



**ENFORCEMENT AND COMPOUNDING COMMITTEE  
MEETING MATERIALS  
DECEMBER 17, 2014**

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

Note: The committee may not discuss or take action on any matter raised during this public comment section that is not included on this agenda, except to recommend whether to place the matter on the agenda of a future meeting. [Government Code Sections 11125, 11125.7(a)]

**II. ENFORCEMENT MATTERS**

**a. PRESENTATION: San Mateo County Supervisor Adrienne Tissier on the San Mateo County Safe Medicine Drop-off Program**

**Attachment 1**

At this meeting, San Mateo County Supervisor Adrienne Tissier has requested the opportunity to provide information about their county's drug take back program.

Launched in 2006, San Mateo County's Pharmaceutical Disposal Program provides a convenient, environmentally sound way for citizens to dispose of both human and veterinary pharmaceutical drugs by providing disposal sites at law enforcement agencies throughout the county. Background from their website is provided in **Attachment 1**.

**b. DISCUSSION: The Drug Enforcement Administration's Regulations for the Take Back of Prescription Medication**

**Attachment 2**

On Tuesday, 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 2**.

The board will need to develop regulations for this program for California. At this meeting the committee will review the components of the federal requirements and initiate discussion to develop proposed regulations.

Also in **Attachment 2** is a newspaper article providing information about one of the country's largest reverse distributors and criminal arrests.

**c. PRESENTATION: New York's E-Prescribing Requirements for Controlled Substances**

**Attachment 3**

E-prescribing will be required for all New York State prescriptions effective March 27, 2015, pursuant to regulations adopted by New York State. At this meeting, the committee will hear a presentation by New York's Board of Pharmacy Executive Officer Larry Mokhiber. A copy of the regulation is provided in **Attachment 3**.

Provided as background on this topic is a 2013 project report of two locations in California that were pilot testing e-prescribing. This report is provided in **Attachment 3**.

**d. DISCUSSION: Evaluation of 16 CCR section 1744 Regarding Required Warning Labels on Prescription Container Labels**

**Attachment 4**

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. The revised version of Business and Professions Code section 4074, which AB 1136 amended, is provided in **Attachment 4**.

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. These comments are integrated into the draft below.

#### 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)

At the September 16, 2014 committee meeting, the committee revised these comments into the version below that was referred to the board for action.

#### 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).

However, at the October Board Meeting, the board sent the language back to the committee for further discussion and review. An excerpt of the comments from this meeting is provided in the draft minutes of the October Board Meeting in **Attachment 4**.

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

**Attachment 5**

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. The following tables display the losses of controlled substances reported to the board.

Year	2009	2010	2011	2012	2013	2014 (6 mo.)
Number of Reports	614	749	536	639	1224	678
<b>Loss Type</b>	<b>Total Count Reported</b>					
Armed Robbery		70,786	35,773	106,787	80,464	
Customer Theft		9,550	4,598	5,684	13,175	
Employee Pilferage		252,225	452,877	372,926	125,305	
Lost in Transit		13,239	412,168	*1,657,875	22,310	
Night Break In		505,016	80,971	689,925	154,156	
Other		121,635	532,441	518,432	94,267	
Totals		972,450	1,518,828	3,351,628	489,677	

\* In transit losses

### DEA 106 Reports by License Category

<b>Category</b>	<b>2011</b>	<b>2012</b>	<b>2013</b>	<b>2014</b>
Pharmacy	376	460	943	551
Hospital	115	104	230	97
Wholesaler	33	35	58	35
Out of State				
Distributor	1	6	8	4
Correctional Facility	10	5	2	5
Clinic	1	2	0	0
Non Resident				
Pharmacy	0	1	0	0
Drug Room	0	0	1	0
Other	0	0	2	1
<b>Total</b>	<b>536</b>	<b>613</b>	<b>1244</b>	<b>693</b>

#### 2013 Losses

	No. of Reports	Dosage Units Lost
Chain Store:	652	564,061
Community:	291	533,045
Hospital:	230	28,073

#### 2014 Losses (6 months only)

Chain Store	443	226,866
Community	108	289,751
Hospital	97	990

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.

Note: 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 committee's September 16, 2014 meeting, the committee voted to recommend that the board adopt the following proposed language:

**1715.65 Monthly Inventory Counts of Fastest Moving Controlled Substances**

- (a) Every June 30<sup>th</sup>, 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.

At the October 28-29, 2014 board meeting, the board voted to oppose the committee's recommendation and send the matter back to the committee for additional discussion (an excerpt of the minutes of this part of the board meeting is provided in **Attachment 5**). Among the concerns expressed were:

- Monthly inventory would cause undue hardships for small community pharmacies
- Employees could purposely divert non-top ten drugs in order to avoid detection
- Conducting inventory on controlled substances purchased each month rather than dispensed each month would be more effective as drugs are often diverted at the time of delivery or prior to delivery

Enforcement Chair Gutierrez has worked with the executive officer to simplify the language. These individuals are still revising the language as this packet is being prepared. A draft will be brought to the committee meeting.

- f. **DISCUSSION: Board Comments Regarding the FDA’s Guidance on the Effect of Section 585 on the Food, Drug, and Cosmetics Act on Drug Product Tracing, and Wholesale Drug Distributor and Third-Party Logistics Provider Licensing Standards and Requirements**

**Attachment 6**

On November 14, 2014, the board provided comments to the Food and Drug Administration regarding the aforementioned draft guidance on the effect of section 585 Federal Food, Drug, and Cosmetic Act. These comments and a copy of the guidance document itself are provided in **Attachment 6**.

- g. **DISCUSSION: NABP Report Highlighting the Proliferation of Rogue Online Drug Sellers and the Drug Abuse Epidemic**

**Attachment 7**

On October 31, 2014, the NABP issued a report highlighting a connection between the proliferation of rogue online drug sellers and the prescription drug abuse epidemic. This report is provided in **Attachment 7** and is for information.

- h. **DISCUSSION: Medication Error Reduction Continuing Education Online Course Developed by Oregon State University**

**Attachment 8**

On November 17, 2014, Oregon State University released a new online continuing education course titled Patient Safety and Medication Error Prevention for Pharmacy. A copy of this document is provided, for your information, in **Attachment 8**.

i. **PRESENTATION: Omnicell’s Presentation and Proposal For Restocking Automated Dispensing Cabinets in Post-Acute Care Settings**

**Attachment 9**

Omicell has requested an opportunity to provide a presentation of their software for restocking of automated dispensing by technicians in a post-acute care setting.

They have provided background for this presentation in **Attachment 9**.

One relevant code section regarding the use of automated devices in skilled nursing facilities is Health and Safety Code section 1261.6. A copy of this section is provided also in **Attachment 9**.

j. **DISCUSSION: Use of Automated Technology in Hospitals and Skilled Nursing Facilities and the Tools for identification of Medication Diversion from These Units**

At the September 16, 2014 Enforcement Committee meeting, the committee discussed the need to schedule a future agenda item to learn about drug storage security features of automated devices already in use in California health care facilities and how many of these features can be used to deter diversion.

Several board members attended the American Society of Health-System Pharmacists meeting in Anaheim on December 8, 2014, and received demonstrations of the new technology by two vendors.

The committee will discuss how to ensure that these security systems are used to identify at stop drug diversion at the earliest possible time.

k. **DISCUSSION: Proposed Regulations for Third-Party Logistics Providers; Proposed Amendments to 16 California Code of Regulations Sections 1780 -1786**

**Attachment 10**

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.

**Attachment 10** contains a proposed mock-up of existing requirements for drug wholesalers that has been amended to include third-party logistics providers. This document is not yet completed as a self-assessment process is proposed much like the process required of drug wholesalers. Additionally the third-party logistic provider community needs to be advised of the developing regulations as well so that they may participate in the process.

### III. COMPOUNDING MATTERS

#### a. **PRESENTATION: Dynalabs on Their DVx Testing Device**

At this meeting, Dynalabs has requested an opportunity to provide information about their testing programs. Christine Versichele will be providing this information.

#### b. **INFORMATION: Report of Sterile Compounding Pharmacy Inspections Conducted**

### **Attachment 11**

Supervising Inspector Robert Ratcliff will provide information about sterile compounding inspections and violations identified since the last meeting.

**Attachment 11** contains an article about drug recalls and patient trust in their medications.

### IV. FUTURE MEETING DATES

The committee has selected 2015 meeting dates that will be announced at the meeting.

# Attachment 1

## Board of Supervisors



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## Pharmaceutical Disposal Program

*Updated July 2009*

### ***Abstract of the Program***

The San Mateo County Pharmaceutical Disposal Program offers the public a convenient, viable and environmentally friendly alternative to flushing pills or medicinal liquids into the wastewater stream or placement in municipal landfills. Launched in September 2006, the program is believed to be a national first, as it operates year-round and legally accepts all pharmaceuticals, including those defined as controlled substances. Simultaneously, the program addresses law enforcement issues centered on the dangerous, recreational use of pharmaceuticals, plus health and safety concerns involving citizens – especially seniors – with multiple prescriptions resulting in large amounts of look-alike pills presenting potential dosage errors.

During the first four months of operations, the program collected more than 585 pounds of medicines discarded by the public at four locations countywide. In late-April 2007, in conjunction with Earth Week and National County Government Week, “*Protecting The Environment*,” the program expanded by seven cities to total 11 drop-off sites countywide. As of summer 2009, 15 Peninsula law enforcement agencies are managing 16 drop-off sites countywide.

In May 2009, a report by the San Mateo County civil grand jury described the program as providing the public with, “... a convenient, cost-effective, safe and secure alternative to the disposal of pharmaceuticals.”

In November 2008, the San Mateo County Pharmaceutical Disposal Program received a Governor’s Environmental and Economic Leadership Award, presented by the California Department of Environmental Protection. GEELA is considered California’s highest environmental honor.

In June 2007, the program garnered an Achievement Award from the National Association of Counties. In September 2007, the program received an Honorable Mention from the San Francisco Bay Regional Water Quality Control Board in connection with its first-ever Dr. Teng-Chung Wu P2 Award, intended to promote excellence in pollution prevention.

### ***Need for the Program***

When San Mateo County Sup. Adrienne J. Tissier’s father passed in 2004, she found herself sorting through a large supply of prescription medications, including powerful painkillers and sedatives. Soon after taking office in January 2005 as the newest member of the Board of Supervisors, Adrienne started researching methods of disposal, since she already knew of the environmental risks. The supervisor

set out to create a permanent disposal program when her research revealed that a clear and convenient disposal path did not exist; in fact, the Web site of one of the country's largest retail pharmacy chains actually supported the flushing of unwanted medicines down the toilet. The reaction from environmental advocates was immediate and uniformly positive. However, they also cautioned Adrienne regarding the challenges posed by strict federal regulations governing the handling of medicines defined as controlled substances.

As a gauge of public need, the supervisor worked with the county's Environmental Health Services Division and set up a one-time collection event during Earth Week in April 2005. During that week, collection points in 13 San Mateo County cities received a total of some 235 pounds of medicines. The public need was more than obvious, especially in the context of the recreational use of pharmaceuticals.

Beyond manufacturing methamphetamines with over-the-counter decongestants containing pseudoephedrine, burgeoning evidence indicate teenagers and young adults are participating in so-called "pharm parties," where fistfuls of various, unidentified pills are dubbed "trail mix" and swallowed – often washed down with alcohol.

Working with the San Mateo County Police Chiefs and Sheriffs Association, Adrienne assembled a program offering convenience for the public, with minimal costs to the county and minimal staff commitments by the participating law enforcement departments. Pharmaceutical disposal receptacles – refurbished surplus US Postal Service collection boxes, repainted and appropriately labeled – were placed at three police departments (City of Daly City, City of Pacifica and City of San Bruno) and at the Sheriff's Office inside the county Hall of Justice in Redwood City, Calif. This satisfied the federal rules concerning controlled substances.

The San Mateo County Pharmaceutical Disposal Program officially launched the week of Sept. 18, 2006, and by the end of June 2009, had collected more than 25,200 gross pounds of discarded pharmaceuticals. In other words, the program has diverted more than **12.5 tons** of medicines and packaging from the solid waste and wastewater streams, and prevented their unintended use by children and seniors. Simultaneously, these drugs were no longer available for recreational purposes.

During that same September 2006 – June 30, 2009, period, disposal costs to the county were less than **\$1.50 per pound**, including pick-up fees.

### ***Description of the Program***

The San Mateo County Pharmaceutical Disposal Program is a public service trifecta, benefiting the environment, youth and seniors and their families. It offers a convenient way for the proper disposal of expired or otherwise unwanted pharmaceuticals through participating local law enforcement agencies. As of 2009, more than a dozen city police departments hosted disposal receptacles, plus an additional two containers controlled by the Sheriff's Office.

Anyone can walk into each site, place the unwanted medicines in the receptacle and walk away. The steel receptacles are easily seen at each location and each is clearly marked in English and Spanish. Keeping the medicines in their original containers, especially the liquids, helps prevent leakage; and removal of prescription labels helps protect privacy.

The program's three main goals are to help seniors avoid dangerous medication dosage errors, help reduce or prevent recreational pharmaceutical use and to help stop the continuing contamination of the environment by myriad medicines flushed down countless drains every day. The environmental risk

stems from the fact that the majority of sewage treatment facilities are not designed to filter out medicines. So everything from antibiotics to the hormones found in birth control pills is showing up in fish and amphibians – so-called “indicator species.”

The San Mateo County Pharmaceutical Disposal Program does not accept illegal substances, such as marijuana, ecstasy or methamphetamines.

The disposal receptacles were placed with law enforcement agencies because that was the only way to create a program able to legally accept ALL pharmaceuticals, including those defined as controlled substances. Each participating department is responsible for securing its own receptacle, monitoring its contents and capacity and regularly transporting the deposited medicines to three consolidation points located at two police departments and the county jail, where the transporting officer deposits his or her department’s collected medicines into another locked container. That locked container is then picked up by a licensed and bonded hazardous waste disposal company, which in-turn disposes of the medicines in an appropriate, commercial incinerator.

Media coverage, physical and electronic flyers as well as word-of-mouth all helped in publicizing the program. Participating cities placed flyers at city halls, senior centers and public libraries, while at least one major chain pharmacy accepted flyers for 10 of its retail locations in the county.

As word spread, inquiries arrived from as far away as the Tualatin Valley (Ore.) Water District; Macomb County (Mich.) Health Department; Brown County (Wisc.) Port & Solid Waste Department; Summit County (Ohio) General Health District; Franklin County (Mass.) Solid Waste District and the Miami-Dade County (Fla.) Police Department.

### ***Costs of the Program***

Similar to any other public program, the San Mateo County Pharmaceutical Disposal Program includes hard and soft costs, with recurring hard costs designed to be minimal.

The largest initial expense was the preparation of the disposal receptacles. A generous local postmaster granted the county four surplus mail collection boxes, with the caveat that the containers must not be used for any mail-related activities. These steel boxes were in such poor condition that they were taken to an auto-body shop for refurbishment and a thick coat of white paint. The boxes were then taken to a commercial sign manufacturer for blue lettering in English and Spanish declaring, on three sides:

*Pharmaceutical Disposal Only*  
*No Mail*  
*No Batteries*  
*No Trash*  
*No Syringes*

*Deshechos Farmaceuticos Solamente*  
*No Correo*  
*No Baterias*  
*No Basura*  
*No Jeringas*

Each receptacle also displays three, large, red biohazard logos. The refurbishment and graphics for the four original containers totaled \$1,600 in county funds. Starting in spring 2007, the expansion departments purchased courier boxes resembling the book-drop receptacles found outside many public libraries. These were purchased from a Southern California vendor and repainted by the same sign manufacturer previously mentioned. Total cost to each department was in the \$700 to \$800 range. (The expansion departments purchased courier boxes because surplus USPS boxes were no longer available.)

The sole recurring hard cost is the disposal contract between the Sheriff's Office and the disposal company (All Chemical Disposal, Inc., of San Jose, Calif.), set at \$60 per pickup, plus \$0.75 per pound. Any syringes or other "sharps" incur additional charges.

In terms of soft costs, the largest component by far is the staff-time commitment borne by each participating agency, which conducts an initial examination of the deposited items to look for items, such as sharps, trash, mail, batteries and any illegal drugs. Depending on a receptacle's frequency of use by the public, a particular agency's property officer might have to store some materials until the next-appropriate transport to a consolidation point.

### **Results/Success of the Program**

The three main goals of the San Mateo County Pharmaceutical Disposal Program are to:

- 1) Help seniors avoid potentially dangerous medication dosage errors;
- 2) Help reduce or prevent recreational pharmaceutical use; and to
- 3) Help stop the continuing contamination of the environment.

The program seeks to achieve these goals by providing a convenient, effective and legal method for the public to dispose of unwanted household medicines, including those defined as controlled substances. The public's response has been overwhelmingly, if not entirely, complimentary and positive. The sole criticism has been the unavailability of disposal receptacles at neighborhood pharmacies and/or senior centers. However, the collected volume underscores the program's success.

Perhaps the best summation of the program was printed in the November-December 2006 issue of the *Loma Prieta*, the newsletter of the Loma Prieta chapter of the Sierra Club, which covers the California counties of San Benito, Santa Clara and San Mateo:

*The Precautionary Principle suggests that we should act now to address the fact that an increasing number of chemicals from pharmaceuticals and personal care products are entering our environment and we only know a portion of the effects of a subset of these chemicals.*

*Thanks to Supervisor Adrienne J. Tissier, San Mateo County has created a convenient way for the proper disposal of expired or otherwise unwanted pharmaceuticals.*

###

### **Contacts**

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# Attachment 2



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

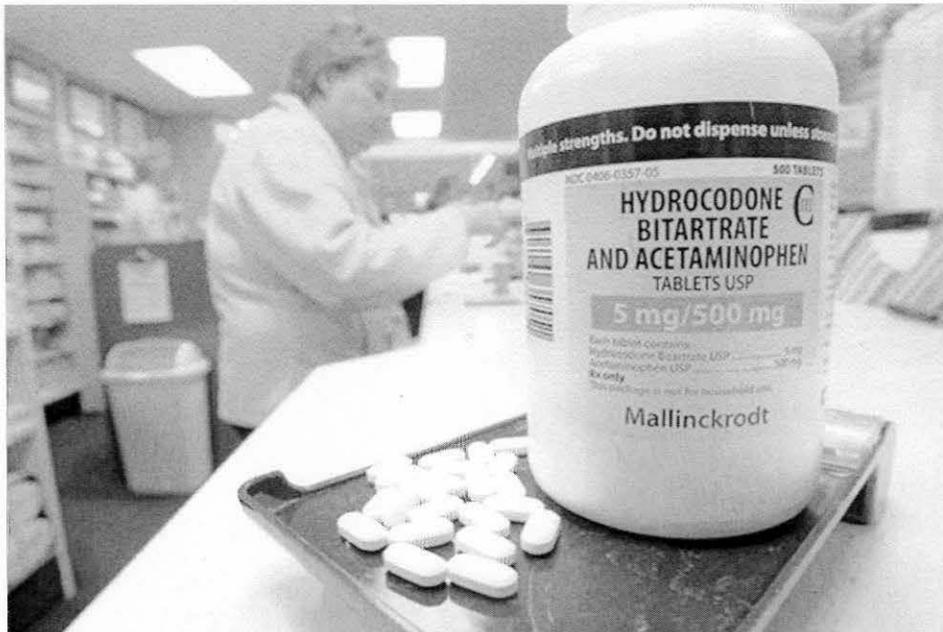
Devlin Barrett and WSJ This Morning's  
Gordon Deal discuss this pill return program

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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](mailto: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)

<b>Business Activity</b>	<b>Controlled Substances</b>	<b>DEA Application Forms</b>	<b>Application Fee (\$)</b>	<b>Registration Period (years)</b>	<b>Coincident Activities Allowed</b>
(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](http://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](http://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](http://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]

# Attachment 3

**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



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## Final Report

### Evaluation of the Electronic Prescribing of Controlled Substances Pilot

**Submitted To:**

California HealthCare Foundation

**Submitted By:**

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# 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

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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.

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## I. INTRODUCTION

Numerous studies have shown benefits to electronic prescribing (e-prescribing), such as improved patient safety and efficiency.<sup>1,2,3,4,5</sup> 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.<sup>6</sup> 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.<sup>7</sup>

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.<sup>8</sup>

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.”<sup>9</sup> 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).<sup>10</sup> 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.

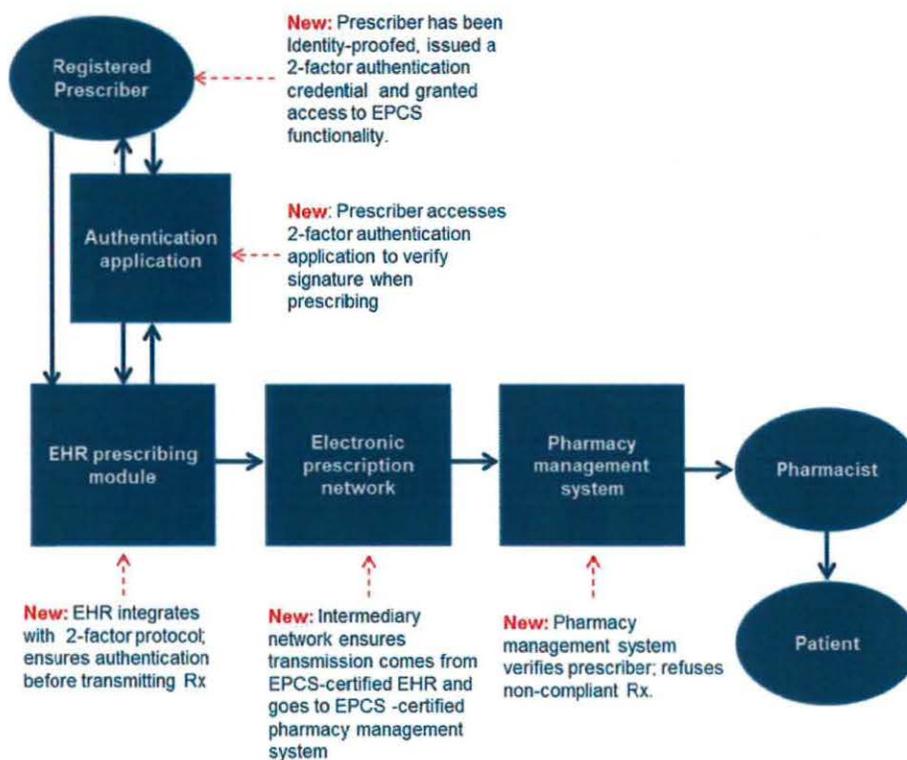
*Prescriber registration.* Before ever writing an electronic prescription for a controlled substance, the prescriber (who must be a DEA registrant) undergoes a set of processes this evaluation terms *registration*. Registration comprises: (1) identity proofing; (2) issuing a two-factor authentication 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 <sup>st</sup> 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"> <li>• 23 clinics in two urban counties</li> <li>• 119 medical staff providers and 68 per diem providers</li> </ul>	<ul style="list-style-type: none"> <li>• 6 clinics in one largely rural county</li> <li>• 39 full-time providers and 16 contracted specialists</li> </ul>
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.

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## 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.

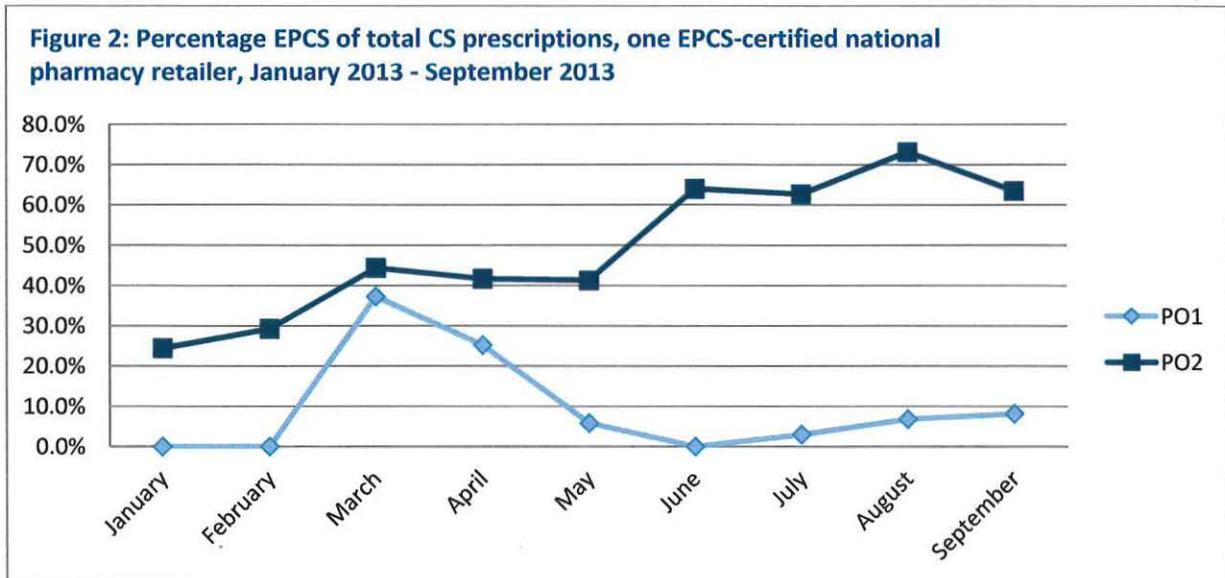
**Table 4. Prescriber organization volume results**

	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**

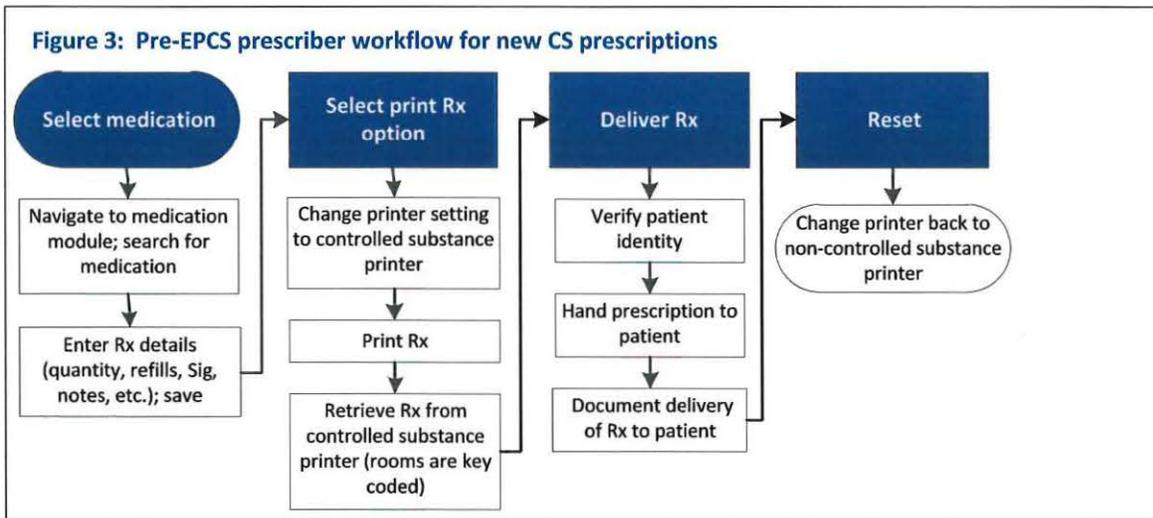
*For new prescriptions, post-EPCS processes were nearly the same as for other e-prescribing.*

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.

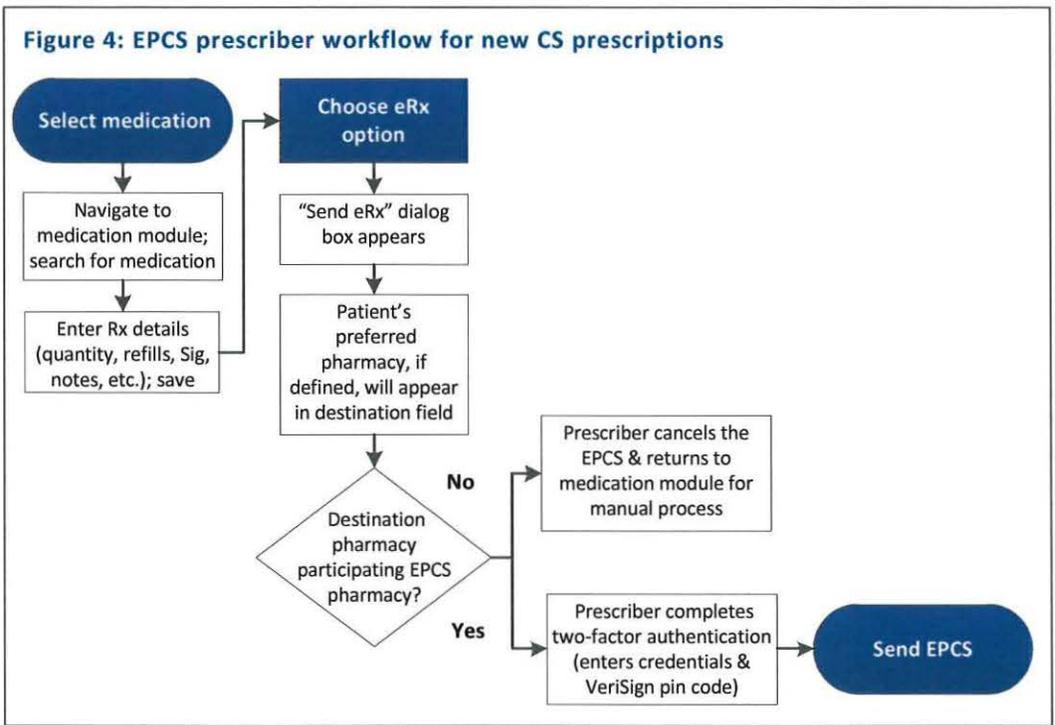
**EPCS eliminates secure printer, secure paper and “wet signature” steps for prescribers.** In the absence of EPCS, prescribers must use DEA-certified prescription paper for controlled substances. This paper includes features that can help a pharmacist distinguish a legitimate prescription from a fraudulent 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.

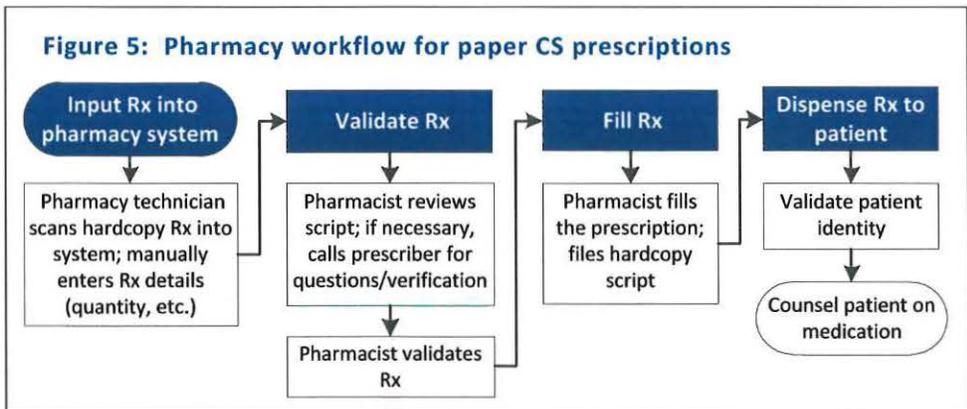
Figure 3 displays PO2’s description of the steps for filling a new prescription for a controlled substance without EPCS.



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.

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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.

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***"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)***

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***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.

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***"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)***

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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

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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.

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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.

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*"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)*

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**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.<sup>11</sup> Prescribers saw the additional security as adding value, given their worries about the security of current paper processes.

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**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-

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*“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)*

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**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.

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*“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)*

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## 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.

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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.

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*“...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*

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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.<sup>12</sup> Since audit costs are borne by the

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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.

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*“... 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)*

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**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.

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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.*

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*“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...”*

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*(Front-line staff member, PO2)*

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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).

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*"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."*

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*(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

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*"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."*

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*(Front-line staff member, PO2)*

## VI. POLICY IMPLICATIONS

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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.<sup>13</sup> 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.

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## 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.

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*“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)*

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## 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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## NOTES

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- <sup>10</sup> American Medical Association, American Academy of Family Physicians, American College of Physicians, Medical Group Management Association, eHealth Initiative, & The Center for Improving

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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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### International

Egypt  
Honduras  
Ivory Coast  
Kenya  
Liberia  
Malawi  
Pakistan  
South Africa  
Zambia

# Attachment 4

Chair Gutierrez reported that existing law requires a pharmacist to inform a patient orally or in writing of the harmful effects of a drug: (1.) if the drug poses a substantial risk to the person consuming the drug, when taken in combination with alcohol, or if the drug may impair a person's ability to drive a motor vehicle, whichever is applicable, and (2.) the drug is determined by the Board of Pharmacy to be a drug or drug type for which the warning shall be given.

Chair Gutierrez explained that Assembly Bill 1136 amends 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. She noted that the required label may be printed on an auxiliary label that is affixed to the prescription container.

Chair Gutierrez stated that 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. As this section has not been revised in a number of years, the schools of pharmacy were asked to provide comments to the list of medications listed in this regulation.

Chair Gutierrez reported that the committee reviewed the comments provided by pharmacy schools and it was recommended to keep the language as broad as possible as the drugs will change over time. Chair Gutierrez noted that this would allow the pharmacist to use his or her professional judgment. It was also suggested to include a portion of the language in the statute as part of the introduction to 1744.

Dr. Gutierrez stated that the committee made the following recommendation (motion): Adopt the revisions to section 1744 of the Title 16 California Code of Regulations as provided in the meeting materials.

Mr. Law commented that this should be a wake-up call to all pharmacists; they should not have needed to pass legislation to make pharmacists provide proper consultations.

Michael Santiago, DCA legal counsel, commented that some of the proposed language is lifted directly from Business and Profession Code 4074. He warned that the Office of Administrative Law may have a problem with this because the language is duplicative. Ms. Sodergren commented that the committee recognized that the language may be duplicative; however they felt it was important that the public had all of the information in one place.

Mr. Santiago expressed concern that not all of the drugs that would require a warning are listed in the language. Dr. Gutierrez responded that a list of drugs that could cause drowsiness is so extensive that it could not be listed in its entirety. Mr. Santiago argued that the pharmacists need to know for which drugs the board expects them to provide warnings.

Ms. Veale asked if classes of drugs could be listed instead of specific drugs. Mr. Santiago agreed that this was a possibility as long as the list of drug classes was comprehensive. He stated that the phrase “examples of drug classes” would need to be removed as it implies that there are more drug classes not listed in the regulation.

Chair Gutierrez commented that the committee had a lengthy discussion on what drugs or drug classes should be listed; however, they concluded that the language should be broad so that it allows a pharmacist to use their professional judgment. Mr. Santiago commented the board must provide a list of drugs that *always* require a warning; a pharmacist has the ability to use their professional judgment to provide warnings on drugs above and beyond what the board requires.

Robert Stine commented that the way the classes of drugs are listed in the draft regulation language seems to be duplicative and perhaps could be simplified.

The board chose not to vote on the committee’s recommendation (motion) and sent the language back to the committee for further discussion and review.

# Attachment 5

Chair Gutierrez reported that at the March 2014 Enforcement and Compounding Committee, she led a discussion of losses of controlled substances reported to the board as required by California Pharmacy law. Subsequently, board's staff compiled some statistics regarding drug losses reported to the board over the last few years.

The following tables display the losses of controlled substances reported to the board.

California State Board of Pharmacy Data Captured from Controlled Substance Drug Loss Reports						
Year	2009	2010	2011	2012	2013	2014 (6 mo.)
Number of Reports	614	749	536	639	1224	678
<b>Loss Type</b>	<b>Total Count Reported</b>					
Armed Robbery		70,786		35,773	106,787	80,464
Customer Theft		9,550		4,598	5,684	13,175
Employee Pilferage		252,225		452,877	372,926	125,305
Lost in Transit		13,239		412,168	*1,657,875	22,310
Night Break In		505,016		80,971	689,925	154,156
Other		121,635		532,441	518,432	94,267
<b>Totals</b>		<b>972,450</b>		<b>1,518,828</b>	<b>3,351,628</b>	<b>489,677</b>
* In transit losses						

### DEA 106 Reports by License Category

<b>Category</b>	<b>2011</b>	<b>2012</b>	<b>2013</b>	<b>2014</b>
Pharmacy	376	460	943	551
Hospital	115	104	230	97
Wholesaler	33	35	58	35
Out of State				
Distributor	1	6	8	4
Correctional Facility	10	5	2	5
Clinic	1	2	0	0
Non Resident				
Pharmacy	0	1	0	0
Drug Room	0	0	1	0
Other	0	0	2	1
<b>Total</b>	<b>536</b>	<b>613</b>	<b>1244</b>	<b>693</b>

Chair Gutierrez highlighted that in 2013, 3.06 million dosage units of controlled substances were reported to the board as lost. This includes 1.7 million units reported by a major manufacturer who had a truck stolen.

Chair Gutierrez reported that at the March 2014 Enforcement and Compounding Committee Meeting, it was noted that these numbers were 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.

Chair Gutierrez reported that at the April 2014 board meeting when this topic was discussed, the board asked the Enforcement Committee to draft regulation language to require monthly counts of a pharmacy's fastest selling controlled substances as a form of inventory control. When the Enforcement Committee met in September 2014, the committee heard comments from the public wherein it was noted that requiring hospital pharmacies and clinics to perform monthly counts would be too difficult. The committee suggested that the regulation focus on community pharmacies and add hospitals and clinics to the regulation at a later date.

Mr. Law agreed that drug losses is a huge issue however, he felt that monthly inventory may cause undue hardships for small community pharmacies. He suggested that only pharmacies

with high volume narcotic sales be required to conduct monthly inventories. Mr. Brooks agreed with Mr. Law.

Ms. Veale and Dr. Gutierrez commented that when the inventories are conducted it should be done on a strength basis. For example you wouldn't just count morphine as one item; you would break it out and count it by the different strengths.

Ms. Veale commented that pharmacies already have to count each individual Schedule II pill. It was clarified that this was only required once every two years.

Ms. Veale noted that the board has seen cases where an employee was purposefully diverting a "non-top ten" drug in order to evade detection. She noted that she is worried that the employees will know how to find a loop-hole in the inventory.

The board discussed if conducting an inventory of the dispensed controlled substances would be effective, as often the drugs are diverted when they are delivered (and in some cases prior to their delivery). The board concluded that it would be more effective for the inventory to be conducted on the controlled substances purchased each month rather than dispensed each month.

Chair Gutierrez noted that when she reviewed the DEA-106 reports most of them only provided estimates of the losses because the pharmacy had no idea how long the diversion had been occurring. Mr. Room commented that often the numbers reported are only what the employee will admit they diverted.

Mr. Law commented that employees are more likely to divert from a pharmacy with a high volume of narcotics passing through it each day. He again recommended that the board create a threshold for the number of drugs purchased so that small pharmacies would not have to conduct inventories. Chair Gutierrez responded that if the board creates a threshold then pharmacies will simply place orders under the threshold to avoid inventories.

Mr. Brooks asked if the pharmacist in charge places the orders. Ms. Herold responded that often it is staff that places orders.

Dr. Wong commented that he felt that the board should change the inventory requirement from the top ten controlled substances to all schedule II drugs.

Anne Chung, from Rite Aid pharmacy, stated that Rite Aid conducts an annual count of all controlled substances and a monthly count of schedule II drugs. She also reported that Rite Aid uses a perpetual inventory system that is reconciled during the monthly inventory. Ms. Veale asked if schedule III, IV and V are counted in the same way. Ms. Chung responded that they were not.

Brian Warren, from CPHA, recommended that this topic be sent back to the committee for further discussion. He recommended that the committee look at what the top ten diverted drugs are, so that the board requires the appropriate drugs be counted.

John Cronin, pharmacy attorney, asked the purpose of the proposed regulation. Chair Gutierrez responded that it is an attempt to get a handle on the long, ongoing diversion that is happening without the pharmacy being aware of it. Mr. Cronin stated that the use of a perpetual inventory system would accomplish this goal without requiring such a detailed regulation.

Mr. Cronin asked what type of loss the category “other” covered in the statistics. Ms. Herold responded that the category “other” is used when a pharmacy reports a loss but has no idea how the loss occurred.

Mr. Brooks commented that the board needs to find a balance between creating a barrier for diversion without creating an undue burden for pharmacies.

Ms. Veale asked if there is already a requirement for a pharmacist to be in control of drug security.

Dr. Ratcliff, supervising inspector, commented that 1714(b) requires the business to have security in place to discourage theft and 1714(d) requires the individual pharmacist to be responsible for drug security.

Ms. Veale asked if there is a requirement for pharmacies to conduct monthly inventories. Dr. Ratcliff responded that at this time there is no requirement. Ms. Veale stated that the board should create a regulation that requires a monthly inventory and leave it up to the individual pharmacy as to how they will accomplish this.

Dr. Law asked if there is a requirement for a pharmacy to have a perpetual inventory system in place for schedule II drugs. Dr. Ratcliff stated that while it is a good practice, currently there is no state or federal requirement for a perpetual inventory system.

Karen Unbee, pharmacist at Cedar Sinai Hospital, reported that their hospital requires a monthly inventory of all schedule II-IV drugs.

Mr. Brooks asked how the board would handle a pharmacy that created written policies, but they were not adequate and diversion still occurred. Mr. Room stated that the board has found that rather than creating policies, pharmacies have simply purchases them from an online source. The board has also seen cases in which the pharmacy had written policies but they were not implemented by staff. Mr. Room stated that simply requiring policies and procedures would not be enough without specifying both what has to be in the policies, and how you have to comply with the policies.

Mr. Brooks commented that while he does not believe in overregulation, the statistics clearly indicate the pharmacies are not taking steps to prevent diversion, which should be a priority for all pharmacies.

Rebecca Cupp, from Ralph's, commented that they have been doing perpetual inventory on Hydrocodone for seven years because their statistics showed that it was one of their top diverted drugs. Ms. Cupp offered to share with board members Ralph's diversion policies and procedures. President Weisser asked if Ralph's has seen improvement since the implementation of their policies. Ms. Cupp responded that they have seen dramatic improvement.

Dianne McKellan, from PIH Hospital in Whittier, warned that pharmacies need to be sure that if they use a perpetual inventory system that they go back far enough to catch medications that have not been dispensed in a while.

Dr. Gutierrez recommended that this topic be sent back to the committee for further discussion, she also asked that chain pharmacies come to the committee meeting to discuss their ant-diversion efforts. Mr. Brooks asked that the committee also consider how the regulation will affect community pharmacies. Mr. Room recommended that the board vote down the committee recommendation (motion) so that the topic could be sent back to the committee.

**Committee Recommendation (motion):** Adopt the proposed language to add as section 1715.65 to 16 California Code of Regulations, for community pharmacies only, as follows:

**1715.65 Monthly Inventory Counts of Fastest Moving Controlled Substances**

- (a) Every June 30<sup>th</sup>, each pharmacy 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 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 shall sign each monthly inventory performed under this section indicating he or she has reviewed the inventory taken.

The pharmacist-in-charge shall perform a quality assurance review of the monthly and annual inventories and take appropriate actions to maintain secure methods to prevent losses of all dangerous drugs.

Support: 0    Oppose: 10    Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks		X		
Butler		X		
Castellblanch				X
Gutierrez		X		
Hackworth				X
Law		X		
Lippe		X		
Murphy		X		
Schaad		X		
Veale		X		
Weisser		X		
Wong		X		
<b>Total</b>	<b>0</b>	<b>10</b>	<b>0</b>	<b>2</b>

# Attachment 6



**California State Board of Pharmacy**

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STATE BUSINESS, CONSUMER SERVICES, AND HOUSING AGENCY  
DEPARTMENT OF CONSUMER AFFAIRS  
EDMUND G. BROWN, JR., GOVERNOR

November 14, 2014

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

RE: COMMENTS OF THE CALIFORNIA STATE BOARD OF PHARMACY  
**Docket No. FDA-2014-D-1411**

*The Effect of Section 585 of the FD&C Act on Drug Product Tracing and Wholesale Drug Distributor and Third-Party Logistics Provider Licensing Standards and Requirements: Questions and Answers – Guidance for Industry*

To Whom It May Concern:

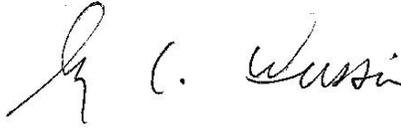
I write on behalf of the California State Board of Pharmacy (Board). We are pleased to have this opportunity to submit comments on Docket No. FDA-2014-D-1411, titled “The Effect of Section 585 of the FD&C Act on Drug Product Tracing and Wholesale Drug Distributor and Third-Party Logistics Provider Licensing Standards and Requirements: Questions and Answers – Guidance for Industry.” We will be brief. We strongly support this Draft Guidance. We believe it accurately conveys the effects of section 585 (Uniform National Policy) of the Federal Food, Drug and Cosmetic Act (FD&C Act) added by Title II (the Drug Supply Chain Security Act, or DSCSA) of the Drug Quality and Security Act (DQSA), enacted November 27, 2013. We also support this effort to clarify and settle the impacts of section 585 on federal and state laws.

We concur with your conclusions regarding the preemptive effect of the DSCSA on state prescription product tracing requirements, and the more limited preemptive effect of the DSCSA provisions regarding uniform national standards for wholesale drug distributors and third party logistics providers. California has already acted in conformity with your proposed interpretation. For instance, California has acknowledged the preemption of its state pedigree (track and trace) laws, and has effected their repeal. And California has set up a separate licensing category for third party logistics providers that distinguishes them from wholesale distributors yet holds them to similar standards of registration and safety to protect the drug supply. We look forward to the development of the minimum licensure standards and requirements for wholesale distributors and third party logistics providers that will be forthcoming under sections 583 and 584, and we pledge our commitment that California’s licensure of these entities will never fall below those minimum standards to be established by the forthcoming regulations. In fact, we expect that we will continue to be an industry leader in how these entities are regulated.

We also concur with your conclusion that section 503(e)(1)(A) (as amended) requires that a wholesale distributor “be licensed by the State from which the drug is distributed or else by the Secretary of Health and Human Services if the distributing wholesale drug distributor’s State chooses not to have a licensing program” and, “[i]n addition, . . . by the State into which the drug is distributed (if required by that State).” We presume the effect of identical language in section 584, as to third party logistics providers, is the same (licensure may be required by both states). It may be helpful to also have that specified in the final version of the Guidance document.

Thank you for your attention to these matters, and for your willingness to hear our input. We look forward to continuing to work together to secure the nation’s drug supply. Please feel free to contact the Board at any time if we can be of assistance. The best route for contact is via Executive Officer Virginia Herold, at (916) 574-7911, or [Virginia.Herold@dca.ca.gov](mailto:Virginia.Herold@dca.ca.gov).

Sincerely,

A handwritten signature in black ink, appearing to read "S. C. Weiss". The signature is fluid and cursive, with the first letter of the first name being a large, stylized 'S'.

STANLEY C. WEISSER, R.Ph.  
President, California State Board of Pharmacy

# FDA outlines expectations for human drug compounders, including registered outsourcing facilities

## For Immediate Release

July 1, 2014

### Release

Today, the U.S. Food and Drug Administration issued several policy documents regarding compounded drug products for human use, as part of the agency's continuing effort to implement the compounding provisions of the [Drug Quality and Security Act](#) (DQSA), enacted in November 2013. The policy documents consist of a draft interim guidance, a proposed rule, a final guidance, and two revised requests for nominations for the bulk drug substances lists.

"Providing clarity to the compounding industry on the agency's expectations for these unapproved drug products is a priority for the agency," said Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research. "These actions are essential next steps in providing the compounding industry with the appropriate tools to comply with the law and advancing the FDA's efforts to continue protecting patients." The documents available today are:

- [Draft interim guidance](#) that describes the FDA's expectations regarding compliance with current good manufacturing practice (CGMP) requirements for facilities that compound human drugs and register with the FDA as outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The guidance focuses on CGMP requirements related to sterility assurance of sterile drug products and the general safety of compounded drug products.
  
- A [proposed rule](#) that would revise the FDA's current list of drug products that may not be compounded because the drug products have been withdrawn or removed from the market because they were found to be unsafe or not effective. The proposed rule would modify the description of one drug product on the list and add 25 drug products to the list. The list set forth in the proposed rule would apply to both compounders and outsourcing facilities seeking to compound drugs for human use under sections 503A and 503B, respectively.
  
- [Final guidance](#) for individuals or pharmacies that intend to compound drugs under section 503A, now that the FD&C Act has been amended by the DQSA. The guidance generally restates the provisions of section 503A, describes the FDA's

interim policies with respect to specific provisions that require implementing regulations or other actions, and contains a non-exhaustive list of potential enforcement actions against individuals or pharmacies that compound human drug products in violation of the FD&C Act.

□ Two Federal Register Notices stating the FDA is reopening the nomination process for two lists of bulk drug substances (active pharmaceutical ingredients) that may be used to compound drug products. [One list is for drug products compounded in accordance with section 503A](#), and [the other list is for drug products compounded in accordance with section 503B](#) of the FD&C Act. In response to a December 2013 request for nominations, the agency received nominations that were not for bulk drug substances used in compounding, and that did not provide sufficient information to justify inclusion of the substances on the lists.

The FDA is providing more detail on what information is needed to evaluate the nominations for placement on the lists. The draft interim guidance and proposed rule are available for public comment for 60 days, and the dockets are open for the public to nominate bulk drug substances for compounding under section 503A or 503B for 90 days.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

Compliance), those steps must be done to comply with this AD; any steps that are not labeled as RC are recommended. Those steps that are not labeled as RC may be deviated from, done as part of other actions, or done using accepted methods different from those identified in the specified service information without obtaining approval of an AMOC, provided the steps labeled as RC can be done and the airplane can be put back in a serviceable condition. Any substitutions or changes to steps labeled as RC require approval of an AMOC.

**(k) Related Information**

(1) For more information about this AD, contact Marie Hogestad, Aerospace Engineer, Systems and Equipment Branch, ANM-130S, Seattle Aircraft Certification Office (ACO), FAA, 1601 Lind Avenue SW., Renton, WA 98057-3356; phone: 425-917-6418; fax: 425-917-6590; email: [marie.hogestad@faa.gov](mailto:marie.hogestad@faa.gov).

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P. O. Box 3707, MC 2H-65, Seattle, WA 98124-2207; telephone 206-544-5000, extension 1; fax 206-766-5680; Internet <https://www.myboeingfleet.com>. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

Issued in Renton, Washington, on June 24, 2014.

**Jeffrey E. Duven,**  
Manager, Transport Airplane Directorate,  
Aircraft Certification Service.

[FR Doc. 2014-15505 Filed 7-1-14; 8:45 am]

BILLING CODE 4910-13-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 216**

[Docket No. FDA-1999-N-0194 (Formerly 99N-4490)]

RIN 0910-AH10

**Additions and Modifications to the List of Drug Products That Have Been Withdrawn or Removed From the Market for Reasons of Safety or Effectiveness**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule; withdrawal of previous proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is proposing to amend its regulations to revise the list of drug products that may not be compounded under the exemptions provided by the Federal Food, Drug, and Cosmetic Act (the

FD&C Act) because the drug products have been withdrawn or removed from the market after the drug products or components of such drug products were found to be unsafe or not effective. Specifically, the proposed rule would add 25 drug products to this list of drug products and modify the description of one drug product on this list to add an exception. These revisions are necessary because new information has come to the Agency's attention since March 8, 1999, when FDA published the original list as a final rule. FDA is also withdrawing the previous proposed rule regarding additions to this list (see the **Federal Register** of January 4, 2000).

**DATES:** Submit either electronic or written comments on the proposed rule by September 2, 2014. The January 4, 2000, proposed rule (65 FR 256) is withdrawn as of July 2, 2014.

**ADDRESSES:** You may submit comments, identified by Agency name and Docket No. FDA-1999-N-0194 and/or Regulatory Information Number (RIN) number 0910-AH10, by any of the following methods:

*Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

*Written Submissions*

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**Instructions:** All submissions received must include the Agency name, Docket No. FDA-1999-N-0194, and RIN 0910-AH10 for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "Request for Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

**Docket:** For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Edisa Gozun, Center for Drug Evaluation

and Research (HFD-310), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5199, Silver Spring, MD 20993-0002, 301-796-3110.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Section 503A of the FD&C Act (21 U.S.C. 353a) describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist or licensed physician to be exempt from the following three sections of the FD&C Act: (1) Section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice); (2) section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use); and (3) section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)).

One of the conditions that must be satisfied to qualify for the exemptions under section 503A of the FD&C Act is that the licensed pharmacist or licensed physician does not compound a drug product that appears on a list published by the Secretary in the **Federal Register** of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective (see section 503A(b)(1)(C) of the FD&C Act).

*A. Court Decisions Regarding the Pharmacy Compounding Provisions of the FD&C Act*

As originally enacted, section 503A of the FD&C Act included prohibitions on the advertising and solicitation of prescriptions for any particular compounded drug, class of drug, or type of drug. Seven compounding pharmacies challenged the advertising and solicitation provisions of section 503A of the FD&C Act as an impermissible regulation of commercial speech. In February 2001, the U.S. Court of Appeals for the Ninth Circuit held that the prohibition on advertising and promotion in section 503A(c) and the provision of section 503A(a) of the FD&C Act that requires that the prescription be "unsolicited," were unconstitutional restrictions on commercial speech. (See *Western States Med. Ctr. v. Shalala*, 238 F.3d 1090 (9th Cir. 2001).) Furthermore, the Ninth Circuit held that the advertising and solicitation provisions could not be severed from the rest of section 503A and, as a result, found section 503A of the FD&C Act to be invalid in its

entirety. In April 2002, the U.S. Supreme Court affirmed the Ninth Circuit's decision that the advertising and solicitation provisions were unconstitutional; it did not, however, rule on the severability of section 503A of the FD&C Act. (See *Thompson v. Western States Med. Ctr.*, 535 U.S. 357 (2002).)

In light of these decisions, FDA issued a Compliance Policy Guide in 2002 to provide guidance on FDA's approach concerning the regulation of pharmacy compounding. (See the **Federal Register** of June 7, 2002 (67 FR 39409).)

In September 2004, 10 pharmacies brought suit in the U.S. District Court for the Western District of Texas challenging FDA's authority to regulate compounded drugs. In August 2006, the District Court held, in part, that compounded human drugs are implicitly exempt from the "new drug" definition in section 201(p) of the FD&C Act and, as a result, are not subject to the FD&C Act's new drug approval requirements. (See *Medical Ctr. Pharm. v. Gonzales*, 451 F. Supp. 2d 854 (W.D. Tex. 2006).) The District Court also held that the advertising and solicitation provisions in section 503A of the FD&C Act that the Supreme Court had found to be unconstitutional were severable from the rest of that section.

The Federal Government appealed the decision of the U.S. District Court for the Western District of Texas. In July 2008, the U.S. Court of Appeals for the Fifth Circuit reversed the District Court's finding of an implicit exemption for compounded drugs from the new drug approval requirements in the FD&C Act, holding, instead, that compounded drugs fall within the definition of "new drug" in the FD&C Act and, therefore, are subject to regulation by FDA. (See *Medical Ctr. Pharm. v. Mukasey*, 536 F.3d 383 (5th Cir. 2008).) The Fifth Circuit also held that the advertising and solicitation provisions are severable from the rest of section 503A of the FD&C Act, and as a result, the other provisions of section 503A remain in effect.

The Fifth Circuit's severability ruling conflicted with the earlier Ninth Circuit decision, which held that the advertising and solicitation provisions cannot be severed from section 503A of the FD&C Act, and rendered all of section 503A void. Following a fungal meningitis outbreak in September 2012, FDA sought legislation to, among other things, resolve the split in the Circuits to clarify that section 503A of the FD&C Act was valid nationwide.

### B. 2013 Drug Quality and Security Act

On November 27, 2013, President Obama signed the Drug Quality and Security Act (Pub. L. 113-54) (DQSA) that contains important provisions relating to the oversight of compounding of human drugs. This new law removes from section 503A of the FD&C Act the provisions that had been held unconstitutional by the U.S. Supreme Court in 2002. By removing these provisions, the new law clarifies that section 503A of the FD&C Act applies nationwide. In addition, the DQSA adds a new section 503B of the FD&C Act (21 U.S.C. 353b) that creates a new category of "outsourcing facilities." Outsourcing facilities, as defined in section 503B of the FD&C Act, are facilities that meet certain conditions described in section 503B, including registering with FDA as an outsourcing facility. If these conditions are satisfied, a drug compounded for human use by or under the direct supervision of a licensed pharmacist in an outsourcing facility is exempt from three sections of the FD&C Act: (1) Section 502(f)(1), (2) section 505, and (3) section 582 (21 U.S.C. 360eee); but not section 501(a)(2)(B). One of the conditions in section 503B of the FD&C Act that must be satisfied to qualify for the exemptions is that the drug does not appear on a list published by the Secretary 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 (see section 503B(a)(4)).

Given that nearly identical criteria apply for a drug to be included on the list referred to in section 503A(b)(1)(C) and the list referred to in section 503B(a)(4) of the FD&C Act, FDA is proposing to revise and update the list at § 216.24 (21 CFR 216.24) for purposes of both sections 503A and 503B. Accordingly, the proposed rule that published in the **Federal Register** of January 4, 2000, which would have amended the list in § 216.24, is withdrawn (see **DATES**).

### C. Regulatory History of the List

#### 1. Original List

In the **Federal Register** of October 8, 1998 (63 FR 54082), FDA proposed a rule to establish the original list of drug products that have been withdrawn or removed from the market because the drug products or the components of such drug products were found to be unsafe or not effective (1998 proposed rule). The 1998 proposed rule was presented to the Pharmacy Compounding Advisory Committee (Advisory Committee) at a meeting held

on October 14 and 15, 1998 (63 FR 47301, September 4, 1998). The Advisory Committee did not have any adverse comments on the 1998 proposed rule and did not suggest any changes. A transcript of the October 1998 Advisory Committee meeting may be found at the Division of Dockets Management (see **ADDRESSES**) and at <http://www.fda.gov/Drugs/Guidance/ComplianceRegulatoryInformation/PharmacyCompounding/ucm290713.htm>.

In the **Federal Register** of March 8, 1999 (64 FR 10944), FDA published a final rule that codified the original list in § 216.24 (1999 final rule).

#### 2. 2000 Proposed Rule and Additional Drug Products for the List in § 216.24

In the **Federal Register** of January 4, 2000 (65 FR 256), FDA proposed a rule to amend § 216.24 (2000 proposed rule). Specifically, FDA proposed to add all drug products containing aminopyrine and all drug products containing astemizole to the original list of drug products withdrawn or removed from the market because they have been found to be unsafe or not effective. After the 2000 proposed rule published, three additional drug products (cisapride, grepafloxacin, and troglitazone) were identified as candidates for addition to the list. These five drug products were presented to the Advisory Committee at a meeting held on July 13 and 14, 2000 (65 FR 40104, June 29, 2000). The Advisory Committee voted to include aminopyrine, astemizole, cisapride, grepafloxacin, and troglitazone to the list of drug products that have been withdrawn or removed from the market because they were found to be unsafe or not effective. A transcript of the July 2000 Advisory Committee meeting may be found at the Division of Dockets Management (see **ADDRESSES**) and at <http://www.fda.gov/Drugs/Guidance/ComplianceRegulatoryInformation/PharmacyCompounding/ucm290713.htm>.

#### 3. New Proposed Rule To Amend the List in § 216.24

This proposed rule would add to § 216.24 the five drug products identified in section I.C.2 and additional drug products that have been withdrawn or removed from the market since the publication of the 1999 final rule because the drug products or components of such drug products were found to be unsafe or not effective. FDA also proposes to modify the description of one drug product contained in the original list to add an exception that would allow the product to be compounded under certain

circumstances. These revisions are necessary to ensure the list of drugs in § 216.24 reflects new information that has come to the Agency's attention since FDA published the original list in the 1999 final rule. As with the original list, the primary focus of this proposed rule is on drug products that have been withdrawn or removed from the market because they were found to be unsafe. FDA may propose at a later date to add other drug products to the list that have been withdrawn or removed from the market because they were found to be not effective, or to update the list as new information becomes available to the Agency regarding products that were removed from the market because they were found to be unsafe.

This proposed rule would replace the 2000 proposed rule. The list set forth in this proposed rule would apply to compounders and outsourcing facilities seeking to qualify for the exemptions under either section 503A or section 503B of the FD&C Act. Accordingly, the 2000 proposed rule to amend § 216.24 is withdrawn. In preparing this proposed rule, FDA has taken into consideration the discussions held by the July 2000 Advisory Committee and that Advisory Committee's vote to include aminopyrine, astemizole, cisapride, grepafloxacin, and troglitazone on the list of drug products that have been withdrawn or removed from the market because they were found to be unsafe or not effective.

Additional nominations for this list can be submitted to FDA for consideration in comments to this proposed rule.

## II. Procedural Issue for Comment

Section 503A of the FD&C Act describes the list in section 503A(b)(1)(C) as a list published by the Secretary in the **Federal Register** of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective. This suggests that FDA can develop the 503A(b)(1)(C) list by publishing it in the **Federal Register** and does not need to go through notice and comment rulemaking. Section 503A(c)(1) of the FD&C Act, however, states that the Secretary shall issue regulations to implement section 503A, and that before issuing regulations to implement section 503A(b)(1)(C) pertaining to the withdrawn or removed rule, among other sections, the Secretary shall convene and consult an advisory committee on compounding unless the Secretary determines that the issuance of such regulations before consultation

is necessary to protect the public health. In 1998 and 1999, FDA used rulemaking to develop the original list of drug products that had been withdrawn or removed from the market, and consulted the Pharmacy Compounding Advisory Committee about the list. In 2000, FDA also proposed to amend the list through rulemaking after consultation with the Advisory Committee.

Meanwhile, new section 503B of the FD&C Act describes the list in section 503B(a)(4) as a list published by the Secretary 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. Section 503B(c) of the FD&C Act requires that the Secretary implement through regulations, following consultation with an advisory committee, a list of drugs or categories of drugs that present demonstrable difficulties for compounding that are reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug or category of drugs and therefore may not be compounded under section 503B. (See section 503B(a)(6) of the FD&C Act.) Section 503B does not, however, include any similar requirement for rulemaking or consultation with an advisory committee to establish the list of drugs that may not be compounded under section 503B of the FD&C Act because they 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.

As noted, FDA plans to publish a single list of drug products (referred to as "the withdrawn or removed list" or "the list") that cannot be compounded for human use under the exemptions provided by either section 503A or 503B of the FD&C Act because they have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective. FDA invites comments on the appropriate procedure to update the list in the future. The Agency believes that the timely sharing of information about safety concerns relating to compounding drugs for human use without undue delay is essential to the protection of public health. FDA is concerned that consulting with the advisory committee and completing the rulemaking process are likely to contribute to substantial delay in updating the list to reflect current safety information. FDA therefore is seeking an alternative procedure to update the withdrawn or removed list in the future. Although FDA is publishing a proposed rule today to add 25 drugs to the list, FDA is also

soliciting public input through this **Federal Register** notice on alternative procedures for updating the list and requests that this input be submitted to FDA for consideration in comments to this proposed rule. FDA will specify in the final rule the procedure it will use to update the list in the future.

## III. Description of This Proposed Rule

### A. Amendments to Introductory Text

FDA is proposing to add the phrase "or section 503B(a)" to the introductory text of § 216.24 to clarify that drug products included in the list in § 216.24 will not qualify for the exemptions under either section 503A(a) or section 503B(a) of the FD&C Act when compounded.

### B. Amendments To Add Drug Products to the List

FDA is proposing to amend § 216.24 to include the 25 drug products described in the following paragraphs that have been withdrawn or removed from the market since the 1999 final rule was published (March 1999) because such drug products or components of such drug products have been found to be unsafe or not effective.

A drug product that is included in the list codified at § 216.24 is not entitled to the exemptions provided in section 503A(a) of the FD&C Act, and is subject to sections 501(a)(2)(B), 502(f)(1), and 505 of the FD&C Act, in addition to other applicable provisions. In addition, a drug that is included in the list codified at § 216.24 is not entitled to the exemptions provided in section 503B(a) of the FD&C Act, and is subject to sections 502(f)(1) and 505 of the FD&C Act, in addition to other applicable provisions.

The listed drugs are ineligible for the exemptions set forth in sections 503A and 503B of the FD&C Act because they have been withdrawn or removed from the market because they were found to be unsafe or not effective. Most drugs on the list may not be compounded in any form. There are, however, two categories of exceptions. In the first category, a particular formulation, indication, dosage form, or route of administration of a drug is explicitly excluded from an entry on the list because an approved drug containing the same active ingredient(s) has not been withdrawn or removed from the market. For such drugs, the formulation, indication, dosage form, or route of administration expressly excluded from the list may be eligible for the exemptions provided in sections 503A and 503B of the FD&C Act. In the second category, some drugs are listed only with regard to certain

formulations, concentrations, indications, routes of administration, or dosage forms because they have been found to be unsafe or not effective in those particular formulations, concentrations, indications, routes of administration, or dosage forms. For drugs that are listed with these types of limitations, any compounding of the drug will be closely scrutinized to ensure that the compounding of the drug does not create a product that is unsafe or not effective. If it appears to do so, FDA may determine that the drug is not entitled to the exemptions provided in sections 503A and 503B of the FD&C Act. Those compounding these particular drugs should take note of the reasons FDA has cited for including a drug on this list, and carefully consider these reasons when considering whether or not to compound a drug that is so listed.

The following drug products are arranged alphabetically by the established names of the active ingredients contained in the drug products and are proposed for inclusion in § 216.24. For many of the drugs, the proprietary or trade name of some or all of the drug products that contained the active ingredient are also given in the preamble paragraphs describing the withdrawn or removed drug products. In several cases, the withdrawn or removed drug products are identified according to the established name of the active ingredient, listed as a particular salt or ester of the active moiety. The following list includes a brief summary of the reasons why each drug product is being proposed for inclusion.

**Alatrofloxacin mesylate:** *All drug products containing alatrofloxacin mesylate.* Alatrofloxacin mesylate, formerly marketed as TROVAN Injection, was associated with serious liver injury. On June 9, 1999, FDA announced in a Public Health Advisory that the NDA holder agreed to a limited distribution of TROVAN (alatrofloxacin mesylate) Injection and TROVAN (trovafloxacin mesylate) tablets, 100 milligrams (mg) and 200 mg, to inpatient healthcare facilities (Ref. 1). Subsequently, in the **Federal Register** of June 16, 2006 (71 FR 34940), FDA announced that it was withdrawing the approval of the NDA for TROVAN Injection after the NDA holder notified the Agency that the drug product was no longer marketed and requested that the approval of the NDA be withdrawn.

**Aminopyrine:** *All drug products containing aminopyrine.* Aminopyrine was associated with agranulocytosis, a condition characterized by a decrease in the number of certain blood cells and lesions on the mucous membrane and

skin. Some cases of agranulocytosis were fatal. In 1964, FDA declared drug products containing aminopyrine to be new drugs and invited NDAs for these drug products, but only for use as an antipyretic in serious situations where other, safer drugs could not be used. FDA received no NDAs for drug products containing aminopyrine, and those unapproved drug products were removed from the market (see the **Federal Register** of October 4, 1977 (42 FR 53954), and January 4, 2000 (65 FR 256)). Aminopyrine was presented to the Advisory Committee at the July 2000 meeting, and the Advisory Committee voted to include aminopyrine on the withdrawn or removed list (see the **Federal Register** of June 29, 2000 (65 FR 40104)).

**Astemizole:** *All drug products containing astemizole.* Astemizole, formerly marketed as HISMANAL 10-mg tablets, was associated with life-threatening heart arrhythmias. Patients with liver dysfunction or who were taking other drugs that interfered with the metabolism of astemizole were also found to be at risk of serious cardiac adverse events while taking astemizole. On June 18, 1999, the NDA holder withdrew HISMANAL (astemizole) 10-mg tablets from the market. In the **Federal Register** of August 23, 1999 (64 FR 45973), FDA announced its determination that HISMANAL (astemizole) 10-mg tablets were removed from the market for safety reasons. (See also the **Federal Register** of January 4, 2000 (65 FR 256).) Astemizole was presented to the Advisory Committee at the July 2000 meeting, and the Advisory Committee voted to include astemizole on the withdrawn or removed list (see the **Federal Register** of June 29, 2000 (65 FR 40104)).

**Cerivastatin sodium:** *All drug products containing cerivastatin sodium.* Cerivastatin sodium, formerly marketed as BAYCOL tablets, was associated with increased risk of rhabdomyolysis. Fatal rhabdomyolysis was reported most frequently when used at higher doses, when used in elderly patients, and particularly, with concomitant use of gemfibrozil (LOPID). In an August 8, 2001, "Dear Healthcare Professional Letter," the NDA holder stated that it discontinued the marketing and distribution of all dosage strengths of BAYCOL (Ref. 2).

**Chloramphenicol:** *All oral drug products containing chloramphenicol.* Chloramphenicol was formerly marketed as CHLOROMYCETIN (chloramphenicol) Capsules. In a letter dated October 9, 2007, the application holder requested withdrawal of the

ANDA for CHLOROMYCETIN (chloramphenicol) Capsules, 50 mg, 100 mg, and 250 mg. In the **Federal Register** of February 11, 2009 (74 FR 6896), FDA announced that it was withdrawing approval of the ANDA, effective March 13, 2009. Armenpharm, Ltd., submitted a citizen petition dated February 7, 2011 (Docket No. FDA-2011-P-0081), under § 10.30 (21 CFR 10.30), requesting that the Agency determine whether CHLOROMYCETIN (chloramphenicol) Capsules, 250 mg, were withdrawn from sale for reasons of safety or effectiveness. After considering the citizen petition, FDA determined that the drug product was withdrawn for reasons of safety or effectiveness. With the approval of additional therapies with less severe adverse drug effects, FDA determined that the risks associated with CHLOROMYCETIN (chloramphenicol) Capsules, 250 mg, as then labeled, outweighed the benefits. Furthermore, CHLOROMYCETIN (chloramphenicol) Capsules, 250 mg, may cause a number of adverse reactions, the most serious being bone marrow depression (anemia, thrombocytopenia, and granulocytopenia temporally associated with treatment). Additionally, prior to the removal of the capsule drug product from the market, a boxed warning in the prescribing information for both chloramphenicol sodium succinate injection and chloramphenicol capsules stated that serious hypoplastic anemia, thrombocytopenia, and granulocytopenia are known to occur after administration of chloramphenicol. The boxed warning also described fatal aplastic anemia associated with administration of the drug and aplastic anemia attributed to chloramphenicol that later terminated in leukemia. There is published literature that suggests that the risk of fatal aplastic anemia associated with the oral formulation of chloramphenicol may be higher than the risk associated with the intravenous formulation (see the **Federal Register** of July 13, 2012 (77 FR 41412)). FDA is not aware of any oral drug products containing chloramphenicol currently being marketed.

**Cisapride:** *All drug products containing cisapride.* Cisapride, formerly marketed as PROPULSID tablets and suspension, was associated with serious cardiac arrhythmias and death. In an April 12, 2000 "Dear Healthcare Professional Letter," the NDA holder stated that it would discontinue marketing the drug as of July 14, 2000, and make the product available only through an investigational limited access program

(Ref. 3). Cisapride was presented to the Advisory Committee at the July 2000 meeting, and the Advisory Committee voted to include cisapride on the withdrawn or removed list (see the **Federal Register** of June 29, 2000 (65 FR 40104)).

**Esmolol hydrochloride:** All parenteral drug products containing esmolol HCl that supply 250 mg/milliliter (mL) of concentrated esmolol per 10-mL ampule. Esmolol hydrochloride (HCl), 250 mg/mL per 10-mL ampule, formerly marketed as BREVIBLOC Injection 250 mg/mL per 10-mL ampule, was associated with increased risk of medication errors resulting in serious adverse events, including deaths. The NDA holder sent a letter to FDA on June 28, 2007, notifying the Agency that the company had decided to cease the manufacture and distribution of BREVIBLOC (esmolol HCl) Injection, 250 mg/mL, 10-mL ampule. In a citizen petition dated March 27, 2008 (Docket No. FDA-2008-P-0284), submitted under § 10.30 and in accordance with 21 CFR 314.122 and 314.161, Bedford Laboratories (Bedford) requested that the Agency determine whether BREVIBLOC (esmolol HCl) Injection, 250 mg/mL, 10-mL ampule, was withdrawn from sale for reasons of safety or effectiveness. In the **Federal Register** of May 5, 2010 (75 FR 24710), FDA announced its determination that BREVIBLOC (esmolol HCl) Injection 250 mg/mL, 10-mL ampule, was withdrawn from the market for safety reasons.

**Etretinate:** All drug products containing etretinate. Etretinate was formerly marketed as TEGISON Capsules. In a letter dated September 23, 1999, the NDA holder requested that FDA withdraw the approval of the NDA for TEGISON (etretinate) Capsules because it had discontinued marketing the product. The letter also stated that the drug was not withdrawn for safety reasons. However, in an acknowledgement letter dated December 30, 2002, FDA informed the NDA holder that TEGISON (etretinate) Capsules was removed from the market because it posed a greater risk of birth defects than SORIATANE (acitretin), the product that replaced TEGISON (etretinate) Capsules (see the **Federal Register** of September 10, 2003 (68 FR 53384)). Subsequently, in the **Federal Register** of September 10, 2003, FDA announced it was withdrawing approval of the NDA.

**Gatifloxacin:** All drug products containing gatifloxacin (except ophthalmic solutions). Gatifloxacin was formerly marketed as TEQUIN tablets, injection, and oral suspension. In January 2003, FDA received revised product labeling relating to several

approved supplements for TEQUIN (gatifloxacin). This revised labeling deleted references to TEQUIN injection, 10 mg/mL (200 mg), indicating that this product was no longer being marketed; therefore, the product was moved from the prescription drug product list to the "Discontinued Drug Product List" section of the "Approved Drug Products With Therapeutic Equivalence Evaluations" (the Orange Book). In response to a citizen petition from Apotex Corp. (Docket No. FDA-2005-P-0369),<sup>1</sup> FDA determined, as set forth in the **Federal Register** of February 3, 2006 (71 FR 5858), that TEQUIN injection, 10 mg/mL (200 mg), was not withdrawn for reasons of safety and effectiveness. On May 1, 2006, Public Citizen Research Group submitted a citizen petition (Docket No. FDA-2006-P-0081),<sup>2</sup> under § 10.30, requesting that FDA immediately ban TEQUIN because of the increased risk of dysglycemia (hypoglycemia, low blood sugar, and hyperglycemia, high blood sugar) in humans. In June 2006, the NDA holder announced that it would no longer market TEQUIN. In the **Federal Register** of September 9, 2008 (73 FR 52357), FDA announced its determination that all dosage forms and strengths of TEQUIN (gatifloxacin) were withdrawn from the market for safety reasons. There are currently approved gatifloxacin ophthalmic solutions on the market. Thus, FDA is proposing to include all drug products containing gatifloxacin, except ophthalmic solutions, on the withdrawn or removed list.

**Grepafloxacin:** All drug products containing grepafloxacin. Grepafloxacin, formerly marketed as RAXAR tablets, was associated with cardiac repolarization, manifested as QTc interval prolongation on the electrocardiogram, which could put patients at risk of Torsade de Pointes. The NDA holder sent a letter to FDA on March 5, 2003, requesting that FDA withdraw the approval of the NDA for RAXAR tablets, stating that the product was no longer being marketed. In an acknowledgment letter dated June 20, 2003, FDA stated that RAXAR (grepafloxacin) tablets had been removed from the market because of safety concerns. In a followup letter

<sup>1</sup> This citizen petition was originally assigned docket number 2005P-0023/CP1. The number was changed to FDA-2005-P-0369 as a result of FDA's transition to its new docketing system (<http://www.regulations.gov>) in January 2008.

<sup>2</sup> This citizen petition was originally assigned docket number 2006P-0178. The number was changed to FDA-2006-P-0081 as a result of FDA's transition to its new docketing system (<http://www.regulations.gov>) in January 2008.

dated January 12, 2007, FDA informed the NDA holder that the RAXAR NDA should be withdrawn because of the cardiovascular risks stated previously. The NDA holder sent a letter to FDA on March 20, 2007, agreeing with FDA's determination to initiate the withdrawal of the RAXAR NDA, and FDA subsequently announced that approval of the NDA was withdrawn (see the **Federal Register** of June 14, 2007 (72 FR 32852), and July 9, 2007 (72 FR 37244)). Grepafloxacin was presented to the Advisory Committee at the July 2000 meeting, and the Advisory Committee voted to include grepafloxacin on the withdrawn or removed list (see the **Federal Register** of June 29, 2000 (65 FR 40104)).

**Methoxyflurane:** All drug products containing methoxyflurane.

Methoxyflurane, formerly marketed as PENTHRANE Inhalation Liquid, 99.9 percent, was associated with serious, irreversible, and even fatal nephrotoxicity and hepatotoxicity in humans. In the **Federal Register** of August 16, 2001 (66 FR 43017), FDA announced that it was withdrawing the approval of the NDA after the NDA holder notified the Agency that PENTHRANE (methoxyflurane) Inhalation Liquid was no longer being marketed under the NDA and requested withdrawal of the application. In a citizen petition dated August 25, 2004 (Docket No. FDA-2004-P-0337),<sup>3</sup> submitted under § 10.30, and in accordance with § 314.161, AAC Consulting Group requested that the Agency determine whether PENTHRANE (methoxyflurane) Inhalation Liquid, 99.9 percent, was withdrawn from sale for reasons of safety or effectiveness. In the **Federal Register** of September 6, 2005 (70 FR 53019), FDA announced its determination that PENTHRANE Inhalation Liquid, 99.9 percent, was withdrawn from the market for safety reasons.

**Novobiocin sodium:** All drug products containing novobiocin sodium.

Novobiocin sodium, formerly marketed as ALBAMYCIN capsule, 250 mg, was associated with adverse reactions that included relatively common skin reactions, jaundice, hepatic failure, and blood dyscrasias (neutropenia, anemia, and thrombocytopenia). Literature also revealed concerns about the development of novobiocin-resistant *Staphylococci* during treatment and a potential for drug interactions. On June

<sup>3</sup> This citizen petition was originally assigned docket number 2004P-0379. The number was changed to FDA-2004-P-0337 as a result of FDA's transition to its new docketing system (<http://www.regulations.gov>) in January 2008.

9, 1999, the NDA holder sent an annual report to FDA that indicated that ALBAMYCIN (novobiocin sodium) capsule, 250 mg, was no longer being manufactured, and on June 27, 2007, the NDA holder sent a letter to FDA notifying the Agency that ALBAMYCIN (novobiocin sodium) capsule, 250 mg, had been discontinued. In the **Federal Register** of February 11, 2009 (74 FR 6896), FDA announced that it was withdrawing approval of the NDA in response to the NDA holder's withdrawal request. Crixmore LLC submitted a citizen petition dated July 9, 2008 (Docket No. FDA-2008-P-0431), under § 10.30, requesting that the Agency determine whether ALBAMYCIN (novobiocin sodium) capsule, 250 mg, was withdrawn from sale for reasons of safety or effectiveness. In the **Federal Register** of January 19, 2011 (76 FR 3143), FDA announced its determination that ALBAMYCIN (novobiocin sodium) capsule, 250 mg, was withdrawn from the market for reasons of safety or effectiveness.

*Oxycodone hydrochloride: All extended-release drug products containing oxycodone hydrochloride that have not been determined by FDA to have abuse-deterrent properties.* OXYCONTIN (oxycodone hydrochloride) extended-release tablets were approved in multiple strengths under NDA 20-553 in 1995. The formulation was often abused by manipulating the product to defeat its extended-release mechanism, causing the oxycodone to be released more rapidly. This product was voluntarily withdrawn from sale following introduction of a reformulated version, also marketed as OXYCONTIN (oxycodone hydrochloride) extended-release tablets, which was developed with physicochemical properties intended to make the tablets more difficult to manipulate for purposes of abuse or misuse and was approved in multiple strengths under NDA 22-272 in 2010. Several parties submitted citizen petitions under § 10.30, requesting that the Agency determine whether original OXYCONTIN (oxycodone HCl) extended-release tablets were voluntarily withdrawn from sale for reasons other than safety or effectiveness.<sup>4</sup> In a letter to FDA dated

March 19, 2013, the NDA holder requested withdrawal of approval of NDA 20-553 for original OXYCONTIN. In the **Federal Register** of April 18, 2013 (78 FR 23273), FDA published notice of its determination that original OXYCONTIN, NDA 20-553, was withdrawn from sale for reasons of safety or effectiveness. The notice concluded that "[o]riginal OXYCONTIN . . . poses an increased potential for abuse by certain routes of administration, when compared to reformulated OXYCONTIN. Based on the totality of the data and information available to the Agency at this time, FDA concludes that the benefits of original OXYCONTIN no longer outweigh its risks." In the **Federal Register** of August 7, 2013 (78 FR 48177), FDA announced that it was withdrawing the approval of NDA 20-553. In addition, because the drug approval process is the most appropriate way for FDA to evaluate the effect and labeling of products with potentially abuse-deterrent properties, compounding of opioid products with potentially abuse-deterrent properties will be closely scrutinized.

*Pemoline: All drug products containing pemoline.* Pemoline, formerly marketed as CYLERT tablets and chewable tablets, was associated with liver failure. FDA determined that the overall risk of liver toxicity from CYLERT and generic pemoline outweighed the benefits of the drug. On October 24, 2005, FDA announced in an FDA Alert that the NDA and ANDA holders chose to stop sales and marketing of CYLERT and generic pemoline in May 2005 (Ref. 4).

*Pergolide mesylate: All drug products containing pergolide mesylate.* Pergolide mesylate, formerly marketed as PERMAX tablets, was associated with increased risk of heart valve damage. On March 29, 2007, FDA announced in a Public Health Advisory that the NDA and ANDA holders agreed to withdraw PERMAX and generic pergolide mesylate from the market (Ref. 5).

*Phenylpropanolamine (PPA): All drug products containing PPA.* A study demonstrated that PPA was associated with increased risk of hemorrhagic stroke. On November 6, 2000, FDA announced in a Public Health Advisory that it was taking steps to remove PPA from all drug products and requested that all drug companies discontinue marketing products containing PPA (Ref. 6). In response to FDA's request, companies reformulated their products

withdrawal of the 160 mg strength, Docket No. FDA-2001-P-0473 (formerly Docket No. 2001P-0426) (September 18, 2001).

to exclude PPA. In a notice published in the **Federal Register** on August 14, 2001 (66 FR 42665), FDA offered an opportunity for a hearing on a proposal to issue an order, under section 505(e) of the FD&C Act, withdrawing approval of 13 NDAs and 8 ANDAs for products containing phenylpropanolamine. (Although the August 14, 2001, notice stated that FDA proposed to withdraw approval of 16 NDAs and 8 ANDAs, the notice listed only 13 NDAs and 8 ANDAs.) FDA withdrew approval of ANDA 71-099 for BROMATAPP Extended-Release Tablets in a notice published in the **Federal Register** of February 20, 2002 (67 FR 7702) after the application holder informed FDA that the product was no longer being marketed and requested withdrawal. In the **Federal Register** of February 20, 2014 (79 FR 9744), FDA announced that the NDA and ANDA products containing PPA were no longer shown to be safe for use under the conditions that formed the basis upon which the applications were approved, and thus the Agency was withdrawing approval of 20 products containing PPA.

*Polyethylene glycol (PEG) 3350, sodium chloride, sodium bicarbonate, potassium chloride, and bisacodyl: All drug products containing PEG 3350, sodium chloride, sodium bicarbonate, and potassium chloride for oral solution, and 10 mg or more of bisacodyl delayed-release tablets.* PEG 3350, sodium chloride, sodium bicarbonate, and potassium chloride for oral solution, and four bisacodyl delayed-release tablets, 5 mg (20-mg bisacodyl), formerly marketed as HALFLYTELY AND BISACODYL TABLETS BOWEL PREP KIT (20-mg bisacodyl), was associated with ischemic colitis. The NDA holder informed FDA that it ceased to manufacture and market HALFLYTELY AND BISACODYL TABLETS BOWEL PREP KIT (20-mg bisacodyl) as of September 25, 2007. On July 15, 2008, FDA received a citizen petition (Docket No. FDA-2008-P-0412), submitted under § 10.30, from Foley & Lardner LLP. The petition requested that the Agency determine whether HALFLYTELY AND BISACODYL TABLETS BOWEL PREP KIT (PEG-3350, sodium chloride, sodium bicarbonate, and potassium chloride for oral solution and four bisacodyl delayed release tablets, 5 mg) (HALFLYTELY AND BISACODYL TABLETS BOWEL PREP KIT (20-mg bisacodyl)), manufactured by Baintree Laboratories, Inc. (Baintree), was withdrawn from sale for reasons of safety or effectiveness. In the **Federal Register** of

<sup>4</sup> Varam, Inc., Docket No. FDA-2011-P-0473 (June 9, 2011) (10, 15, 20, 30, 40, 50, 80, and 160 mg); Sheppard, Mullin, Richter & Hampton LLP, Docket No. FDA-2010-P-0540 (October 8, 2010) (10, 15, 20, 30, 40, 60, and 80 mg); Lachman Consultant Services, Inc., Docket No. FDA-2010-P-0526 (September 30, 2010) (10, 15, 20, 30, 40, 60, 80, and 160 mg). Lachman also submitted a petition in 2001 concerning just Purdue Pharma LP's 2001

March 19, 2010 (75 FR 13292), FDA announced its determination that HALFLYTELY AND BISACODYL TABLETS BOWEL PREP KIT (20-mg bisacodyl) was withdrawn from the market for reasons of safety or effectiveness. Similarly, PEG 3350, sodium chloride, sodium bicarbonate, and potassium chloride for oral solution, and two bisacodyl delayed-release tablets, 5 mg (10-mg bisacodyl), formerly marketed as HALFLYTELY AND BISACODYL TABLETS BOWEL PREP KIT (10-mg bisacodyl), was associated with ischemic colitis. The NDA holder informed FDA that it ceased to manufacture and market HALFLYTELY AND BISACODYL TABLETS BOWEL PREP KIT (10-mg bisacodyl) as of July 17, 2010. On September 23, 2010, FDA received a citizen petition (Docket No. FDA-2010-P-0507), submitted under § 10.30, from Perrigo Company (Perrigo) requesting that the Agency determine whether HALFLYTELY AND BISACODYL TABLETS BOWEL PREP KIT (PEG-3350, sodium chloride, sodium bicarbonate, and potassium chloride for oral solution and two bisacodyl delayed release tablets, 5 mg) (HALFLYTELY AND BISACODYL TABLETS BOWEL PREP KIT (10-mg bisacodyl)), manufactured by Braintree, was withdrawn from sale for reasons of safety or effectiveness. In the **Federal Register** of August 17, 2011 (76 FR 51037), FDA announced its determination that HALFLYTELY AND BISACODYL TABLETS BOWEL PREP KIT (10-mg bisacodyl) was withdrawn from the market for reasons of safety or effectiveness.

*Propoxyphene: All drug products containing propoxyphene.* Propoxyphene, formerly marketed under various names such as DARVON and DARVOCET, was associated with serious toxicity to the heart. In a drug safety communication dated November 19, 2010, FDA announced it had requested that companies voluntarily withdraw propoxyphene from the U.S. market and that FDA was recommending against the continued use and prescribing of the pain reliever propoxyphene because new data showed that the drug can cause serious toxicity to the heart, even when used at therapeutic doses. FDA concluded that the safety risks of propoxyphene outweighed its limited benefits for pain relief at recommended doses. The Agency's recommendation was based on all available data including data from a then-new study that evaluated the effects that increasing doses of propoxyphene have on the heart. The

results of the study showed that when propoxyphene was taken at therapeutic doses, there were significant changes to the electrical activity of the heart which can increase the risk for serious abnormal heart rhythms (Ref. 7). In the **Federal Register** of March 10, 2014 (79 FR 13308), FDA announced that due to this safety risk, the Agency was withdrawing approval of 54 propoxyphene products with agreement from holders of the affected applications. On that date, FDA also published a notice of opportunity for a hearing on its proposal to withdraw approval of three additional propoxyphene products for which FDA had not received correspondence from the application holders requesting that FDA withdraw approval (see the **Federal Register** of March 10, 2014 (79 FR 13310)).

*Rapacuronium bromide: All drug products containing rapacuronium bromide.* Rapacuronium bromide, formerly marketed as RAPLON for Injection, was associated with the occurrence of bronchospasm. In a letter dated March 27, 2001, the NDA holder announced that it voluntarily withdrew all batches of RAPLON for Injection from the market (Ref. 8). FDA subsequently announced in the **Federal Register** of March 19, 2012 (77 FR 16039) that it was withdrawing the approval of the NDA.

*Rofecoxib: All drug products containing rofecoxib.* Rofecoxib, formerly marketed as VIOXX, was associated with increased risk of serious cardiovascular events, including heart attack and stroke. On September 30, 2004, FDA announced in a Public Health Advisory that the NDA holder voluntarily withdrew VIOXX from the market (Ref. 9).

*Sibutramine hydrochloride: All drug products containing sibutramine hydrochloride.* Sibutramine hydrochloride (HCl), formerly marketed as MERIDIA oral capsules, was associated with increased risk of heart attack and stroke. In a letter dated October 12, 2010, the NDA holder requested that FDA withdraw the approval of the NDA for MERIDIA. In an acknowledgment letter dated November 1, 2010, FDA stated that the benefits of MERIDIA (sibutramine HCl) oral capsules no longer outweighed the risks in any identifiable population. FDA subsequently announced in the **Federal Register** of December 21, 2010 (75 FR 80061) that it was withdrawing approval of the NDA.

*Tegaserod maleate: All drug products containing tegaserod maleate.* Tegaserod maleate, formerly marketed as ZELNORM, was associated with a

higher chance of heart attack, stroke, and worsening heart chest pain that can become a heart attack, compared to a placebo. On March 30, 2007, FDA announced in a Public Health Advisory that the NDA holder agreed to stop selling ZELNORM (Ref. 10). On July 27, 2007, FDA announced that it was permitting the restricted use of ZELNORM (tegaserod maleate) under a treatment investigational new drug (IND) protocol to treat irritable bowel syndrome with constipation (IBS-C) and chronic idiopathic constipation (CIC) in women younger than 55 who meet specific guidelines (Ref. 11). On April 2, 2008, FDA announced that the sponsor of ZELNORM notified FDA that it would no longer provide ZELNORM (tegaserod maleate) under a treatment IND protocol to treat IBS-C and CIC in women younger than 55; however, the sponsor agreed to continue to supply ZELNORM for use in emergency situations (Ref. 12).

*Troglitazone: All drug products containing troglitazone.* Troglitazone, formerly marketed as REZULIN and PRELAY Tablets, a treatment for type 2 diabetes, was shown to be more toxic to the liver than two other more recently approved drugs that offered a similar benefit. In a letter dated May 1, 2002, the holder of the NDA for REZULIN (troglitazone) Tablets requested that FDA withdraw the NDA for REZULIN (troglitazone) Tablets because it had discontinued marketing the product in March 2000. FDA subsequently announced in the **Federal Register** of January 10, 2003 (68 FR 1469) that it was withdrawing the approval of the NDA for REZULIN. In a letter dated December 31, 2002, the holder of the NDA for PRELAY (troglitazone) Tablets requested that FDA withdraw the approval of the NDA for PRELAY (troglitazone) Tablets because it never marketed the drug and had no plans to market the drug in the future. In the **Federal Register** of August 11, 2003 (68 FR 47581), FDA concluded that PRELAY was voluntarily withdrawn after review of safety data showed that REZULIN was more toxic to the liver than two other more recently approved drugs that offered a similar benefit, and FDA announced that it was withdrawing approval of the NDA for PRELAY. Troglitazone was presented to the Advisory Committee at the July 2000 meeting, and the Advisory Committee voted to include troglitazone on the withdrawn or removed list (see the **Federal Register** of June 29, 2000 (65 FR 40104)).

*Trovafloxacin mesylate: All drug products containing trovafloxacin mesylate.* Trovafloxacin mesylate,

formerly marketed as TROVAN tablets, 100 mg and 200 mg, was associated with serious liver injury. On June 9, 1999, FDA announced in a Public Health Advisory that the NDA holder agreed to a limited distribution of TROVAN (atrofloxacin mesylate) injection and TROVAN (trovafloxacin mesylate) tablets, 100 mg and 200 mg, to inpatient healthcare facilities (Ref. 1). The holders of the NDAs for TROVAN (trovafloxacin mesylate) tablets, 100 mg and 200 mg, and TROVAN/ZITHROMAX COMPLIANCE PAK (trovafloxacin mesylate/azithromycin for oral suspension) notified the Agency that the drug products were no longer marketed and requested that the approval of the NDAs be withdrawn (see the **Federal Register** of September 22, 1999 (64 FR 51325), and June 16, 2006 (71 FR 34940)). FDA announced it was withdrawing approval of the NDAs in the **Federal Register** of September 22, 1999 (64 FR 51325), and June 16, 2006 (71 FR 34940).

*Valdecoxib: All drug products containing valdecoxib.* Valdecoxib, formerly marketed as BEXTRA, was associated with increased risk of serious cardiovascular events and an increased risk of serious skin reactions (e.g., toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema multiforme) compared to other nonsteroidal anti-inflammatory drugs. On April 7, 2005, FDA announced in an FDA Alert that it had concluded that the overall risk versus benefit profile of BEXTRA (valdecoxib) was unfavorable and that the NDA holder had voluntarily removed BEXTRA from the market (Ref. 13). In letters dated May 27, 2011, August 8, 2011, and October 31, 2011, the holder of the NDA for BEXTRA (valdecoxib) Tablets requested that FDA withdraw the NDA for BEXTRA (valdecoxib) Tablets. FDA subsequently announced in the **Federal Register** of August 2, 2013 (78 FR 46984) that it was withdrawing approval of the NDA.

#### C. Amendment To Modify the Description of a Drug Product on the List

FDA is proposing to amend § 216.24 to modify the description of bromfenac sodium on the list.

*Bromfenac sodium: All drug products containing bromfenac sodium (except ophthalmic solutions).* The use of bromfenac sodium, formerly marketed as DURACT (bromfenac sodium) Capsules, was associated with fatal hepatic failure. The manufacturer of DURACT Capsules voluntarily withdrew the drug from the market on June 22, 1998 (see the **Federal Register** of October 8, 1998 (63 FR 54082)). On

March 8, 1999, FDA included all drug products containing bromfenac sodium in the list codified at § 216.24 when FDA published the 1999 final rule (64 FR 10944). Since then, FDA has approved bromfenac ophthalmic solutions, and although one of these, XIBROM (bromfenac ophthalmic solution) 0.09%, was discontinued by the NDA holder in 2011, FDA announced its determination in the **Federal Register** of May 13, 2011 (76 FR 28045) that it was not withdrawn for reasons of safety or effectiveness. (See also Docket No. FDA-2011-P-0128.) Approved bromfenac ophthalmic solutions are currently on the market. Thus, FDA is proposing to include all drug products containing bromfenac sodium on the list with an exception for ophthalmic solutions.

For the convenience of the reader, the regulatory text of § 216.24 provided with this proposed rule includes the drug products proposed for addition and modification discussed in this document and the drug products codified by the 1999 final rule.

#### IV. Environmental Impact

FDA has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

#### V. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612) and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because small businesses are not expected to incur any compliance costs or loss of sales due to this regulation, we propose to certify that this rule will not have a significant

economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is \$141 million, using the most current (2013) Implicit Price Deflator for the Gross Domestic Product. We do not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

This rule proposes to amend § 216.24 concerning pharmacy compounding. Specifically, the proposed rule would add to or modify the list of drug products that may not be compounded under the exemptions provided by sections 503A and 503B of the FD&C Act because the drug products were withdrawn or removed from the market because such drug products or components of such drug products were found to be unsafe or not effective (see section III). The Agency is proposing to add 25 drug products to the list and to modify the description of 1 drug product on the list to add an exception. The Agency is not aware of any routine use of these drug products in pharmacy compounding and, therefore, does not estimate any compliance costs or loss of sales as a result of the prohibition against compounding these drugs for human use. However, the Agency invites the submission of comments and solicits current compounding usage data for these drug products, if they are compounded for human use.

Unless an Agency certifies that a rule will not have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires Agencies to analyze regulatory options to minimize any significant economic impact of a regulation on small entities. Most pharmacies meet the Small Business Administration definition of a small entity, which is defined as having annual sales less than \$25.5 million for this industry. The Agency is not aware of any routine compounding of these drug products and does not estimate any compliance costs or loss of sales to small businesses as a result of the prohibition against compounding these drugs. Therefore, the Agency proposes to certify that this proposed rule will not have a significant

economic impact on a substantial number of small entities.

## VI. Paperwork Reduction Act of 1995

The submission of comments on this proposed rule and the submission of additional nominations for the list that is the subject of this rulemaking would be submissions in response to a **Federal Register** notice, in the form of comments, which are excluded from the definition of "information" under 5 CFR 1320.3(h)(4) of OMB regulations on the Paperwork Reduction Act (i.e., facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the Agency's full consideration of the comment). The proposed rule contains no other collection of information.

## VII. Request for Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in the brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

## VIII. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>. (FDA has verified the Web site addresses in this reference section, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. FDA Public Health Advisory Letter from Murray M. Lumpkin, Deputy Center Director (Review Management), Center for Drug Evaluation and Research, FDA, Re: Food and Drug Administration TROVAN (Trovafloracin/Alatrofloxacin Mesylate) Interim Recommendations (June 9, 1999), <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHealthcare>

[Professionals/PublicHealthAdvisories/ucm053103.htm](http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm053103.htm).

2. Letter from E. Paul Mac Carthy, Vice President, Head U.S. Medical Science, Bayer Corporation, to Healthcare Professional, Re: Market withdrawal of Baycol (cerivastatin) (August 8, 2001), <http://www.fda.gov/downloads/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/UCM173692.pdf>.
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## List of Subjects in 21 CFR Part 216

Drugs, Prescription drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, the proposed rule that published on January 4, 2000 (65 FR 256), is withdrawn and it is proposed that 21 CFR part 216 be amended as follows:

## PART 216—HUMAN DRUG COMPOUNDING

■ 1. The authority citation for 21 CFR part 216 is revised to read as follows:

**Authority:** 21 U.S.C. 351, 352, 353a, 353b, 355, and 371.

■ 2. The heading for part 216 is revised to read as set forth above.

■ 3. Section 216.24 is revised to read as follows:

### § 216.24 Drug products withdrawn or removed from the market for reasons of safety or effectiveness.

The following drug products were withdrawn or removed from the market because such drug products or components of such drug products were found to be unsafe or not effective. The following drug products may not be compounded under the exemptions provided by section 503A(a) or section 503B(a) of the Federal Food, Drug, and Cosmetic Act:

*Adenosine phosphate:* All drug products containing adenosine phosphate.

*Adrenal cortex:* All drug products containing adrenal cortex.

*Alatrofloxacin mesylate:* All drug products containing alatrofloxacin mesylate.

*Aminopyrine:* All drug products containing aminopyrine.

*Astemizole:* All drug products containing astemizole.

*Azaribine:* All drug products containing azaribine.

*Benoxapofen:* All drug products containing benoxapofen.

*Bithionol:* All drug products containing bithionol.

*Bromfenac sodium:* All drug products containing bromfenac sodium (except ophthalmic solutions).

*Butamben:* All parenteral drug products containing butamben.

*Camphorated oil:* All drug products containing camphorated oil.

*Carbetapentane citrate*: All oral gel drug products containing carbetapentane citrate.

*Casein, iodinated*: All drug products containing iodinated casein.

*Cerivastatin sodium*: All drug products containing cerivastatin sodium.

*Chloramphenicol*: All oral drug products containing chloramphenicol.

*Chlorhexidine gluconate*: All tinctures of chlorhexidine gluconate formulated for use as a patient preoperative skin preparation.

*Chlormadinone acetate*: All drug products containing chlormadinone acetate.

*Chloroform*: All drug products containing chloroform.

*Cisapride*: All drug products containing cisapride.

*Cobalt*: All drug products containing cobalt salts (except radioactive forms of cobalt and its salts and cobalamin and its derivatives).

*Dexfenfluramine hydrochloride*: All drug products containing dexfenfluramine hydrochloride.

*Diamthazole dihydrochloride*: All drug products containing diamthazole dihydrochloride.

*Dibromsalan*: All drug products containing dibromsalan.

*Diethylstilbestrol*: All oral and parenteral drug products containing 25 milligrams or more of diethylstilbestrol per unit dose.

*Dihydrostreptomycin sulfate*: All drug products containing dihydrostreptomycin sulfate.

*Dipyrene*: All drug products containing dipyrene.

*Encainide hydrochloride*: All drug products containing encainide hydrochloride.

*Esmolol hydrochloride*: All parenteral dosage form drug products containing esmolol hydrochloride that supply 250 milligrams/milliliter of concentrated esmolol per 10-milliliter ampule.

*Entretinate*: All drug products containing entretinate.

*Fenfluramine hydrochloride*: All drug products containing fenfluramine hydrochloride.

*Flosequinan*: All drug products containing flosequinan.

*Gatifloxacin*: All drug products containing gatifloxacin (except ophthalmic solutions).

*Gelatin*: All intravenous drug products containing gelatin.

*Glycerol, iodinated*: All drug products containing iodinated glycerol.

*Gonadotropin, chorionic*: All drug products containing chorionic gonadotropins of animal origin.

*Grepafloxacin*: All drug products containing grepafloxacin.

*Mepazine*: All drug products containing mepazine hydrochloride or mepazine acetate.

*Metabromsalan*: All drug products containing metabromsalan.

*Methamphetamine hydrochloride*: All parenteral drug products containing methamphetamine hydrochloride.

*Methapyrilene*: All drug products containing methapyrilene.

*Methopholine*: All drug products containing methopholine.

*Methoxyflurane*: All drug products containing methoxyflurane.

*Mibefradil dihydrochloride*: All drug products containing mibefradil dihydrochloride.

*Nitrofurazone*: All drug products containing nitrofurazone (except topical drug products formulated for dermatologic application).

*Nomifensine maleate*: All drug products containing nomifensine maleate.

*Novobiocin sodium*: All drug products containing novobiocin sodium.

*Oxycodone hydrochloride*: All extended-release drug products containing oxycodone hydrochloride that have not been determined by FDA to have abuse-deterrent properties.

*Oxyphenisatin*: All drug products containing oxyphenisatin.

*Oxyphenisatin acetate*: All drug products containing oxyphenisatin acetate.

*Pemoline*: All drug products containing pemoline.

*Pergolide mesylate*: All drug products containing pergolide mesylate.

*Phenacetin*: All drug products containing phenacetin.

*Phenformin hydrochloride*: All drug products containing phenformin hydrochloride.

*Phenylpropanolamine*: All drug products containing phenylpropanolamine.

*Pipamazine*: All drug products containing pipamazine.

*Polyethylene glycol 3350, sodium chloride, sodium bicarbonate, potassium chloride, and bisacodyl*: All drug products containing polyethylene glycol 3350, sodium chloride, sodium bicarbonate, and potassium chloride for oral solution, and 10 milligrams or more of bisacodyl delayed-release tablets.

*Potassium arsenite*: All drug products containing potassium arsenite.

*Potassium chloride*: All solid oral dosage form drug products containing potassium chloride that supply 100 milligrams or more of potassium per dosage unit (except for controlled-release dosage forms and those products formulated for preparation of solution prior to ingestion).

*Povidone*: All intravenous drug products containing povidone.

*Propoxyphene*: All drug products containing propoxyphene.

*Rapacuronium bromide*: All drug products containing rapacuronium bromide.

*Reserpine*: All oral dosage form drug products containing more than 1 milligram of reserpine.

*Rofecoxib*: All drug products containing rofecoxib.

*Sibutramine hydrochloride*: All drug products containing sibutramine hydrochloride.

*Sparteine sulfate*: All drug products containing sparteine sulfate.

*Sulfadimethoxine*: All drug products containing sulfadimethoxine.

*Sulfathiazole*: All drug products containing sulfathiazole (except for those formulated for vaginal use).

*Suprofen*: All drug products containing suprofen (except ophthalmic solutions).

*Sweet spirits of nitre*: All drug products containing sweet spirits of nitre.

*Tegaserod maleate*: All drug products containing tegaserod maleate.

*Temafloxacin hydrochloride*: All drug products containing temafloxacin.

*Terfenadine*: All drug products containing terfenadine.

*3,3',4',5-tetrachlorosalicylanilide*: All drug products containing 3,3',4',5-tetrachlorosalicylanilide.

*Tetracycline*: All liquid oral drug products formulated for pediatric use containing tetracycline in a concentration greater than 25 milligrams/milliliter.

*Ticrynafen*: All drug products containing ticrynafen.

*Tribromsalan*: All drug products containing tribromsalan.

*Trichloroethane*: All aerosol drug products intended for inhalation containing trichloroethane.

*Troglitazone*: All drug products containing troglitazone.

*Trovafloxacin mesylate*: All drug products containing trovafloxacin mesylate.

*Urethane*: All drug products containing urethane.

*Valdecoxib*: All drug products containing valdecoxib.

*Vinyl chloride*: All aerosol drug products containing vinyl chloride.

*Zirconium*: All aerosol drug products containing zirconium.

*Zomepirac sodium*: All drug products containing zomepirac sodium.

Dated: June 25, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-15371 Filed 7-1-14; 8:45 am]

BILLING CODE 4164-01-P

# Attachment 7



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nabp

# Internet Drug Outlet Identification Program

Progress Report for State and  
Federal Regulators: October 2014

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nabp

### **INTERNET DRUG OUTLET IDENTIFICATION PROGRAM PROGRESS REPORT: October 2014**

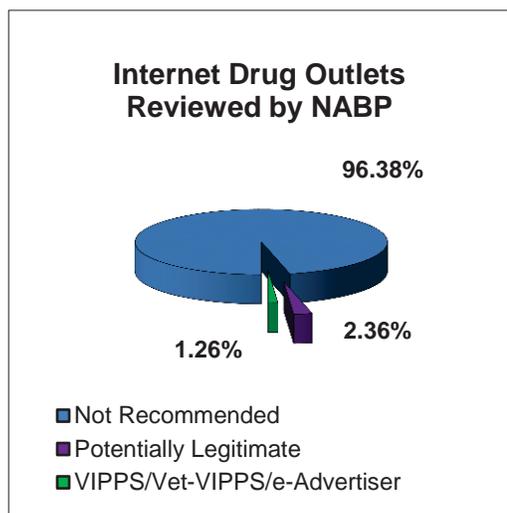
#### **I. INTRODUCTION**

Trick-or-treating for candy is one thing; trick-or-treating for medicine is quite another. Still, many individuals leave their health and safety to chance by taking medicine of unknown content from unknown sources. Those familiar with prescription drug abuse epidemic in the United States have probably heard of “Skittles parties.” In this modern-day Russian roulette, teenagers obtain various medicines from their family’s or friends’ medicine cabinets, or wherever else they can get them easily, and toss them into a bowl, concocting a candy-colorful assortment of tablets and capsules. Partygoers grab and swallow a random handful and see what happens. This is just one example of risky behaviors involving prescription medications worth mentioning during October, dubbed National Medicine Abuse Awareness Month by Community Anti-Drug Coalitions of America. Prescription drug abuse is rampant in the US. Perhaps not-so-coincidentally, so are illegal online drug sellers, many offering dangerous and addictive drugs without a prescription, contributing to the incidence of misuse and overdose. Prescription opioids, such as Vicodin<sup>®</sup>, OxyContin<sup>®</sup>, Percocet<sup>®</sup>, Xanax<sup>®</sup>, and Valium<sup>®</sup> top the list of drugs frequently misused for non-medical purposes. Research conducted by National Association of Boards of Pharmacy<sup>®</sup> (NABP<sup>®</sup>) in October 2014 revealed just how common it is for online drug sellers to offer these products without a prescription. In fact, three out of five search results for controlled substances online produced links to rogue sites selling addictive drugs without a prescription, as described under Current Trends, below. This exercise was completed aside from NABP’s regular ongoing research, the results of which are reported herein from April 2014 through September 2014.

## II. RESULTS

A. Findings of Site Reviews to Date: As of September 30, 2014, NABP has conducted initial reviews and, via a subsequent review, verified its findings on 10,866 Internet drug outlets selling prescription medications. Of these, 10,473 (96.38%) were found to be operating out of compliance with state and federal laws and/or NABP patient safety and pharmacy practice standards. They are also listed as Not Recommended in the “Buying Medicine Online” section under Consumers on the NABP website, as well as on NABP’s AWARE<sub>x</sub>E<sup>®</sup> Prescription Drug Safety website, [www.AWAREX.ORG](http://www.AWAREX.ORG). The 10,473 Internet drug outlets currently listed as Not Recommended on the NABP website are characterized in the table below.<sup>1</sup>

Of the total 10,866 sites reviewed, 256 (2.36%) appear to be potentially legitimate, ie, meet program criteria that could be verified solely by looking at the sites and their domain name registration information. One hundred-thirty seven (1.26%) of the 10,866 reviewed sites have been accredited through NABP’s Verified Internet Pharmacy Practice Sites<sup>®</sup> (VIPPS<sup>®</sup>) or Veterinary-Verified Internet Pharmacy Practice Sites<sup>CM</sup> (Vet-VIPPS<sup>®</sup>) programs, or approved through the NABP e-Advertiser Approval<sup>CM</sup> Program.



The standards against which NABP evaluates Internet drug outlets are provided in the Appendix A of this report.

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<sup>1</sup> These findings include the total number of websites selling prescription drugs to US patients that NABP staff has reviewed and found to be out of compliance with program standards, including those sites that were found to be noncompliant at the time of review, but may since have been deactivated. The numbers reported here do not represent the entire universe of websites selling prescription drugs illegally, but rather, a representative sampling of the online environment over the last six years.

## Not Recommended Sites

Physical Location:	2,450 (23.4%) outside US
	1,535 (14.7%) inside US
	6,483 (61.9%) no location posted on website
Prescription Requirements:	9,225 (88.1%) do not require valid prescription
	6,192 (59.1%) issue prescriptions per online consultations or questionnaires only
Medications:	5,161 (49.3%) offer foreign or non-FDA-approved medications
	1,260 (12.0%) dispense controlled substances
Encryption:	1,689 (16.1%) do not have secure sites, exposing customers to financial fraud and identity theft
Server Location:	4,351 (41.5%) outside US
	5,659 (54.0%) inside US
	461 (4.4%) have unknown server locations
Affiliations:	9,541 (91.1%) appear to have affiliations with rogue networks of Internet drug outlets

*Sites Listed as Not Recommended, in total, as of September 30, 2014*

- B. Recommended Internet Pharmacies: NABP, along with many patient safety advocates, recommends that US patients use Internet pharmacies accredited through the VIPPS and Vet-VIPPS programs when buying medication online. These sites have undergone and successfully completed the thorough NABP accreditation process, which includes a review of all policies and procedures regarding the practice of pharmacy and dispensing of medicine over the Internet, as well as an on-site inspection of facilities used by the site to receive, review, and dispense medicine. Currently, 59 VIPPS and Vet-VIPPS pharmacy sites are listed as Recommended Internet Pharmacies. The 78 sites currently listed as Approved e-Advertisers also have been found to be safe, reliable, and lawful.
- C. Current Trends: To get a clearer picture of just how easy it is to obtain controlled substances online nowadays, NABP conducted a simple keyword search for five commonly abused prescription drugs and noted how many of the top 10 search results led to rogue Internet drug



outlets selling controlled substances that do not require a valid prescription. The five search terms were:

1. Vicodin online
2. OxyContin online
3. Percocet online
4. Xanax online
5. Valium online

Adding “online” to the search queries turned up more targeted results than the drug names alone. The search was conducted using Bing, but these results are not unique to any one search engine. A cross-check on Google and Yahoo! yielded the same or similar results. Only “organic” results (as opposed to paid ads) were counted. The search engines now successfully screen their online advertisers to block those for rogue Internet drug outlets, requiring such sites to be accredited or approved by NABP. The search engines are facing some pressure from states’ attorneys general, among others, to start screening their organic search results as well.

The search process described above found that three out of five search results for these five controlled drugs provided access to rogue Internet drug outlets selling controlled substances without a valid prescription. The top 10 search results for “Vicodin online” included six results linking to rogue sites; “Oxycontin online,” four results linking to rogue sites; “Percocet online,” seven; “Xanax online,” six; and “Valium online,” seven. That is 30 of the 50 search results.

**“No. You don’t need prescription. You can buy any products that you want.”**

*Hydropharma.com*

Some of the search results showed the URL for a legitimate, non-drug-related site,

**Buy Vicodin Online :: OVERNIGHT Delivery!**

[www.active2030store.com/app.html](http://www.active2030store.com/app.html) ▼

Buy **Vicodin online** from an official certified pharmacy, No prescription is required, Exclusive & competitive discount prices, express shipping & discrete packaging.

**VICODIN ONLINE - HUGE SAVINGS! UP TO 80% DISCOUNT!**

[www.reggae5k.com/vicodin.html](http://www.reggae5k.com/vicodin.html) ▼

Buy **VICODIN without prescription!** High quality **VICODIN online!** Order generic **VICODIN VERY CHEAP!** Free shipping worldwide! Guaranteed Delivery or your ...

but when clicked, these links resolved to another website address. For example, a search for “Vicodin online” turns up a result listing the URL for a fitness apparel retail site (*active2030store.com/app.html*), but when the user clicks this link, it resolves to a different



site (*isearch4health.com*) inviting users to choose from a list of various controlled substances. Selecting the Vicodin link on this page resolves to another search results page with links to sites offering Vicodin, several without a prescription, including *hydropharmacy.com* and *rxonlineph*. On its Frequently Asked Questions page, *hydropharma.com* states, “No. You don’t need prescription. You can buy any products that you want.” (This site offers, among other controlled drugs, hydrocodone, or “Generic Vicodin” from India.) Another result of this search lists a fishing hobbyists site (*rippnlipps.com/about*), but the link actually resolves to *isearch4health.com*, like the one above. Other search results are more straight-forward. For instance, the search for “Vicodin online” also turned up a result for *opioids.com/offshorepharmacy*, providing links to sites selling controlled substances, including *endlessmeds.com*. This site advertises, “Buy Vicodin, Buy Hydrocodone, buy codeine, buy soma, buy oxycodone, buy Vicoprofen, buy oxycontin from Mexican Pharmacies.” This site, in turn, redirects to *confidentialshop.com*, which offers Valium without a prescription.

More keyword search results for controlled substances online are provided in Appendix B of this report.

#### IV. DISCUSSION

- A. Controlled Substances Persist Online: While the number of rogue Internet drug outlets selling controlled substances has declined since the Ryan Haight Online Pharmacy Consumer Protection Act became effective in April 2009, there is still no shortage of addictive prescription medications readily available at the click of a mouse, without a valid prescription or medical oversight. The following six-year overview presents a broad picture of the incidence of the rogue sites selling controlled substances discovered through NABP research. The totals shown reflect the number of rogue sites added to the Not Recommended list per year. The dip from 41% of rogue sites selling controlled substances in 2008 to 8% in 2009 reflects the passage of the Ryan Haight Act. Subsequently, while less direct in their advertising of controlled substances than they once were, the illegal sellers have kept at it, as

demonstrated by the 29% of rogue sites selling controlled substances that NABP reviewed in 2013.

Year	Total Rogue Sites Reviewed	Total Rogue Sites Selling Controlled Substances	% of Rogue Sites Selling Controlled Substances
2008	1024	420	41.02
2009	3899	322	8.26
2010	2060	164	7.96
2011	1345	75	5.58
2012	1491	108	7.24
2013	362	106	29.28
<b>Total</b>	<b>10181</b>	<b>1195</b>	<b>11.74</b>

Because NABP research in 2013 targeted rogue sites thought to pose the highest risk to patient health, including those selling controlled substances, these numbers should not be assumed to represent overall trends in the online prescription drug market, but they clearly indicate an ongoing problem. While they may not be the only, or even the most common source of misused prescription drugs, the evidence is highly suggestive that illegal online drug sellers still play a role today. Remembering that Ryan Haight was a real person who, among others, died from an overdose of prescription drugs he bought online without a prescription, the evidence seems sufficient to support further outreach and education.

- B. Prescription Drug Abuse Tapers, but Only Slightly: Regardless of the source, prescription drug abuse remains prevalent, including among teens. The University of Michigan’s December 2013 *Monitoring the Future* study reports that the use of prescription narcotics has increased sharply among 12<sup>th</sup> graders in recent years, as have emergency room admissions and overdose deaths involving their use. The study, funded by the National Institute on Drug Abuse, finds that use peaked in 2004, with 9.5% of 12<sup>th</sup> graders saying they had used the drugs non-medically in the last year. This number has decreased gradually since then, to 7.1% in 2013. While some teens admitted to buying the drugs online, the majority said the drugs were given for free from a friend or relative, bought from a friend or relative, bought from a drug dealer or other stranger, or taken from a friend or relative without asking. Substance Abuse and Mental Health Services Administration’s (SAMHSA) *Results from the 2013 National Survey on Drug Use and Health: Summary of National Findings* reports that in 2013, there were approximately 6.5 million persons aged 12 or older who used prescription drugs – mostly pain relievers – non-medically. SAMHSA states that, of those who used pain relievers non-medically in the past year, only 0.1% bought them online. By contrast, Digital

Citizens Alliance claims that as of 2011, 15% of college undergraduates have, or have a friend who has ordered drugs online without a prescription.

With over half of all fatal overdoses today reportedly tied to prescription pills, trends like “Skittles parties” underscore the need for public education. “Skittle parties are a hotbed of prescription pill abuse,” the Last Resort Recovery Center reports in a May 2014 blog post on its website. “Addiction to prescription pills is simply exploding right now – it’s expanding much faster than addiction to any other class of drugs. And the most commonly abused medications are usually dangerous painkillers, such as Vicodin, OxyContin, and Percocet.” As noted in a blog post on the Decision Point Center website, “[k]ids do not seem to have a clue that playing in this type of game could very well kill them and it can do it very quickly.”

## V. CONCLUSION

As multiple studies have shown, the misuse and abuse of prescription drugs is significant and problematic, and pose a serious risk to patient health. Attorney General Eric Holder, in a September 8, 2014 Department of Justice news release, calls prescription drug abuse “an ‘urgent and growing threat’ to our nation’s public health.” The factors contributing to this problem are many – patient doctor-shopping, physician over-prescribing, and drug diversion among them. Also, as NABP’s simple keyword search for controlled substances online suggests, websites selling controlled substances illegally, without medical oversight, continue to feed the problem. As the scope of the Internet grows exponentially with the launch of hundreds of new Top-Level Domains (TLDs), the online retail environment will likely become increasingly confusing. Public education is critical to dispel the notion that prescription medications used recreationally are somehow safer than illicit drugs. For its part, NABP is introducing the .pharmacy TLD to help provide clarity about prescription drug use, particularly relating to online sources. In its new role as registry operator for the .pharmacy TLD, NABP and its international partners are better positioned to educate and protect the public health against illegal online drug sellers. Having a .pharmacy domain name adds a layer of credibility to legitimate Internet pharmacies and related online resources, and has the potential to raise public awareness about the dangers posed by fake online pharmacies. The initial registration phase for .pharmacy domain names will begin in December 2014. More information about registration is available on the .pharmacy website, [www.dotpharmacy.net](http://www.dotpharmacy.net).

NABP also plans to launch a consumer outreach campaign to spread the word about .pharmacy and medication safety. This campaign will leverage and build upon NABP’s AWARE Prescription Drug Safety Program, which continues to deliver information about medication

safety, including the dangers of prescription drug abuse and the risks associated with misbranded and counterfeit medication often sold by illegal online drug sellers. The goal is to enable patients to take medicine without taking chances.

## V. APPENDICES

### Appendix A

#### Internet Drug Outlet Identification Program Standards

1. **Pharmacy licensure.** The pharmacy must be licensed or registered in good standing to operate a pharmacy or engage in the practice of pharmacy in all required jurisdictions.
2. **DEA registration.** The pharmacy, if dispensing controlled substances, must be registered with the US Drug Enforcement Administration (DEA).
3. **Prior discipline.** The pharmacy and its pharmacist-in-charge must not have been subject to significant recent and/or repeated disciplinary sanctions.
4. **Pharmacy location.** The pharmacy must be domiciled in the United States.
5. **Validity of prescription.** The pharmacy shall dispense or offer to dispense prescription drugs only upon receipt of a valid prescription, as defined below, issued by a person authorized to prescribe under state law and, as applicable, federal law. The pharmacy must not distribute or offer to distribute prescriptions or prescription drugs solely on the basis of an online questionnaire or consultation without a preexisting patient-prescriber relationship that has included a face-to-face physical examination, except as explicitly permitted under state telemedicine laws or regulations.

**Definition.** A valid prescription is one issued pursuant to a legitimate patient-prescriber relationship, which requires the following to have been established: a) The patient has a legitimate medical complaint; b) A face-to-face physical examination adequate to establish the legitimacy of the medical complaint has been performed by the prescribing practitioner, or through a telemedicine practice approved by the appropriate practitioner board; and c) A logical connection exists between the medical complaint, the medical history, and the physical examination and the drug prescribed.

6. **Legal compliance.** The pharmacy must comply with all provisions of federal and state law, including but not limited to the Federal Food, Drug, and Cosmetic Act and the Federal Controlled Substances Act (including the provisions of the Ryan Haight Online Pharmacy Consumer Protection Act, upon the effective date). The pharmacy must *not* dispense or offer to dispense medications that have not been approved by the US Food and Drug Administration.
7. **Privacy.** If the pharmacy website transmits information that would be considered Protected Health Information (PHI) under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (45 CFR 164), the information must be transmitted in accordance with HIPAA requirements, including the use of Secure-Socket Layer or equivalent technology for the transmission of PHI, and the pharmacy must display its privacy policy that accords with the requirements of the HIPAA Privacy Rule.
8. **Patient services.** The pharmacy must provide on the website an accurate US street address of the dispensing pharmacy or corporate headquarters. The pharmacy must provide on the website an accurate, readily accessible and responsive phone number or secure mechanism via the website, allowing patients to contact or consult with a pharmacist regarding complaints or concerns or in the event of a possible adverse event involving their medication.

9. **Website transparency.** The pharmacy must not engage in practices or extend offers on its website that may deceive or defraud patients as to any material detail regarding the pharmacy, pharmacy staff, prescription drugs, or financial transactions.
10. **Domain name registration.** The domain name registration information of the pharmacy must be accurate, and the domain name registrant must have a logical nexus to the dispensing pharmacy. Absent extenuating circumstances, pharmacy websites utilizing anonymous domain name registration services will not be eligible for approval.
11. **Affiliated Websites.** The pharmacy, website, pharmacy staff, domain name registrants, and any person or entity that exercises control over, or participates in, the pharmacy business must not be affiliated with or control any other website that violates these standards.

Appendix B

Key Word Search Results for Controlled Substances Online

Search Term: "Vicodin Online"

Rogue: 6 of 10

Search Result URL	Resolved URL	Notes
active2030store.com/app.html	isearch4health.com	Typing URL from search result takes user to an apparel retail site, Active 20-30 Store, (no prescription products found).  Clicking on link provided in search result: Site resolves to <a href="http://isearch4health.com">http://isearch4health.com</a> , which allows users to select from a list of various controlled substances. Clicking on Vicodin resolves to a new search results page with links to sites offering Vicodin, several without a prescription; for example: <a href="http://hydropharmacy.com">hydropharmacy.com</a> and <a href="http://rxonlineph.com">rxonlineph.com</a>
reggae5k.com/vicodin.html	reggae5k.com/vicodin.html	Advertises: buy vicodin online without a prescription. Links on page redirect to <a href="http://hydropharma.com">hydropharma.com</a> , which offers controlled substances without a prescription.
opioids.com/offshorepharmacy	opioids.com/offshorepharmacy	Provides links to sites selling controlled substances. Clicking a link on <a href="http://www.endlessmeds.com">www.endlessmeds.com</a> redirects to <a href="http://confidentialshop.com">confidentialshop.com</a> , which offers Valium without a prescription.
rippnlipps.com/about	isearch4health.com	Typing URL from search results takes user to fishing hobbyists site (no prescription drugs found).  Clicking on link provided in search result: Site resolves to <a href="http://isearch4health.com">http://isearch4health.com</a> , which enables customers to select from a list of various controlled substances. Clicking on Vicodin resolves to a new search results page with links to sites offering Vicodin, several without a prescription, such as <a href="http://hydropharmacy.com">hydropharmacy.com</a> and <a href="http://rxonlineph.com">rxonlineph.com</a>
northxeast.com	ipaplace.com	Resolves to an Internet directory of online pharmacies selling controlled substances without a prescription.
hydrocodoneguide.com	hydrocodoneguide.com	Resolves to a site that advertises hydrocodone for sale. Clicking on "buy" redirects the user to <a href="http://ezmedsbiz.com">ezmedsbiz.com</a> , which does not sell hydrocodone, but does sell tramadol, Valium, and Soma <sup>®</sup> based solely on an online consultation.

**Search Term: "Oxycontin Online"****Rogue: 4 of 10**

Search Result URL	Resolved URL	Notes
opioids.com/offshorepharmacy	opioids.com/offshorepharmacy	See above under Vicodin
endlessmeds.com/list_m1.html	endlessmeds.com/list_m1.html	Membership site advertising "Buy Vicodin, Hydrocodone, Codeine, Soma, Oxycodone, Vicoprofen, and Oxycontin from Mexican Pharmacies." Site provides links to Internet sites selling controlled substances without a prescription. Link to Medstore Online, which offers Xanax without a prescription.
netvibes.com/lookingoxycontin	netvibes.com/lookingoxycontin#Oxycontin	Resolves to a Google Health - Google Approved Pharmacy Directory. First site listed in directory, reliefpills4u.com, offers oxycodone, Oxycontin, and Percocet without a prescription.
reggae5k.com/oxycodone.html	reggae5k.com/oxycodone.html	Resolves to a site advertising "Buy Oxycodone online without a prescription." Site provides links to sites that sell controlled substances without a prescription, such as saferxusa.com

**Search Term: "Percocet Online"****Rogue: 7 of 10**

Search Result URL	Resolved URL	Notes
ths.gardenweb.com/forums/load/test/msg0403332410460.html	ths.gardenweb.com/forums/load/test/msg0403332410460.html	Site is a home and garden forum containing a page of information on Percocet. Clicking the link on this page redirects users to <i>theturl.com</i> , which provides search results for sites selling controlled substances without a prescription.
opioids.com/offshorepharmacy	opioids.com/offshorepharmacy	See above, under Vicodin
reggae5k.com/oxycodone.html	reggae5k.com/oxycodone.html	See above, under Oxycontin (This one appeared twice in top 10.)
buypercocets.com	buypercocets.com	Site advertises Percocet for sale. When clicking on Order Now, users are redirected to ipharmacylist.com, which offers controlled substances without a valid prescription.
wheretobuy medication.com	wheretobuy medication.com	Site sells controlled substances, such as Adderall <sup>®</sup> , oxycodone, Vicodin, and Percocet without a prescription. Site states shopping cart is under construction and customers must e-mail a Gmail account to order. Site requires payment using a prepaid Visa or MasterCard.
percocetnorx.com	percocetnorx.com	Site advertises Percocet for sale. When clicking on Go To Pharmacy, users are redirected to ezmedsbiz.com, which offers controlled substances without a valid prescription.

Search Term: "Xanax Online"

Rogue: 6 of 10

Search Result URL	Resolved URL	Notes
jbchosting.com/pack.shtml	controlledpills.com/?aff_id=65994	Site resolves to <i>Controlledpills.com</i> which offers controlled substances without a valid prescription.
compareanaxoffers.com	compareanaxoffers.com	Site advertises controlled substances such as Valium, Ambien <sup>®</sup> , and Xanax. Clicking on Valium redirects users to <i>onlinepharmacytabs24.com</i> , which offers controlled substances without a prescription.
bethelnewlife.org/document/buyxanax	bethelnewlife.org/document/buyxanax	Site advertises controlled substances such as tramadol, Xanax, Ambien, and Valium. Clicking on "Buy Now" redirects to <i>pharmadiscout24.com</i> , which offers controlled substances without a valid prescription.
kishindaiko.com/contact	rxtrue.com	Site resolves to rxtrue.com, which offers controlled substances without a valid prescription.
anxietysrc2013.com	anxietysrc2013.com	Site is a blog about Valium. Includes an advertisement for buying Valium online. Clicking the advertisement redirects users to <i>ezmedsbiz.com</i> , which offers controlled substances without a valid prescription.
xanaxanxiety2013.com	xanaxanxiety2013.com	Site advertises Xanax. Clicking on "Buy Now" redirects users to <i>ezmedsbiz.com</i> , which offers controlled substances without a valid prescription.

Search Term: "Valium Online"

Rogue: 7 of 10

Search Result URL	Resolved URL	Notes
get-diazepam.com	get-diazepam.com	Site advertises Valium for sale without a prescription. When clicking the pharmacy/order button, users are redirected to online-drugs-24h.net, which offers controlled substances without a prescription.
kolder.org/valium-online	kolder.org/valium-online	Site advertises Valium, Xanax, and Ativan <sup>™</sup> for sale. Clicking on the product resolves to ezmedsbiz.com, which offers controlled substances without a valid prescription.
constitutionalist-church.org/valiumonline	constitutionalist-church.org/valiumonline	Site advertises controlled substances without a prescription. When clicking on "Buy Now," site redirects users to pharmadiscount24.com, which offers controlled substances without a valid prescription.
anxietysrc2013.com	anxietysrc2013.com	Site is a blog about Valium. Includes an advertisement for buying Valium online. Clicking the advertisement redirects to www.ezmedsbiz.com, which offers controlled substances without a valid prescription.
247anxietyblog.com/category/valium	247anxietyblog.com/category/valium	Site is a blog about Valium. Includes an advertisement for buying Valium online. Clicking the advertisement redirects to rxtrue.com, where you can purchase controlled substances without a valid prescription.
kishindaiko.com/contact	rxtrue.com	Site resolves to rxtrue.com, which offers controlled substances without a valid prescription.
manateeinn.com/lib/	manateeinn.com/lib/	Site advertises controlled substances without a prescription. When clicking on "Buy Now," users are redirected to <i>pharmadiscount24.com</i> , which offers controlled substances without a valid prescription.

- Medstore-online.cc – Disclaimer: "... The purchaser is responsible for the correct choice and use of ordered drugs and other pharmaceutical products which are available without a prescription." (offers Alprazolam made in India)
- Reliefpills4u.com – Oxycodone, **oxycontin**: "Why are we #1 Pharmacy? ... No Doctor visit"
- Pharmaassists.com – "Pharma-Assists its [sic] an online pharmacy store which has all the solutions for chronic pain relief. Percocet oxycodone roxicodone, **Xanax** and many more chronic pain relievers. **Prescribed drugs can be ordered online without prescription** and get shipped overnight."
- Hydropharma.com – FAQ: "**No. You don't need prescription. You can buy any products that you want.**" (This site offers hydrocodone: "Generic **Vicodin**" from India)
- Wheretobuy medication.com – "Where To Buy Pain Medication and ADHD Medication without a prescription," and "Now you can buy Vicodin without a prescription for a cheap cost..." and "You can buy Generic **Percocet** online without prescription. Cheap Percocet Generic is available for people with no insurance or who do not have access to a doctor for a consultation."
- Rxonlineph.com – also offers "Generic **Vicodin**" and "Generic Hydrocodone" from India. Has same FAQ as above.
- HealthLife offers Xanax, **Valium** (among other Controlled Substances and some unapproved knock-off Erectile Dysfunction medicines): "Online Pharmacy. No Prescription."
- Get-diazepam.com – "Buy **VALIUM** Online Without Prescription"

# Attachment 8

# Patient Safety–Medication Error Reduction for Pharmacists – Online CE Course



Our course was developed collaboratively by Oregon State University's College of Pharmacy and the Oregon Patient Safety Commission. It contains a brief introduction by the Institute for Safe Medication Practices (ISMP) and provides pharmacists with the tools to identify problems, reduce risk and improve communication, leading to increased patient safety within the pharmacy environment. Upon completion, students should be able to:

1. Identify and resolve issues that lead to medication errors.
2. Utilize effective communication skills to improve interactions with patients and caregivers, health care professionals and other members of the pharmacy team.
3. Reduce risks associated with patient transitions between health care facilities, departments or sites.
4. Identify and resolve facility or site-specific challenges in workflows or processes.
5. Use root cause analysis to identify and resolve issues contributing to medication errors.
6. Address proper responsibility, accountability, notification and resolution while working through errors, near misses and patient safety situations.
7. Utilize reporting systems to improve patient safety.



This program has been planned and implemented in accordance with the policies of the Accreditation Council on Pharmaceutical Education through the sponsorship of the Oregon State University College of Pharmacy. The OSU College of Pharmacy is approved by the Accreditation Council on Pharmaceutical Education as a provider of continuing pharmaceutical education.

# Patient Safety–Medication Error Reduction for Pharmacists – Online CE Course

Release Date: Spring 2014.

## Course Description

Our course utilizes an array of learning tools, including:

- Interactive multimedia
- Video case studies
- Real-world examples of managerial tasks

The engaging material is regularly updated to reflect the most recent research findings and newest regulations. It is presented in the following modules:

### Introduction

- Concepts & Biases
- Cost, Risk, & Patient Safety
- Business Effects
- Systems
- Ultrasafe Industries
- Professional Responsibility

### Communication

- Patient & Adult Learning
- Inter-Professional
- Inter-Facility
- Intra-Departmental

### Transitions of Care

- Varying Facilities
- Inter-Professional Communications
- Role Responsibility
- Medication Reconciliation
- Inadequate Safeguard/Gaps

### Workflow and Processes

- Production Pressures
- Design Issues
- Interruptions/Distractions
- Checklists
- Workload overload/under load
- Multi-Tasking
- Working in Silos

### Culture and Error Resolution

- Scenarios in Scripts
- Root Cause Analysis
- Blame vs. Accountability
- Incident Decision Tree
- Communication with Patient
- Disclosure Laws
- Legalities & Concerns
- Process of Reporting

Upon completion of this course, participants will receive 18 contact hours (1.80 CEUs), and an *OSU Patient Safety Medication Error Reduction Course Certificate of Completion*.

The CPE office at the OSU College of Pharmacy shall issue a Statement of Credit to each person who successfully completes the 18 hour online program. Completion requires:

1. Registration for the course
2. For each module, completion of all online pretest questions, activities and post test questions
3. Completion of the online program evaluation

The Statement of Credit will be available to print or download online immediately upon program completion.

**For Additional Information** (including pricing)

877-636-9585 | [osuinfor@apollidon.com](mailto:osuinfor@apollidon.com)

**Oregon State**  
UNIVERSITY

# Attachment 9



## PROPOSAL FOR PHARMACY TECHNICIAN RESTOCKING AUTOMATED DISPENSING CABINETS IN THE POST-ACUTE CARE SETTING

For years, most post-acute care settings have used little to no technology with regards to pharmacy technology and automation. This includes real time electronic patient profiling of Medication Administration Records by pharmacist prior to nursing administration as well as using pharmacy automated dispensing cabinets to store and dispense medications to prevent diversion. Many facilities still use tackle boxes for emergency or first dose needs, making accountability much harder for securing drugs, correct charging and auditing as well as tying up inventory each time a box is opened and needs to be replaced.

A large study done by MHA in 2013<sup>1</sup> showed that the average retail or closed door pharmacy contracted with Long Term Care Facilities serviced less than 2,000 residents but dispenses 11,534 prescriptions, averaging 11 prescriptions per patient along with 3-5 OTC products. This is an increase from 9 prescriptions per patient in 2011.

This same study also reveals an increase in specialty drugs for the third year in a row. 5% in oral oncology, 8% in Multiple Sclerosis treatment, 15% increase in HIV medications and 27% increase to treat inflammatory conditions.

In addition to overall increase prescribing and acuity of medications in this setting, CMS has also had to address emergency and first doses in nursing homes. They provided a memorandum summary statement<sup>2</sup> in November, 2012 for all state surveyors on reducing medication errors due to timely first doses of new admissions, and borrowing of medications.

One could easily conclude that the post-acute care setting is facing significant pressure keeping up with increased drug volume, acuity and security. With these increases, come challenges of keeping these patients safe while continually preventing drug diversion. Without incorporating better automation and technology to help with the volume increase, these settings will fall behind with the new overall healthcare changes.

In order to achieve this goal for post-acute care facilities as well as pharmacy providers, they need to aggressively address this technology gap by seeking out the innovated ways to serve this population.

Both, real time pharmacy verification and pharmacy automation have already proven their importance in the acute setting for well over 20 years but has been slow to take off in the non-acute care setting, partly because of regulatory differences and affordability.

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<sup>1</sup> MHA Independent Long Term Care Member Study, 2013 pg. 24

<sup>2</sup> CMS Memorandum Summary, Nov. 2, 2012, Nursing Homes-Clarification of Guidance related to Medication Errors and Pharmacy Services



Also, some states, such as California have been aggressive in addressing the healthcare issues by leading the way and expanding the scope of practice for pharmacy technicians<sup>3,4</sup>. Pharmacy technicians may now check other technicians when filling floor and unit dose distribution systems in acute care settings. They have also expanded their role in among other things, sealing emergency containers for use in the acute care setting.

With these recent changes in the scope of pharmacy and with improved technology, Omnicell, Inc. is asking to include our products and process in the category of direct Pharmacist supervision electronically since it would be a closed loop medication distribution system for restocking automated dispensing cabinets in post-acute care setting. This process would utilize pharmacy technicians instead of pharmacist to restock these machines remotely. The goal is to eliminate tackle boxes and use specific software to ensure accuracy, accountability and improve safety.

### **PROPOSAL FOR PHARMACY TECHNICIAN RESTOCKING AND ELECTRONIC SUPERVISION BY A PHARMACIST**

Omnicell, Inc. is requesting the use of our SAFETY STOCK® Software for restocking ADCS by technicians. This software technology has been the standard of care for several years in the acute care and non-acute setting adding an extra layer of security to the current barcoding process and provides accountability to restocking process. The benefits of using this electronic supervision are:

1. Chain of command with regards to drug security and diversion in the post-acute care setting would be enhanced. Instant notification to both the DON and PIC when unauthorized attempts to access any drug but the primary focus of CII-V
2. Accountability for drug diversion by doing blind counts
3. Use a closed loop medication dispensing process via Safety Stock® software
4. Improve patient safety by utilizing real time patient profiles by pharmacist prior to administration of emergent or first dosing
5. For drugs needing "override" access, Nursing would now have access to the actual Pharmacy information system and allergies assigned to the patients allergies prior to dispensing
6. Accountability and accurate charge capture of drugs pulled and administered along with time stamps to enable nurse administration audits
7. Decrease drug inventory needed.
8. Narcotic diversion reports available (in most settings for the first time)

This proposal would follow the process outlined below and be enforced by a comprehensive training and a thorough policy and procedure manual:

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<sup>3</sup> Ca. Senate Bill 1039

<sup>4</sup> 1793.8 Technicians in Hospitals with Clinical Pharmacy Programs  
[http://www.pharmacy.ca.gov/laws\\_regs/lawbook.pdf](http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf)



#### **A. DELIVERY OF MEDICATIONS TO THE FACILITY**

All medication delivered to the facility are prepared and checked by a pharmacist prior to leaving the pharmacy and delivered in a bar coded, secure and tamper evident container with a manifest.

- i. The restock reports are verified , initialed and dated by the pharmacist
- ii. All medication to be delivered to the remotes ADCS are placed in barcoded, secured tamper evident container with appropriate paperwork (restock report). All containers are verified, signed and sealed under the direct supervision of the pharmacist before leaving the pharmacy.
- iii. A copy of the restock report is placed on the outside for the locked container and is to be signed by the facility upon delivery and used as a receipt of medication
- iv. Only authorized personal approved to receive and sign for medication will be allowed to sign off on the delivery.
- v. The bar coded container will be scanned upon restock and tracked as received
- vi. The signed refill stock report will be used as a manifest and proof of delivery.

#### **B. MEDICATION REPLENISHMENT FROM THE CENTRAL PHARMACY**

- i. The ADCS provides visibility to par levels and restocking cycles on an agreed upon time and date during the week according to the facility service agreement or as required by law and regulation.
- ii. Medications stocked in the ADCS are maintained at predetermined stock levels. Once levels falls below a par level, a report will be generated at the central pharmacy indicating restocking.
- iii. Replenished stock is prepared by pharmacy and is packaged for delivery to facility
- iv. Replenishment quantities are entered. Any additional comments are added if needed and will appear on the restock report
- v. All oral solid medications dispensed in unit dose or in unit of use containers are clearly labeled according to the Pharmacy's standard operating procedures.
- vi. All medications are labeled as follows:
  1. Name of medication
  2. Medication Strength
  3. Dosage form
  4. Lot number
  5. Expiration date
  6. Any additional requirements by state and federal law
  7. Appropriate and legible bar code whenever possible



- vii. Multiple tablets or capsules of the same medication may be placed in a single sealable plastic bag to allow ease of restocking
- viii. Injectables may be packaged in plastic sealable bags
- ix. Other items such as creams, ointments, infusion solutions and liquids may be dispensed in original containers
- x. All medications dispensed from the central pharmacy will have no less than 3 months expiration dating.
- xi. Pharmacy will print restock bar code reports and affix to container
- xii. All medications being restocked are verified directly by the pharmacist

**C. RESTOCKING and STORAGE of ADCS machines**

The following process will be enforced when stocking ADCS

- All restock containers will be bar-coded and scanned upon restock
- All medications (whenever applicable) will have barcode technology on its label.
- All Omnicell cabinets and table tops will have drawers and bins with lights.
- All CII-V and selected non-controls designated by state regulations will be stored in "HIGH" security closed bins
- All other prescription medications will be in "Standard" security lit bins
- Finger scan (Biometrics) or magnetic card readers can be used for accessing ADCS
- Patient profile and interfaces with the Pharmacy system are available
  - i. When restocking medications in the ADCS, the technician will individual log in to identify the technician
  - ii. The technician will start the restocking by selecting the restock function and scanning the restock container
  - iii. The technician must select the drug to be stocked the cabinet screen, next a light will indicate which drawer to open.
  - iv. Next, the bin dedicated to that drug will light up. Only that bin will open.
  - v. No access to any other drawer is accessible in the high security drawers
  - vi. Any unauthorized attempt to access to other bin will immediately send notification to both the DON and PIC.
  - vii. All other medications (non-controlled drugs) will be filled in the standard drawer, using light technology and rescanning the bins to verify accuracy. The technician cannot properly fill the bin if the barcode does not match the bin location.



#### **D. MEDICATION REMOVAL**

Nursing staff must be trained and competent before removing medications from the ADCS.

- All Nursing staff must have competencies and approval from the DON and PIC.
  - Nursing will use and document on the ADCS patient profiles when withdrawing all medications from the ADCS
  - An approved list of emergency or first dose medications to be accessed and overridden must be approved by both the Facility, its medical director and PIC per ADCS policy and procedure
- 
- i. When dispensing emergency/First dose medications from the ADCS, the Nurse will use either a finer scan (biometrics) or a magnetic card reader to access the cabinet
  - ii. The Nurse will start by selecting the patient needing emergent or first dose medications
  - iii. The Nurse will check for allergies on the patient profile prior to removing any medications
  - iv. All medications for emergency or first dose must have a new prescription from a licensed prescriber sent to the Pharmacy supplying the emergency medication within 24 hours of the drug being taken from the ADCS in order for pharmacist verification.
  - v. Only authorized Nursing staff may add patients to the ADCS after hours per ADCS policy
  - vi. If the medication is needed after hours or after the Pharmacy is closed, Nursing may remove only approved “override drugs” that have been approved by the Facility. (See ADCS policy)
  - vii. Once the drug is selected, the bin dedicated to that drug will light up. Only that bin will open. No access to any other drawer is accessible in the high and medium security drawers
  - viii. The Nurse will open the lit drawer, once opened; only the dedicated lit bin will open.
  - ix. Any unauthorized attempt to access to other bin will immediately send notification to both the DON and PIC.
  - x. All non-controlled medications will be stored in the standard drawer, using light technology and rescanning the bins to verify accuracy.
  - xi. The Nurse must scan the correct bin and drug in order to successfully pull the correct drug. Scanning any other bin will generate an error report.



#### **E. SECURE RETURNING MEDICATION TO THE ADCS**

- i. Medications may be returned by a designated nurse as prompted and only if the medication is in the original tamper-evident packaging (e.g., unit dose package, unopened unit dosed liquid cup) and if permitted by state law.
- ii. The nurse must confirm the identification of the product before returning the product to the return bin.
- iii. Medications will be returned per policy.
- iv. Return of the medication is documented in the ADCS as prompted by the Return function.
- v. Any medication adulterated may not be returned to the ADCS.
- vi. Any oral tablet removed from "blister pack" may not be returned to the ADCS.
- vii. Any medications that cannot be returned must be destroyed per Facility's policy

#### **F. RECALLED MEDICATON**

- i. All recalls will be coordinated and verified through the Pharmacy. If immediate recall is needed, nursing manager in coordination with the PIC will immediately remove recalled drugs and place in the return bin, bagged and clearly marked drug recall.
- ii. The Recall log in the central pharmacy will be noted of the time of the call and if there was any drug being withdrawn and segregated.
- iii. The Pharmacy technician on the next restocking will verify and double check the recalled drug has been withdrawn from the cabinet.
- iv. Any recalled medication administered will follow the Facility/Pharmacy policy on patient notification

#### **G. INVENTORY/RECONCILIATION of CONTROLLED DRUGS (Blind count):**

- i. Schedule II-V controlled substances must be reconciled each time the draw is opened. A blind county is mandatory each time a controlled substance bin is opened.
- ii. Once a blind count is done and a discrepancy is registered, the ADCS will promptly display on the user screen, "MEDICATION DISCREPENY"
- iii. Drugs designated for emergency medications must be inventoried once a month by a pharmacist with proper electronic and paper records available for inspection.



#### **H. DISCREPENCY REPORTING:**

- i. Daily discrepancy reports are generated.
- ii. All discrepancies are rectified by the PIC or pharmacist designee
- iii. The PIC or designee and Nursing manager will review and correct any discrepancies
- iv. Refer to ADCS policy and procedure for more details

#### **I. CONTINUOUS QUALITY IMPROVEMENT**

- i. Daily, weekly and monthly reports are generated and review by both Nursing and Pharmacy managers (Refer to ADC policy manual)
- ii. Diversion reports are generated and reviewed by both Nursing and Pharmacy managers.
- iii. Periodic summary reports are presented to the Facilities Medical Director and Director of Nursing for CQI per Facilities policy.

#### **J. DISASTER PREPAREDNESS: Downtime Procedure:**

- i. In the event there is an internal or external disaster, (power outage, severe weather, etc.), the facility will implement their "Disaster and Emergency Plan" as required by CMS and contact the Pharmacy immediately.
- ii. In the event the ADCS are unavailable (power outage, etc.), the pharmacy will refer to its internal disaster policy and the chain of command.
- iii. During downtime, Nursing staff may be given access to the RAMS device by manual means (e.g., keys) until power is restored.
- iv. Keys for the ADCS may only be accessed by the DON or duly authorized Nurse and agreed upon with the PIC and Medical Director of the Facility.
- v. All medications manually withdrawn for the RAMS, will be documents on paper MARs or equivalent during the disaster:
  - a. Medication name,
  - b. Patient name,
  - c. Date and time removed,
  - d. Nurse removing medication including wastes (if full dose of a controlled substance not given).



In summary, Omnicell, Inc. believes that by using Safety Stock® along with basic barcoding, adds an extra layer of security when stocking the ADCS, prevents drug diversion by only allowing drugs to be placed in the correct bin by light technology, and also reports immediately when attempts to access other controlled drugs.

By closing the loop on medication dispensing and administration, the patient is safe while we now have documentation on administration for the high risk drugs in emergency or First dose situations.

Thank you for your consideration on this matter and look forward to the December Board of Pharmacy meeting.

Regards,

*William C. Maguire, RPh*

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## **HEALTH AND SAFETY CODE - HSC**

### **DIVISION 2. LICENSING PROVISIONS [1200 - 1796.63]**

*( Division 2 enacted by Stats. 1939, Ch. 60. )*

#### **CHAPTER 2. Health Facilities [1250 - 1339.59]**

*( Chapter 2 repealed and added by Stats. 1973, Ch. 1202. )*

#### **ARTICLE 1. General [1250 - 1264]**

*( Article 1 added by Stats. 1973, Ch. 1202. )*

##### **1261.6.**

(a) (1) For purposes of this section and Section 1261.5, an "automated drug delivery system" means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

(2) For purposes of this section, "facility" means a health facility licensed pursuant to subdivision (c), (d), or (k), of Section 1250 that has an automated drug delivery system provided by a pharmacy.

(3) For purposes of this section, "pharmacy services" means the provision of both routine and emergency drugs and biologicals to meet the needs of the patient, as prescribed by a physician.

(b) Transaction information shall be made readily available in a written format for review and inspection by individuals authorized by law. These records shall be maintained in the facility for a minimum of three years.

(c) Individualized and specific access to automated drug delivery systems shall be limited to facility and contract personnel authorized by law to administer drugs.

(d) (1) The facility and the pharmacy shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. Policies and procedures shall define access to the automated drug delivery system and limits to access to equipment and drugs.

(2) All policies and procedures shall be maintained at the pharmacy operating the automated drug delivery system and the location where the automated drug delivery system is being used.

(e) When used as an emergency pharmaceutical supplies container, drugs removed from the automated drug delivery system shall be limited to the following:

(1) A new drug order given by a prescriber for a patient of the facility for administration prior to the next scheduled delivery from the pharmacy, or 72 hours, whichever is less. The drugs shall be retrieved only upon authorization by a pharmacist and after the pharmacist has reviewed the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

(2) Drugs that a prescriber has ordered for a patient on an as-needed basis, if the utilization and retrieval of those drugs are subject to ongoing review by a pharmacist.

(3) Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs may be retrieved from an automated drug delivery system pursuant to the order of a prescriber for emergency or immediate administration to a patient of the facility. Within 48 hours after retrieval under this paragraph, the case shall be reviewed by a pharmacist.

(f) When used to provide pharmacy services pursuant to Section 4119.1 of the Business and Professions Code, the automated drug delivery system shall be subject to all of the following requirements:

(1) Drugs removed from the automated drug delivery system for administration to a patient shall be in properly labeled units of administration containers or packages.

(2) A pharmacist shall review and approve all orders prior to a drug being removed from the automated drug delivery system for administration to a patient. The pharmacist shall review the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

(3) The pharmacy providing services to the facility pursuant to Section 4119.1 of the Business and Professions Code shall control access to the drugs stored in the automated drug delivery system.

(4) Access to the automated drug delivery system shall be controlled and tracked using an identification or password system or biosensor.

(5) The automated drug delivery system shall make a complete and accurate record of all transactions that will include all users accessing the system and all drugs added to, or removed from, the system.

(6) After the pharmacist reviews the prescriber's order, access by licensed personnel to the automated drug delivery system shall be limited only to drugs ordered by the prescriber and reviewed by the pharmacist and that are specific to the patient. When the prescriber's order requires a dosage variation of the same drug, licensed personnel shall have access to the drug ordered for that scheduled time of administration.

(7) (A) Systems that allow licensed personnel to have access to multiple drugs and are not patient specific in their design, shall be allowed under this subdivision if those systems have electronic and mechanical safeguards in place to ensure that the drugs delivered to the patient are specific to that patient. Each facility using such an automated drug system shall notify the department in writing prior to the utilization of the system. The notification submitted to the department pursuant to this paragraph shall include, but is not limited to, information regarding system design, personnel with system access, and policies and procedures covering staff training, storage, and security, and the facility's administration of these types of systems.

(B) As part of its routine oversight of these facilities, the department shall review a facility's medication training, storage, and security, and its administration procedures related to its use of an automated drug delivery system to ensure that adequate staff training and safeguards are in place to make sure that the drugs delivered are appropriate for the patient. If the department determines that a facility is not in compliance with this section, the department may revoke its authorization to use automated drug delivery systems granted under subparagraph (A).

(C) This paragraph shall remain in effect only until January 1, 2012, unless a later enacted statute is enacted on or before January 1, 2012, deletes or extends that date.

(g) The stocking of an automated drug delivery system shall be performed by a pharmacist. If the automated drug delivery system utilizes removable pockets, cards, drawers, or similar technology, the stocking system may be done outside of the facility and be delivered to the facility if all of the following conditions are met:

(1) The task of placing drugs into the removable pockets, cards, or drawers is performed by a pharmacist or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.

(2) The removable pockets, cards, or drawers are transported between the pharmacy and the facility in a secure tamper-evident container.

(3) The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the pockets, cards, or drawers are properly placed into the automated drug delivery system.

(h) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be done in accordance with law and shall be the responsibility of the pharmacy. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.

(i) Drugs dispensed from an automated drug delivery system that meets the requirements of this section shall not be subject to the labeling requirements of Section 4076 of the Business and Professions Code or Section 111480 of this code if the drugs to be placed into the automated drug delivery system are in unit dose packaging or unit of use and if the information required by Section 4076 of the Business and Professions Code and Section 111480 of this code is readily available at the time of drug administration. For purposes of this section, unit dose packaging includes blister pack cards.

*(Amended by Stats. 2006, Ch. 775, Sec. 1. Effective January 1, 2007.)*

# Attachment 10

## **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.

# Attachment 11

**Downing Labs, LLC (NuVision Pharmacy), Dallas, TX**

- [FDA Requested Recall Letter](#) Issued 9/9/2014 (PDF – 941KB)
- [FDA News Release](#): FDA reminds health care professionals and consumers not to use sterile products from Downing Labs/NuVision Pharmacy of Texas (9/9/2014)
- [FDA alerts health care professionals not to use sterile drugs from Downing Labs \(aka NuVision Pharmacy\)](#) (07/18/2014)

**Martin Avenue Pharmacy, Inc., Naperville, IL**

- [Firm Press Release](#): Martin Avenue Pharmacy, Inc., Issues a Voluntary Multi-State Recall of All Compounded Sterile Preparations Due to a Lack of Assurance of Sterility (8/27/2014)

**Oregon Compounding Centers, Inc. (dba Creative Compounds), Wilsonville, OR**

- [Firm Press Release](#): Oregon Compounding Centers, Inc. Issues Voluntary Recall of Unexpired Sterile Products in Oregon and Washington Due to Lack of Sterility Assurance (10/9/2014)

**Pharmacy Creations, Randolph, NJ**

- [Firm Press Release](#): Pharmacy Creations Issues Voluntary Recall of Four Product Lots With Limited Distribution in Florida, New Jersey, New York, and Puerto Rico Due to Potential Non-Sterility (9/4/2014)

**Unique Pharmaceutical, Ltd., Temple, TX**

- Firm Press Release: [Unique Pharmaceuticals, Ltd. Announces a Voluntary Nationwide Recall of all Sterile Compounded Preparations Within Their Expiry Period Due to a Lack of Sterility Assurance](#)
- FDA Statement: [FDA alerts health care professionals not to use sterile drugs from Unique Pharmaceuticals](#)
- [FDA Requested Recall Letter 7/11/14](#) (PDF – 754KB)