy, or physician determines the root cause of the problem that is the subject of the complaint and undertakes sufficient corrective action to eliminate any identified public health risk relating to the complaint, including the risk that future similar complaints may occur.
 5. The State of [insert State] will notify FDA by sending an e-mail to StateMOU@fda.hhs.gov (see section III.c.1 of this MOU) within 72 hours of receiving any complaint relating to a compounded human drug product distributed outside the State involving a public health risk or immediate safety concern, such as a report of a serious adverse drug experience or serious product quality issue. The notification will include the State's initial assessment of the validity of the complaint relating to a compounded human drug product distributed outside the State, as well as a description of any actions the State has taken or plans to take to address such complaints. See Appendix A for definitions of *serious adverse drug experience* and *serious product quality issue*.
 6. The State of [insert State] will maintain records of the complaint, the investigation of the complaint, and any response to or action taken as a result of the complaint, beginning when the State receives notice of the complaint. The State will maintain these records for at least 3 years. The 3-year period begins on the date of final action on a complaint, or the date of a decision that the complaint requires no action.
- b. Distribution of Inordinate Amounts of Compounded Human Drug Products Interstate
1. The State of [insert State] will review compounding records during inspections of compounding pharmacies to identify whether the compounding pharmacy, or the compounding pharmacist or physician, is distributing inordinate amounts of compounded human drug products interstate. See Appendix A for the definition of *distribution*.
 2. The State of [insert State] will notify FDA by sending an e-mail to StateMOU@fda.hhs.gov (see section III.c.1 of this MOU) within 7 days of identifying a pharmacist, pharmacy, or physician within its jurisdiction that has distributed inordinate amounts of compounded human drug products interstate.
 3. The State of [insert State] will take action regarding any pharmacy, pharmacist, or physician that distributes inordinate amounts of

compounded human drug products interstate. State action may include a warning letter, enforcement action, suspension or revocation of a license, or other action consistent with State law. FDA may also take action regarding any pharmacy, pharmacist, or physician that distributes inordinate amounts of compounded human drug products interstate.

4. For purposes of this MOU, a pharmacist, pharmacy, or physician has distributed an inordinate amount of compounded human drug products interstate if the number of units of compounded human drug products distributed interstate during any calendar month is equal to or greater than 30 percent of the number of units of compounded and non-compounded drug products distributed or dispensed both intrastate and interstate by such pharmacist, pharmacy, or physician during that month. Exception: For purposes of this MOU, FDA does not intend to include, in the consideration of inordinate amounts, prescriptions dispensed to a patient (or patient's agent), if the patient (or patient's agent) to whom the drug is dispensed carries the drug across State lines after it has been dispensed to the patient (or patient's agent) at the facility in which the drug was compounded.

c. Submission and Disclosure of Information

1. When submitting information to StateMOU@fda.hhs.gov regarding complaints relating to compounded drug products distributed outside the State or distribution of inordinate amounts of drugs interstate, the following minimum information will be included:
 - Name and contact information of the complainant, in the case of a complaint;
 - Name and address of the pharmacist/pharmacy/physician that is the subject of the complaint or distribution in inordinate amounts;
 - Description of the complaint, or description of the evidence indicating that the pharmacist/pharmacy/physician has distributed inordinate amounts of compounded human drug products interstate, including a description of any compounded drug product that is the subject of the complaint or distribution;
 - State's initial assessment of the validity of the complaint relating to a compounded human drug product distributed outside the State; and

- Description and date of any actions the State has taken to address the complaint or the distribution of inordinate amounts of compounded human drug products interstate.
2. The parties to this MOU will share information consistent with applicable statutes and regulations. The parties recognize that a separate agreement under 21 CFR 20.88 or commissioning of officials under 21 CFR 20.84 may be necessary before FDA can share information that is protected from public disclosure. Such an agreement, or commissioning terms, will govern FDA's sharing of the following types of information:
- confidential commercial information, such as the information that would be protected from public disclosure under Exemption 4 of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(4));
 - personal privacy information, such as information that would be protected from public disclosure under Exemption 6 or 7(C) of the FOIA (5 U.S.C. 552(b)(6) and(7)(C)); or
 - information that is otherwise protected from public disclosure by Federal statutes and their implementing regulations (e.g., Trade Secrets Act (18 U.S.C. 1905)), the Privacy Act (5 U.S.C. 552a), other Freedom of Information Act exemptions not mentioned above (5 U.S.C. 552(b)), the FD&C Act (21 U.S.C. 301 et seq.), the Health Insurance Portability and Accountability Act (Public Law 104-191), and FDA's regulations in parts 20 and 21 (21 CFR parts 20 and 21)).

FDA agrees that information provided to FDA by the State of [insert State] will only be disclosed consistent with applicable federal law and regulations governing the disclosure of such information, including, but not limited to, the FOIA (5 U.S.C. 552(b)), the FD&C Act (21 U.S.C. 301 et seq.), 21 U.S.C. 331(j), 21 U.S.C. 360j(c), the Trade Secrets Act (18 U.S.C. 1905), FDA's regulations in 21 CFR parts 20 and 21, and other pertinent laws and regulations.

IV. ENFORCEMENT AUTHORITIES AND LEGAL STATUS OF AGREEMENT

The parties to this MOU recognize that FDA and the State of [insert State] retain the statutory and regulatory authorities provided by the FD&C Act, other Federal statutes and attendant regulations, and State statutes and regulations. The parties also recognize that this agreement does not restrict FDA or any other Federal agency from taking enforcement action, when appropriate, to ensure compliance with Federal statutes, including the FD&C Act and attendant regulations, or

prevent the State of [insert State] from taking enforcement action, as appropriate, to ensure compliance with applicable State statutes and regulations. This MOU does not create or confer any rights for or on any person. By signing this MOU, the State of [insert State] affirms that it now possesses and will maintain, at the discretion of the State legislature, the legal authority (under State statutes and/or regulations) and the resources necessary to effectively carry out all aspects of this MOU. If State law changes such that the State no longer has the legal authority or resources necessary to effectively carry out all aspects of this MOU, the State will notify FDA.

V. NAME AND ADDRESS OF PARTICIPATING AGENCIES

U.S. Food and Drug Administration
Center of Drug Evaluation and Research
Office of Compliance
Office of Unapproved Drugs and Labeling Compliance
10903 New Hampshire Avenue
Bldg. 51, Suite 5100
Silver Spring, MD 20993-0002
Telephone: (301) 796-3110
E-mail: StateMOU@fda.hhs.gov

[State]
TBD

Upon signing the MOU, each party must designate one or more liaisons to act as points of contact. Each party may designate new liaisons at any time by notifying the other party's liaison(s) in writing. If, at any time, an individual designated as a liaison under this agreement becomes unavailable to fulfill those functions, the parties will name a new liaison within 2 weeks and notify the other party's liaison(s).

VI. PERIOD OF AGREEMENT

- a. When accepted by both parties, this MOU will be effective from the date of the last signature and will continue until terminated by either party. It may be terminated in writing by either party, upon a 30-day notice of termination. Notice of termination will be sent to the address listed in section V of this MOU.
- b. If the State does not adhere to the provisions of this MOU, including conducting an investigation of complaints related to compounded human drug products distributed outside the State, the MOU may be terminated upon 30-days' notice of termination.

In case of termination, FDA will post a notice of the termination on its Web site and the State will notify all pharmacists, pharmacies, and physicians within the

State of the termination and advise them that as of 30 days from the date of the posting of the termination notice, compounded human drug products may be distributed (or caused to be distributed) out of the State only in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by the licensed pharmacist, licensed pharmacy, or licensed physician (section 503A(b)(3)(B)(ii) of the FD&C Act).

VII. APPROVALS

APPROVED AND ACCEPTED FOR THE U.S. FOOD AND DRUG ADMINISTRATION	APPROVED AND ACCEPTED FOR THE STATE OF [insert State]
By (Type Name)	By (Type Name)
Title	Title
Date	Date

Appendix A. Definition of Terms Used in the MOU

- **Adverse Drug Experience:** Any adverse event associated with the use of a drug in humans, whether or not considered drug related, including the following: an adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose, whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and any failure of expected pharmacological action (21 CFR 310.305(b)).
- **Distribution:** *Distribution* means that a compounded human drug product has left the facility in which the drug was compounded. Distribution includes delivery or shipment to a physician's office, hospital, or other health care setting for administration and dispensing to an agent of a patient or to a patient for the patient's own use.

Note: To qualify for the exemptions under section 503A, a compounder must obtain a prescription for an individually identified patient (section 503A(a) of the FD&C Act). This MOU will not alter this condition.

- **Product Quality Issue:** Information concerning (1) any incident that causes the drug product or its labeling to be mistaken for, or applied to, another article; or (2) any bacteriological contamination; any significant chemical, physical, or other change or deterioration in the distributed drug product; or any failure of one or more distributed batches of the drug product to meet the applicable specifications (21 CFR 314.81(b)(1)). Contamination in general, including but not limited to mold, fungal, bacterial, or particulate contamination, is a product quality issue.
- **Serious Adverse Drug Experience:** Any adverse drug experience occurring at any dose that results in any of the following outcomes: death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse (21 CFR 310.305(b)).
- **Serious Product Quality Issue:** Any product quality issue that may have the potential to cause a serious adverse drug experience (e.g., possible contamination, superpotent product).

Attachment 16

Board of Pharmacy Enforcement Statistics Fiscal Year 2014/2015

Workload Statistics July-Sept Oct-Dec Jan-Mar Apr-June Total 14/15

Complaints/Investigations

Received	636	589	651		1876
Closed	855	479	585		1919
4301 letters	19	20	4		43
Pending (at the end of quarter)	1604	1725	1857		1857

Cases Assigned & Pending (by Team) at end of quarter*

Compliance / Routine Team	748	886	775		775
Drug Diversion/Fraud	340	380	365		365
RX Abuse	n/a	17	80		80
Compounding	n/a	4	126		126
Probation/PRP	65	71	54		54
Mediation/Enforcement **	113	101	63		63
Criminal Conviction	335	266	395		395

Application Investigations

Received	210	175	209		594
Closed					
Approved	93	140	98		331
Denied	16	17	32		65
Total ***	145	196	160		501
Pending (at the end of quarter)	181	196	208		208

Letter of Admonishment (LOA) / Citation & Fine

LOAs Issued	43	24	45		112
Citations Issued	320	268	304		892
Total Fines Collected ****	\$464,781.92	\$441,499.91	\$363,661.78		\$1,269,943.61

* 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 3/31/2015 and reports in previous fiscal year.)

Board of Pharmacy Enforcement Statistics Fiscal Year 2014/2015

Workload Statistics July-Sept Oct-Dec Jan-Mar Apr-June Total 14/15

Administrative Cases (by effective date of decision)

Referred to AG's Office*	91	80	76		247
Accusations Filed	87	43	40		170
Statement of Issues Filed	9	3	10		22
Petitions to Revoke Filed	5	8	1		14
Pending					
Pre-accusation	246	244	243		246
Post Accusation	341	279	258		341
Total*	613	585	580		598

Closed

Revocation					
Pharmacist	1	4	2		7
Intern Pharmacist	0	0	1		1
Pharmacy Technician	49	47	27		123
Designated Representative	0	2	2		4
Wholesaler	0	1	2		3
Sterile Compounding	0	0	0		0
Pharmacy	1	1	1		3

Revocation, stayed; suspension/probation					
Pharmacist	4	2	4		10
Intern Pharmacist	0	1	0		1
Pharmacy Technician	0	0	1		1
Designated Representative	0	0	0		0
Wholesaler	0	0	0		0
Sterile Compounding	0	0	0		0
Pharmacy	0	0	0		0

Revocation, stayed; probation					
Pharmacist	8	11	3		22
Intern Pharmacist	1	0	0		1
Pharmacy Technician	5	5	11		21
Designated Representative	0	0	0		0
Wholesaler	0	0	0		0
Sterile Compounding	0	0	0		0
Pharmacy	0	7	3		10

Surrender/Voluntary Surrender					
Pharmacist	3	2	6		11
Intern Pharmacist	0	0	0		0
Pharmacy Technician	11	11	9		31
Designated Representative	0	0	1		1
Wholesaler	0	0	1		1
Sterile Compounding	1	1	1		3
Pharmacy	2	0	5		7

Board of Pharmacy Enforcement Statistics Fiscal Year 2014/2015

Workload Statistics July-Sept Oct-Dec Jan-Mar Apr-June Total 14/15

Public Reprival/Reprimand

Pharmacist	0	2	2		4
Intern Pharmacist	0	0	0		0
Pharmacy Technician	1	0	0		1
Designated Representative	0	0	0		0
Wholesaler	0	0	0		0
Sterile Compounding	0	0	0		0
Pharmacy	1	1	0		2

Licenses Granted

Pharmacist	0	0	0		0
Intern Pharmacist	0	2	0		2
Pharmacy Technician	5	5	2		12
Designated Representative	0	0	0		0
Wholesaler	0	0	0		0
Sterile Compounding	0	0	0		0
Pharmacy	0	1	1		2

Licenses Denied

Pharmacist	0	0	0		0
Intern Pharmacist	0	7	0		0
Pharmacy Technician	5	0	4		9
Designated Representative	0	0	0		0
Wholesaler	0	0	0		0
Sterile Compounding	0	0	0		0
Pharmacy	0	0	0		0

Cost Recovery Requested**	\$230,373.00	\$200,089.67	\$291,032.33		\$721,495.00
Cost Recovery Collected**	\$76,974.01	\$117,478.06	\$129,274.20		\$323,726.27

* This figure includes Citation Appeals

** This figure includes administrative penalties

Immediate Public Protection Sanctions

Interim Suspension Order	0	3	1		4
Automatic Suspension / Based on Conviction	2	0	3		5
Penal Code 23 Restriction	3	2	0		5
Cease & Desist - Sterile Compounding	1	0	0		1

Board of Pharmacy Enforcement Statistics

Fiscal Year 2014/2015

Workload Statistics **July-Sept** **Oct-Dec** **Jan-Mar** **Apr-June** **Total 14/15**

Probation Statistics

Licenses on Probation

Pharmacist	129	137	141		137
Intern Pharmacist	3	3	3		3
Pharmacy Technician	45	38	38		38
Designated Representative	3	2	3		2
Pharmacy	31	35	39		35
Wholesaler	4	2	1		2
Probation Office Conferences	31	18	31		80
Probation Site Inspections	60	79	106		245
Successful Completion	4	11	5		20
Probationers Referred to AG for non-compliance	4	3	2		9

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 March 31, 2015.

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	Sept	Oct – Dec	Jan-Mar	Apr-Jun	Total 14/15
PRP Intakes						
PRP Self-Referrals	1	3	2			6
PRP Board Referrals	3	2	2			7
PRP Under Investigation	2		2			4
PRP In Lieu Of		2				2
Total Number of PRP Intakes	6	7	6			19
New Probationers						
Pharmacists	1		4			5
Interns						
Technicians	5	2				7
Total New Probationers	6	2	6			14
PRP Participants and Contracts						
Total PRP Participants	63	62	67			192
Contracts Reviewed	58	56	63			177
Probationers and Inspections						
Total Probationers	90	90	88			N/A
Inspections Completed	60	79	106			245
PRP Referrals to Treatment						
Referrals to Treatment	4	6	5			15
Drug Tests						
Drug Test Ordered	991	928	910			2829
Drug Tests Conducted	910	872	871			2653
Relapse						
Relapsed	3	2	2			7
Major Violation Actions						
Cease Practice/Suspension	8	6	6			20
Termination - PRP	3	3	2			8
Referral for Discipline	2	3	2			7
Exit from PRP or Probation						
Successful Completion	3	6	5			14
Termination - Probation	3	2	2			7
Voluntary Surrender	5	9	5			19
Surrender as a result of PTR						
Public Risk	2	3	2			7
Non-compliance	18	19	18			55
Other	1	1	1			3
Patients Harmed						
Number of Patients Harmed	None	None				None

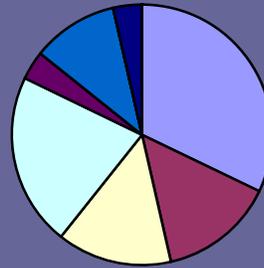
SB 1441 – Program Statistics

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 14/15
Drug of Choice at PRP Intake or Probation					
Pharmacists	July-Sep	Oct-Dec	Jan-Mar	Apr-Jun	Total 14/15
Alcohol	3	2	4		9
Ambien	1	1	2		4
Opiates	2	2			4
Hydrocodone	2	1	3		6
Oxycodone			1		1
Morphine					
Benzodiazepines	1	1	1		3
Barbiturates					
Marijuana		1			1
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Promethazine w/Codeine	1				1
Intern Pharmacists	July-Sep	Oct-Dec	Jan-Mar	Apr-Jun	Total 14/15
Alcohol					
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Promethazine w/Codeine					
Pharmacy Technicians	July-Sep	Oct-Dec	Jan-Mar	Apr-Jun	Total 14/15
Alcohol					
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Promethazine w/Codeine					
Pharmacist Recovery Program	July-Sep	Oct-Dec	Jan-Mar	Apr-Jun	Total 14/15
Participant Files Audited	None	None	None		None

Drug Of Choice - Data entered from July 2014 to June 2015

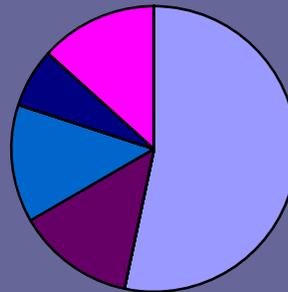
Pharmacist



Intern



Technician



- 1 Alcohol
- 2 Opiates
- 3 Hydrocodone
- 4 Oxycodone
- 5 Benzodiazepines
- 6 Barbiturates
- 7 Marijuana
- 8 Heroin
- 9 Cocaine
- 10 Methamphetamine
- 11 Pharmaceutical Amphetamine

Attachment 17

Sterile Compounding Inspections:

12/1/2014 to 3/18/2015

Sterile Compounding Inspections: 12/1/2014 to 3/18/2015

● Total Inspections by Type:

- N= 220
 - Renewals..... 200
 - New..... 20

Sterile Compounding Inspections: 12/1/2014 to 3/18/2015

● Total Inspections by Location and Type:

N=220

- **Hospital:**
 - Renewal: 125
 - New: 12
- **Pharmacy:**
 - Renewal: 76
 - New: 5
- **Out of State Pharmacy:**
 - Renewal: 19
 - New: 3

Sterile Compounding Inspections: 12/1/2014 to 3/18/2015

○ Finding of 220 inspections:

- 384 total corrections or violations at 165 facilities:
 - 55 **Hospitals**
 - 96 **Pharmacies**
 - 14 **Out of State Pharmacy**

Sterile Compounding Inspections: 12/1/2014 to 3/18/2015

- Findings **Hospitals**: N=55 sites
 - 135 corrections
 - 9 violations

Sterile Compounding Inspections: 12/1/2014 to 3/18/2015

- Findings **Hospitals**: Top 3 corrections
 - 23 corrections for CCR 1751.4; Facility and Equipment Standards
 - 22 corrections for CCR 1735.3; Records for compounded drug products
 - 14 corrections for CCR 1735.8; Compounding Quality Assurance

Sterile Compounding Inspections: 12/1/2014 to 3/18/2015

- Findings **Hospitals**: 9 violations
 - 3 violations for CCR 1735.3; Records for compounded drug products
 - 2 violations for CCR 1751.4; Facility and Equipment Standards
 - 1 violation for CCR 1751.3; Sterile injectable Policies and procedures
 - 1 violation for CCR 1735.2; Compounding Limitations and requirements; self-assessment
 - 1 violation for CCR 1250.4; Compounding Area for Parenteral Solutions

Sterile Compounding Inspections: 12/1/2014 to 3/18/2015

- Findings **Pharmacy**: N= 96 sites
 - 174 corrections
 - 41 violations

Sterile Compounding Inspections: 12/1/2014 to 3/18/2015

- Findings **Pharmacy**: Top 3 corrections
 - 19 corrections for CCR 1735.3; Records for compounded drug products
 - 18 corrections for CCR 1735.2(j); Failure to complete a self-assessment.
 - 18 corrections for CCR 1751.4; Facility and Equipment Standards

Sterile Compounding Inspections: 12/1/2014 to 3/18/2015

- Findings **Pharmacy**: Top 3 violations
 - 5 violations for CCR 1735.2(j); Failure to complete a self-assessment
 - 4 violations for CCR 1751.4; Facility and Equipment Standards
 - 4 violations for CCR 1735.5; Compounding Policies and Procedures

Sterile Compounding Inspections: 12/1/2014 to 3/18/2015

- Findings **Out of State Pharmacy**: N= 14 sites
 - 24 corrections
 - 1 violation

Sterile Compounding Inspections: 12/1/2014 to 3/18/2015

○ Findings **Out of State Pharmacy**: Top 3 corrections

- 4 corrections for CCR 1751.4; Facility and Equipment Standards
- 4 corrections for CCR 1735.3; Records for compounded drug products
- 2 corrections for CCR 1735.2; Compounding Limitations and requirements; self-assessment

Sterile Compounding Inspections: 12/1/2014 to 3/18/2015

- Findings **Out of State Pharmacy**: violation
 - 1 violations for B&PC 4127.2/4112: Failure to notify the board of a change of location.
Unlicensed location shipping into California.

Sterile Compounding Inspections: 12/1/2014 to 3/18/2015

Thank you!

Attachment 18



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

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

DATE: March 26, 2015

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

COMMITTEE MEMBERS

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

COMMITTEE MEMBERS

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

STAFF

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

Call to Order

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

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

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

No public comments were received.

II. ENFORCEMENT MATTERS

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

Background

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

Discussion and Comment

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

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

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

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

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

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

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

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

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

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

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

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

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

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

There was no further public or committee comment.

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

Background

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

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

Discussion and Comment

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

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

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

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

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

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

Public Comment

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

There was no further public or committee comment.

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

Background

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

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

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

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

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

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

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

Discussion and Comment

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

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

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

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

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

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

There was no further public or committee comment.

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

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

Background

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

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

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

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

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

Discussion and Comment

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

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

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

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

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

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

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

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

There was no further public or committee comment.

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

The meeting reconvened at 12:51 pm.

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

Background

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

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

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

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

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

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

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

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

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

1744. Drug Warnings

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

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

(1) Muscle relaxants.

- ~~(2) Analgesics with central nervous system depressant effects.~~
- ~~(3) Antipsychotic drugs with central nervous system depressant effects including phenothiazines.~~
- (43) Antidepressants with central nervous system depressant effects.
- (54) Antihistamines, motion sickness agents, antipruritics, anti-nauseants, anticonvulsants and antihypertensive agents with central nervous system depressant effects.
- (65) All Schedule II, III, IV and V agents with central nervous system depressant effects, or narcotic controlled substances as set forth in Health and Safety Code at Section 11055 et seq. prescribed in doses which could have an adverse effect on a person's ability to operate a motor vehicle.
- ~~(76) Anticholinergic agents and other drugs which may that impair vision.~~
- (b) The following are examples of drugs which may have harmful effects when taken in combination with alcohol. ~~While these~~ These may or may not affect a person's ability to operate a motor vehicle they still require a written warning notice on the label to alert the patient about possible problems:
- (1) Disulfiram and other drugs (e.g., chlorpropamide, metronidazole) which may cause a disulfiram-like reaction.
 - (2) Mono amine oxidase inhibitors.
 - (3) Nitrates.
 - (4) Cycloserine.
 - (5) Insulin (hypoglycemia) antidiabetic agents including insulin and sulfonylureas (due to risk of hypoglycemia).

Discussion and Comment

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

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

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

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

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

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

There was no further public or committee comment.

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

Background

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

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

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

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

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

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

1715.65 Monthly Inventory Counts of Controlled Substances

- (a) Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall maintain a perpetual inventory for all controlled substances acquired by the licensee. A perpetual inventory as used in this article shall mean an inventory system whereby the pharmacy's or clinic's records about stock on hand for every controlled substance acquired and dispensed are continuously updated to reflect the actual quantity of stock on hand. Such an accounting will include all acquisitions and all dispositions for each controlled substance.
- (b) As an alternative to the maintenance of a perpetual inventory in subdivision (a), a pharmacy or clinic must have a written policy that identifies a monthly reconciliation process for the 10 highest volume controlled substances acquired by the licensee in the last year (or as determined by the last DEA biennial inventory, or as purchased by the pharmacy if there has been no biennial inventory taken). This policy shall address reconciliation of all purchases and acquisitions, dispensings, transfers and current inventory, including the inventory in quarantine for a reverse distributor. The pharmacy or clinic shall perform a count of these 10 controlled substances pursuant to this policy every month.
- (c) The pharmacist-in-charge of a hospital pharmacy or of pharmacy servicing skilled nursing homes wherever an automated drug delivery system is used shall review at least once each month all controlled substances removed from or added into each automated drug delivery machine operated by the pharmacy. Any discrepancy or unusual access identified shall be investigated. Controlled drugs inappropriately accessed or removed from the automated delivery shall be reported to the board within 14 days.
- (d) Losses of controlled substances identified by pharmacies from the perpetual inventory or monthly audit shall be reported to the board as required by section 1715.6 and California Business and Profession Code section 4104.
- (e) A clinic shall report to the board all losses detected from the perpetual inventory or monthly audit undertaken pursuant to this section within 14 and no later than 30 days.
- (f) The pharmacist-in-charge or consultant pharmacist for the clinic shall sign and date each monthly reconciliation within 14 days of completion. These signed reconciliations shall be retained by the licensed premises for three years and be readily retrievable for review by the board.

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

Discussion and Comment

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

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

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

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

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

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

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

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

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

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

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

1715.65 Monthly Inventory Counts of Controlled Substances

- (a) Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall maintain a perpetual inventory for all Schedule II controlled substances acquired by the licensee. A perpetual inventory as used in this article shall mean an inventory system whereby the pharmacy's or clinic's records about stock on hand for every Schedule II controlled substance acquired and dispensed are continuously updated to reflect the actual quantity of stock on hand. Such an accounting will include all acquisitions and all dispositions for each Schedule II controlled substance.
- (g) As an alternative to the maintenance of a perpetual inventory for Schedule II controlled substances in subdivision (a), a pharmacy or clinic must have a written policy that identifies a monthly reconciliation process for the five highest volume controlled substances acquired by the licensee in the last year (or as determined by the last DEA biennial inventory, or as purchased by the pharmacy if there has been no biennial inventory taken). This policy shall address reconciliation of all purchases and acquisitions, dispensings, transfers and current inventory, including the inventory in quarantine for a reverse distributor. The pharmacy or clinic shall perform a count of these five controlled substances pursuant to this policy at least every month.
- (h) The pharmacist-in-charge of a hospital pharmacy or of pharmacy servicing skilled nursing homes wherever an automated drug delivery system is used shall review at least once each month all controlled substances removed from or added into each automated drug delivery machine operated by the pharmacy. Any discrepancy or unusual access identified shall be investigated. Controlled drugs inappropriately accessed or removed from the automated delivery shall be reported to the board within 14 days.
- (d) Losses of controlled substances identified by pharmacies from the perpetual inventory or monthly audit shall be reported to the board as required by section 1715.6 and California Business and Professions Code section 4104.

- (e) A clinic shall report to the board all losses detected from the perpetual inventory or monthly audit undertaken pursuant to this section within 14 and no later than 30 days.
- (f) The pharmacist-in-charge or consultant pharmacist for the clinic shall sign and date each monthly reconciliation within 14 days of completion. These signed reconciliations shall be retained by the licensed premises for three years and be readily retrievable for review by the board.
- (g) The pharmacist-in-charge of a pharmacy or consultant pharmacist shall review all inventories and reconciliations to establish and maintain secure methods to prevent losses of dangerous drugs.

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

There was no further public or committee comment.

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

Background

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

Discussion and Comment

Representatives from Carefusion provided information regarding Pyxis technologies and its various reports used to monitor for diversion with a Pyxis machine.

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

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

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

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

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

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

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

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

There was no further public or committee comment.

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

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

Background

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

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

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

Discussion and Comment

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

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

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

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

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

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

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

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

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

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

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

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

Discussion and Comment

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

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

There were no comments from the public.

j. DISCUSSION: Regarding the Adoption of e-Prescribing

Background

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

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

Discussion and Comment

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

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

There were no public comments.

k. DISCUSSION: Regarding Duty Inspector

Background

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

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

Discussion and Comment

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

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

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

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

III. COMPOUNDING MATTERS

a. INFORMATION: Report of Sterile Compounding Pharmacy Inspections Conducted

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

There were no public or committee comments.

IV. REMAINING MEETING DATES FOR 2015

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

June 24, 2015

September 2, 2015

December to be determined

There were no public or committee comments.

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

Maximize the security, availability and predictability of medications

CUBIE® system for Pyxis® technologies

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

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



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

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

Pyxis®

 CareFusion

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

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



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

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

Facilitating medication safety, CUBIE system helps:

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

Increasing choice and storage capacity to optimize customization

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

Half-height CUBIE pockets

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

Available for all Pyxis MedStation systems.

Full-height CUBIE pockets

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

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

CareFusion
San Diego, CA

carefusion.com



Diversion prevention and detection

Pyxis MedStation™ system and Pyxis C"Safe™ system

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

The purpose of this document is to:

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

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

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

- **Pyxis Profile:** Profile limits user access to those medications that were ordered for a specific patient and were verified and entered into the pharmacy information system by the pharmacist. This prevents the user from removing a controlled substance that was not ordered by the physician. The exception would be those medications available via override that the user has the privilege to remove.
- **BioID fingerprint identification system:** Use of this system physically verifies a user's identity with a fingerprint scan prior to granting access to the station. The system enhances security by decreasing the chances of diversion due to lost, stolen or shared passwords or swipe cards. Use of the BioID system meets state regulatory requirements for physical identification of users.
- **Clinical Data Categories (CDCs):** CDCs can be used to require a reason for overriding a medication. This may help reduce chances of diversion because of the perception of increased monitoring of the user and override reason.
- **Too Close removal warning:** A Too Close removal warning can be set to appear when a user removes a medication on a patient that previously had the same medication removed within a defined time frame. The warning will appear even if the medication was removed at another Pyxis MedStation system, as long as it is the same med ID and within the defined time frame. The warning will appear at both profile and non-profile Pyxis MedStation systems. Users can override the remove warnings, but they are required to document a reason (select from predetermined list or type in) before continuing with the removal. A report of the warning overrides can be printed at the console and reviewed for appropriateness. This feature will discourage a diverter from removing multiple doses in a short period of time.
- **Override settings:** The Override settings allow a user to remove a medication from a profile Pyxis MedStation system prior to a pharmacist review and verification of the order. The ability to remove a drug via override can be limited by drug and by user. Limiting the number of controlled substances available via override (especially oral medications) can decrease the potential for diversion.
- **Witness on Override:** When the Witness on Override setting is turned on at the console, a witness is required

each time a medication is removed from a profile Pyxis MedStation system via override. This feature will stop a diverter from removing controlled substances via override independently. Consider the availability of a witness to override before deciding to use this feature.

- **Return bins:** Return bins are a standard feature of the Pyxis MedStation system. Returning all controlled substances to the return bin for inspection by pharmacy personnel prevents a tampered with medication from being returned to stock.
- **Witness to Empty Return Bins:** The Witness to Empty Return Bins setting can be turned on at the console. Requiring a witness protects the pharmacy technician and the user from suspicion of diversion.
- **Menu Time Out:** The Menu Time Out is set at the console for each Pyxis MedStation system and will automatically log out the user if there is no activity during this time. Set the menu time out for 1 minute 30 seconds or less. A time out of two minutes or more gives a diverter ample time to remove a controlled substance under another user's name, if that user does not exit prior to walking away from the Pyxis MedStation system.
- **Discharge Delay:** Discharge Delay is set at the console for each Pyxis MedStation system to allow a user to return or waste a medication on a patient that was recently discharged. Set the discharge delay for two hours or less. A long discharge delay provides a diverter an opportunity to remove controlled substances on a patient that is discharged.
- **Lock Loops:** Security Lock Loops can be installed on Pyxis MedStation systems that are located in areas that are not staffed 24 hours per day.

Policies that help deter controlled substance diversion

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

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

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

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

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

Reports used to monitor for diversion

Pyxis MedStation system station reports

- **Activities reports:**

- **Run reports:** Encourage staff to print an Activity report by user at the end of each shift to verify activity. This identifies problems with password security and failure to log off of the system. Users may also print an Activity report for controlled substances on their patients. This will identify another user removing controlled substances for their patients.
- **Review reports:** Encourage nurse managers to review Activity reports for controlled substances to verify that activity is limited to nurses assigned to the unit and shift. Activity reports can also be used to conduct concurrent audits of activity by drug, user or patient. Printed activity for one of these parameters can be compared with the patient's orders to assure the removal matched the order, the removal matched the order time frame, documentation of administration matched the order and removal, waste matched the order and removal and there was a clinical indication for the ordered medication.

- **Discrepancy reports:**

- **Run reports:** All discrepancies should be resolved according to hospital policy (usually by the end of each shift). The oncoming and offgoing charge nurses should check to make sure there are no icons on the Pyxis devices, which indicate an open discrepancy. Some hospitals have the charge nurse leave documentation that they looked for open discrepancies and that all are resolved. They run an Open Discrepancy report at the end of the shift, review and sign the report and leave it for the nurse manager to review. There should be no open discrepancies on the report.

- **Review reports:** Encourage nurse managers to review the discrepancy report on the Pyxis MedStation system for compliance with hospital policy and to look for trends and patterns. The nurse managers need to know the number of discrepancies occurring on their units. This includes resolved and unresolved discrepancies. When reviewing each discrepancy, note the reason for the discrepancy and whether it makes sense. Look for the same user or pairs of users consistently creating/resolving discrepancies.

- **Return/Waste reports:** Recommend nurse managers routinely print the Return/Waste report by user and perform random audits of nurses for accurate documentation of controlled substances removed from and wasted at the Pyxis MedStation system. Wastage of partial controlled drugs can be performed either at the time of withdrawal or after administration. Predetermined waste locations can be added to the waste CDC to avoid having to type in the location.
- **Override report:** Removing controlled substances via override can be a source of diversion. Nurse managers can monitor the Override report at the station to assure there is an order for the medication removed on override and that the circumstances warrant an override. Also look for users that override medications even though there is a profiled order for that medication.

Pyxis MedStation system console reports

- **Daily reports:**

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

- **All Discrepancies report:** Review discrepancy resolution reasons for appropriateness. Follow up on any variances with nurse managers. Review daily.
- **Weekly reports:**
 - **User Modification report:** Review to make certain users added/modified are legitimate. Follow up with nurse managers or pharmacy leadership for any questionable transactions.
 - **Patients Added at the Console or Station report:** Sort by User to review temporary patients added to the system. Look for trends of users adding more temporary patients than their colleagues.
 - **Profile Override Report for Controlled Substances by User report:** Review for an unusually high amount of controlled substance removals on override or users that remove via override even though a profiled order for that medication exists.
 - **Waste Activity by User report:** Review for unusually high amount of waste activity for specific user compared with other staff.
 - **Outdated Med Removal report:** Review the Outdated Med Removal report to make certain that only appropriate pharmacy personnel are removing expired medications. Look for any non-pharmacy employees who might be using this function as a source of diversion.
 - **Service Message report:** Review for log-in failures, unusually long log-in time and drawer left open messages. These could indicate attempts at diversion.
- **On-demand reports:**
 - **All Station Events by User report:** Run this report to review user-specific transactions. (Use Pyxis C¹Safe system Proactive Diversion Search report to identify high-access users.)
 - **All Station Events by Station/Med report:** Run this report as needed for specific medication/nursing unit to aid in discrepancy resolution.

Pyxis C¹Safe system reports

See Pyxis C¹Safe system reporting clinical white paper on the CareFusion Customer Connection website at pyxis.com/CustomerConnection.aspx.

- **Open Discrepancies report:** This report lists items in the Pyxis C¹Safe system with counts different than what's expected. Run this report at the end of each shift.
- **All Pyxis C¹Safe Events report:** This report shows all Pyxis C¹Safe system drug transactions for the prior 24-hour period. The report automatically runs at midnight.
- **Pyxis C¹Safe Compare report:** Run this report after all deliveries are completed to make sure all controlled substances sent from the Pyxis C¹Safe system were placed into the appropriate Pyxis MedStation system. It assists in detecting potential diversion as well as detecting pocket refill, unload or load errors.
- **Reconcile Physical Counts report:** Use this report to verify and document the counts of the controlled substance vault.
- **Pyxis MedStation system Transaction report:** This report provides a record of the Pyxis MedStation system transactions that happened prior to the last 31 days. It can be used to research outliers found on the Proactive Diversion Search report and to review Pyxis MedStation system cancelled transactions.
- **Review Transaction Corrections report:** This report provides a list of the corrections that have been made to certain transactions (i.e., compound, prescription, receive, return, sale, send or waste). It provides specific details for the transaction such as who corrected it, why and witness if applicable. This report allows management to monitor any transaction corrections.
- **Review Resolve Discrepancies report:** This report prints all discrepancies that have been documented using the discrepancy resolution feature on the Pyxis C¹Safe system. The Resolve Discrepancy function should be reserved to those circumstances when the controlled substance transaction cannot be fixed (with a second transaction) or corrected (via the Transaction Correction routine), and is therefore irresolvable.

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

Integrated Analytics Solutions

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

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

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

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San Diego, CA

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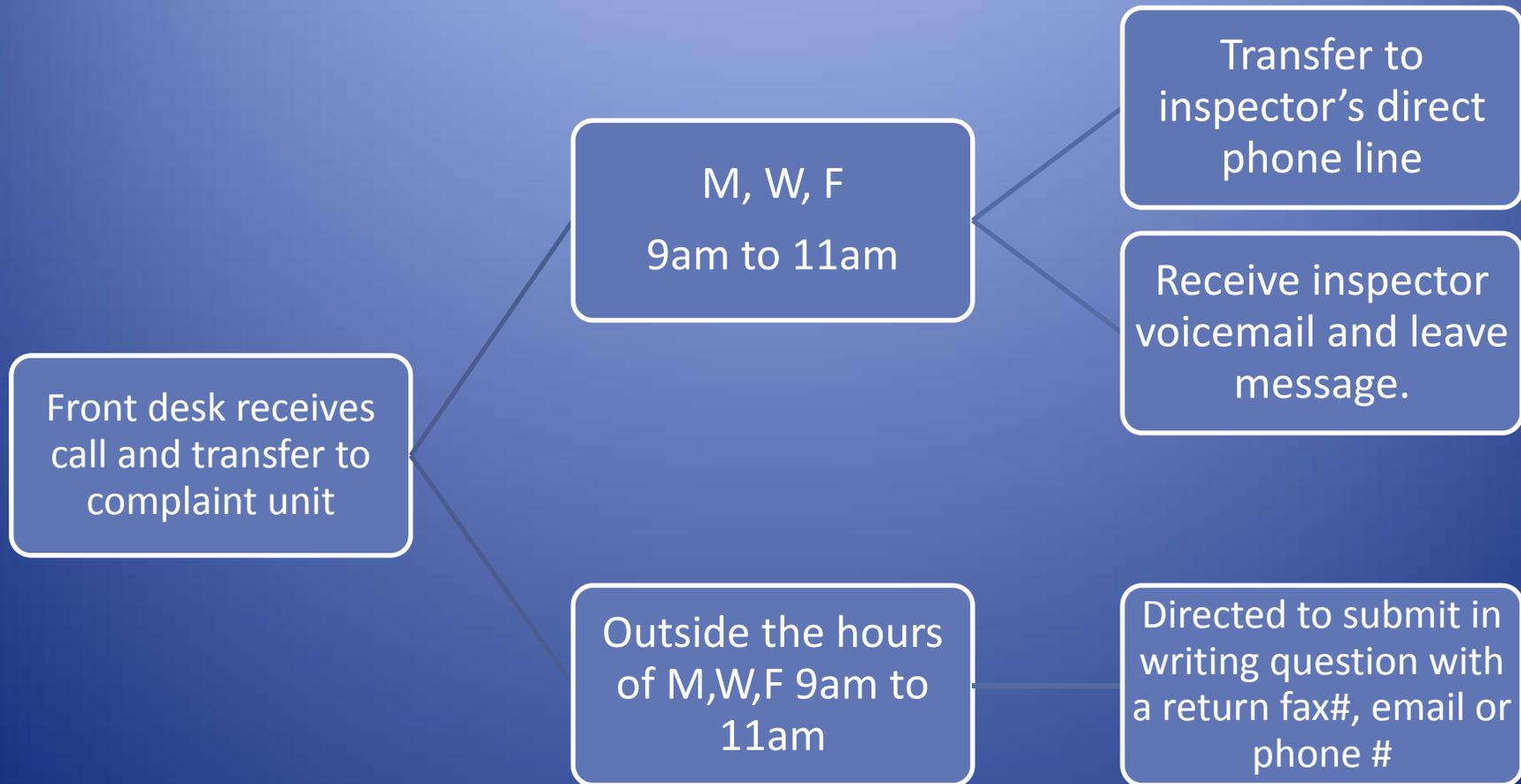
Phone Duty
10/18/14 to 3/20/15

California State Board of Pharmacy

Phone Duty

- Pilot test: 10/13/2014
 - 31 questions
- Implemented: 10/18/2014
- Assigned inspector rotation
 - Each inspector is assigned to cover 1-week
 - M, W, F from 9am to 11am to answer phone
 - Responsible for all questions for the week

Phone Duty



Phone Duty

- **Total # of questions: 531 questions**
 - Average # per week: 24
 - Highest # per week: 55 (week of 3/7-3/13)
 - Lowest # per week: 1 (week of 1/3-1/9)
- **Total time spent: 245 hours (22 weeks)**
 - Average time spent per question: 27 minutes
 - Average inspector time per week: 648 minutes (10.75 hours/week)

Phone Duty

(Number of Calls Per Week)

Week 1: 15	Week 12: 1 (lowest) 1/3/15/to 1/9/15
Week 2: 24	Week 13: 5
Week 3: 33	Week 14: 45
Week 4: 20	Week 15: 27
Week 5: 42	Week 16: 12
Week 6: 5	Week 17: 28
Week 7: 23	Week 18: 28
Week 8: 32	Week 19: 31
Week 9: 15	Week 20: 46
Week 10: 11	Week 21: 55 (highest) 3/7/15 to 3/13/15
Week 11: 9	Week 22: 26

Phone Duty – Question Type

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

Phone Duty – Question Type: Other

- Inquiring about collaborative agreements between pharmacy and physicians.
- Inquiring about laws regarding the use of sporicidal agents.
- Can a pharmacy share space with a licensed laboratory?
- Can a non-rph own a pharmacy?
- How do you open a wholesaler and a pharmacy, what are the requirements?
- Can an out-of-state pharmacist work under a licensed pharmacist under CA law?
- Where can I find details about protocols, credentialing and other requirements of SB 493?
- I am working for a client to determine what licensing, if any, is needed to open an ambulatory infusion center.
- What type of containers are required to store expired/discarded/discontinued medications from patients at an unlicensed facility? The facility is an apartment complex and holds no license.
- Does a small business need a license from the BOP to arrange a contract for emergency use only oxygen from an industrial setting?
- Owners of organic fruit and vegetables wants to name their business “farmacy”. Does this violate any regulations?
- Any laws that prohibit an LVN from writing a note on a bubble-packed medicine for a SNF or assistant living facility for a medication already dispensed to the patient without the direction or okay from the prescriber?

Phone Duty – Question Type: Other

(continued)

- Does CA authorize a pharmacy to contract or sub-contract dispensing activities? \
- Is it against HIPPA to place a flyer at a pharmacy looking for research subjects?
- Can a NRP have a CA licensed RPH do consulting and rx verification for the NRP? NPR in Pennsylvania.
- Is a license required from the BOP for a courier company to ship to contact lens from a prescriber to a patient?
- Is a wholesaler license required to sell acupuncture needles? (question asked multiple times)
- A new company created a new medical device to assist pharmacies when dispensing meds. What type of license would be required in order to purchase various controlled and non-controlled drugs to test their devices during the manufacturing process to insure accuracy?
- Would a non-resident pharmacy license be approved for mailing non-prescription animal health products?
- A sterilization lab that completes process validation testing for sterile compounding pharmacies, is asking if they need to be licensed by the BOP.
- What type of restrooms do we need to have, a unisex or separate male and female restrooms?

Phone Duty – Caller Type

Question Type:	Count:	%:	Time (hrs)
RPh	200	37.66%	83 hrs
Other *	82	15.44%	37.5 hrs
Consumer	58	10.92%	27.3 hrs
Prescriber	33	6.21%	15 hrs
Administrator	32	6.03%	21 hrs
Lawyer	24	4.52%	12.3 hrs
Technician	14	2.64%	5.25 hrs
Healthcare Mgmt	11	2.07%	8.75 hrs
Manager	11	2.07%	4.5 hrs
Manufacturer	10	1.88%	5.5 hrs
RN	10	1.88%	5.25 hrs
WLS	10	1.88%	3 hrs
Intern	7	1.32%	3 hrs
DVM	5	0.94%	2.75 hrs

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

Phone Duty – Caller Type: Other

Sampling:

- National account managers.
- Pharmacy software vendors.
- Billing software vendors.
- Occupational therapist.
- Organic food company.
- Research company.
- Assistant living facility.
- Builders
- Acupuncturist.
- Sterilizing company.
- Architects.

Questions